

Making medicines safer for children— guidance for the use of unlicensed medicines in paediatric patients

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Making medicines safer for children—guidance for the use of unlicensed medicines in paediatric patients

Steve Tomlin¹, Helen Cockerill², Ian Costello³, Richard Griffith⁴, Rob Hicks⁵, Alastair Sutcliffe⁶, Catherine Tuleu⁷, Ian C K Wong⁸, David Wright⁹

¹Consultant Pharmacist, Children's Services, Evelina Children's Hospital, Guy's & St Thomas' NHS Foundation Trust, London; ²Consultant Speech and Language Therapist, Evelina Children's Hospital, Guy's & St Thomas' NHS Foundation Trust, London; ³Chief Pharmacist, Royal Marsden Hospital, London; ⁴Lecturer in Healthcare Law, Swansea University; ⁵General Practitioner, London; ⁶Reader in General Paediatrics; Honorary Consultant Paediatrician, University College London Hospital and Great Ormond Street Hospital, London; ⁷Reader in Pharmaceutics and Director, Centre for Paediatric Pharmacy Research, UCL School of Pharmacy; ⁸Professor and Head of Department of Pharmacology and Pharmacy, University of Hong Kong; ⁹Professor of Pharmacy Practice, University of East Anglia

Introduction

Around 1 in 10 children seen in general practice is prescribed at least one unlicensed medicine.¹ This is a necessary part of caring for children in primary care, but risks are involved for both the patient and the prescriber. The guidance that follows is designed to help minimise the potential pitfalls associated with unlicensed prescribing in the paediatric population, while helping to improve understanding of the clinical, ethical and legal issues. General information on good medicines management (especially at the primary and secondary care interface) is also included, along with three case studies that summarise problems that have occurred in practice.

Background

The use of licensed medicines maximises patient safety while minimising liability; however, in the UK, unlicensed or off-label products (i.e. licensed products used outside their licence) account for: 11% of medicines used for children in general practice, 25% in hospital general wards, 40% in paediatric intensive care units, and 80% in neonatal intensive care units.² The extent of essential but unlicensed prescribing for children is not surprising given that more than 50% of medicines used in children in the European Union have never actually been studied in this age group.³

Unlicensed medicines may take the form of:⁴

- 'Specials'—medicines made under a specials licence by a manufacturer
- Imports—products with a licence, usually in another country, which are imported into the UK
- Extemporaneous products ('extemp's')—formulations for an individual patient and an individual purpose made by a pharmacist combining ingredients
- Manipulated products—medicines in which the formulation has been altered (e.g. by crushing tablets or opening capsules)

The *National Service Framework for children, young people and maternity services* provides guidance on the use of unlicensed and off-label medicines for children: it recommends that customised formulations for individual children should be used only when the patient has a clinical need that cannot be adequately met by a licensed medicine.¹

Prescribing of unlicensed or off-label medicines is usually initiated in secondary care. This can lead to problems with prescribing exactly the same medicine when the patient returns to primary care. For example, in one study 1 in 3 patients discharged with unlicensed and off-label medicines from a specialist children's hospital reported problems in obtaining medicines in primary care.⁵ These difficulties may arise because:

- The pharmacist is unable to supply exactly the same medicine⁵
- The GP may lack the relevant expertise to prescribe the same product confidently⁵
- The GP may have concerns about the legal implications of unlicensed prescribing

Problems can also arise if there is a lack of comprehensive discharge information sent to the GP by the hospital. This can lead to a GP unintentionally changing the patient's prescription, which could potentially cause:

- Pharmacological problems such as reduced efficacy or increased side-effects
- Adherence issues, as alterations in the taste or appearance of the medicine may be unacceptable to the child

Such difficulties can lead to treatment disruption,⁵ which may adversely affect the patient's clinical management.

The World Health Organization (WHO) has identified medicine accuracy as a key issue in ensuring patient safety when patients move between care providers (e.g. moving from secondary to primary care). It has published a number of recommendations for improving medicine accuracy and safety at such transitions, and many of these are integrated into this guidance.⁶

Box 1: Sources of further information

You can obtain further information on a product or formulation prescribed for children from:

- › your local community pharmacist or secondary care pharmacist
- › the original prescriber
- › United Kingdom Medicines Information Pharmacists Group:
 - www.ukmi.nhs.uk
- › *BNF for Children*⁷
 - bnf.org/bnf
- › the manufacturer

Box 2: General Medical Council guidance on the use of unlicensed medicines

The GMC's guidance states that when an unlicensed medicine is prescribed, the prescriber must:⁸

- › be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- › take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow-up treatment, or ensure that arrangements are made for another suitable doctor to do so
- › make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine

Guidance on making medicines safer for children

Working in partnership with parents

Communication between the healthcare professional and the parents/carers is important for all types of treatment and will ensure that any medicines given at home can be correctly administered.

- › As soon as it becomes apparent that an unlicensed or off-label product is going to be the best option for the treatment of a child—whether this decision is made in hospital or when the child is back at home—it is essential that the parent/carer is made aware of the reasons for the decision
- › The parent/carer should be educated to report any problems with symptom control, adverse events, or change of taste or volume of dose once the medicine supply changes from the hospital pharmacy to one in the community (see section on medicines review for children, page 6)

Making unlicensed prescribing safer

Although GPs most commonly prescribe licensed medicines, they will inevitably be involved in prescribing unlicensed products, particularly for children. The GP should take the following steps:

- › Step 1—check the *BNF for Children*⁷ to see if a suitable licensed product is available

Case study 1: Potential problems with extemporaneous suspensions

A child with epilepsy was prescribed clobazam tablets, which are licensed for epilepsy for children aged 3 years and older. The mother reported that the child was struggling to swallow the tablets and the GP decided that it was necessary to prescribe a liquid preparation. *The BNF for Children*⁷ confirmed that no licensed liquid was available, so the GP typed out a prescription for the appropriate dose and strength of liquid clobazam. The community pharmacist subsequently dispensed this unlicensed medicine as an extemporaneous product. The mother returned a week later reporting that the child had increased fitting.

Although the GP prescribed clobazam liquid at the appropriate dose and strength and the pharmacist dispensed the correct medicine, clobazam is very hard to suspend. This means that unless the unlicensed liquid dispensed has an appropriate formula and production method and the bottle is shaken well before dosing, the amount of active ingredient that the child will receive in each dose will vary enormously. Indeed, in some bottles, clobazam is so caked on the bottom of the bottle that the strength of the suspension is only 20% of that expected even after vigorous shaking.

While it is hard for the GP to avoid such a problem advice could be sought from the original prescriber or pharmacist to ensure that the child receives the most appropriate unlicensed medicine. They should also be prepared to closely monitor the patient and warn parents/carers that symptom control may vary when swapping between products that are not licensed.

Changing preparations may impact on symptom control and result in adverse events

- › Step 2—consider a licensed product that may be used outside its licence (i.e. an off-label product), for example, a medicine licensed for an older child but used for a younger patient—if further information on a product or formulation is required, a number of sources of information are available (see Box 1)
- › Step 3—consider whether an unlicensed medicine is appropriate
 - There are several methods of procurement, but all carry potential associated risks as well as benefits⁴
 - Specials and licensed imports should be considered first, bearing in mind the pros and cons in each individual case, followed by extemporaneous medicines, and then manipulation
 - Table 1 (page 5) provides more detailed information on unlicensed medicines
- › Case study 1 provides an example of how changing the preparation can result in adverse events
- › Further guidance on the use of unlicensed medicines is provided by the General Medical Council (see Box 2)⁸
- › Additional support for guidance is given by Royal Pharmaceutical Society⁹ and the National Prescribing Centre¹⁰

Table 1: Classification, advantages, considerations and examples of unlicensed products commonly used in paediatric practice. Adapted from Tomlin⁴

Class	Description	Advantages	Consideration when prescribing and purchasing unlicensed medicines for children
Special*	<ul style="list-style-type: none"> Product made under a specials licence by a manufacturer 	<ul style="list-style-type: none"> Much greater quality assurance than extemporaneous medicines Manufactured to set formulations and manufacturing processes MHRA inspected site 	<ul style="list-style-type: none"> Product may not be suitable for a particular patient with a particular condition—e.g. may contain too much alcohol for a neonate[†] Different manufacturers will use different formulations and manufacturing methods, this could potentially alter clinical outcome and taste acceptability Patient information sheets may not be provided
Import*	<ul style="list-style-type: none"> Product with a licence, usually in another country, that is imported into the UK 	<ul style="list-style-type: none"> The quality is reasonably guaranteed if the product is imported from a country with similar regulatory standards 	<ul style="list-style-type: none"> The product may or not be licensed for the age group or condition for which it is now being prescribed Regulatory standards in some countries may not be as stringent as in the UK Product may contain excipients inappropriate for children, or the condition in which it is being used may be outside of its licence[‡] Packaging and labelling may not be in English Importation costs may be expensive Counterfeit medicines could contain the wrong ingredients, with insufficient or no active ingredients, or with high levels of impurities and contaminants
Extemporaneous medicine ('extemp')	<ul style="list-style-type: none"> Product made by a pharmacist compounding (combining) ingredients for an individual patient and an individual purpose 	<ul style="list-style-type: none"> If the ingredients are in stock in the pharmacy, the formulation may be able to be produced immediately, which avoids any delay in treatment or return visits for the patient/carer 	<ul style="list-style-type: none"> Very little built-in or no pharmaceutical analysis/quality assurance Lack of data on dose uniformity (see Case study 1, page 4) Formulations and manufacturing processes may not be validated Pharmacist may be checking his/her own work, so no robust second-check process is in place
Manipulation	<ul style="list-style-type: none"> Altering formulation (e.g. by crushing tablets) or emptying capsules and dispersing in water 	<ul style="list-style-type: none"> Cheapest and fastest method for dispensing a medicine to a child 	<ul style="list-style-type: none"> Crushing modified-release tablets can alter drug release and dissolution rates, leading to potential underdosing or overdosing Crushing and suspending tablet contents in liquid can lead to more rapid degradation of ingredients Lack of pharmaceutical quality assurance—e.g. dose uniformity (see Case study 3, page 7) Volume measured may not contain the amount of medicine prescribed if product is dispersible rather than dissolvable Manipulated products may be safe to use, but in general we do not have evidence to support their use and dosing is likely to be variable so they should be avoided if at all possible

*Specials and licensed imports should be considered first, bearing in mind the pros and cons in each individual case, followed by extemporaneous medicines, and then manipulation.

[†]Although a special should be made to the requirements of the individual patient, it is rare for a prescriber or pharmacist to engage with a manufacturer about formulation and excipients. It is essential that pharmacists understand the requirements of children and that prescribers understand the problems that using an unlicensed medicine entails. A specials manufacturer will not be able to provide specific requirements as in a batched special and in reality would have to supply an extemporaneous medicine.

[‡]The imported product may be licensed in the originating country for exactly the same condition that it is being imported to treat (e.g. captopril can be imported from Australia as a liquid licensed for children). However, products are often imported because they are available in the required form but may be licensed for a different indication and/or for use only in adults. This latter situation is when the product must be considered in detail for its suitability for the child in whom it is to be used.

Box 3: Swapping products can alter clinical outcomes

A study of 22 hospitals found that nine different captopril oral liquids were being used in many strengths: three of the liquids were provided by specials manufacturers, one was manufactured in an NHS pharmacy manufacturing unit, one was imported, and four were extemporaneously prepared.¹¹ Of these nine products, only the import had comprehensive data on the stability of the products containing this relatively unstable medicine, and bioavailability equivalence had not been investigated at all. As each child moved between tertiary, secondary, and primary care, his/her medicine was often swapped with no consideration for the altered effect of this medicine with a narrow therapeutic range, thus leading to changes in symptom control and adverse events.

Box 4: The importance of the formulation and strength

Although the dose is important, it is just as important for any prescription to state the formulation required and the strength of that formulation. Parents tend to remember the number of millilitres they give, so changing the strength of a medicine is likely to lead to underdosing or overdosing.

For example, numerous children prescribed phenytoin have been taken back to hospital with phenytoin toxicity because they were discharged on phenytoin 30 mg/5 ml suspension, which was later changed to 90 mg/5 ml suspension but the parents continued to give the same volume.

Optimising transition between primary and secondary care

To ensure optimum clinical outcomes, it is essential that exactly the same medicine is prescribed in primary care as was prescribed for the patient in secondary care. As there are several ways that pharmacists may procure the medicine prescribed by the GP, problems may inadvertently arise unless the GP takes all possible measures to minimise the risk of the pharmacist dispensing a product other than that intended. Possible measures include:

1. All instructions from the discharge summary/letter should be carefully transferred to repeat prescriptions so that the patient always receives exactly the same formulation—the study summarised in Box 3 shows how product formulations can be swapped as patients move between primary, secondary and tertiary care,¹¹ and Box 4 highlights the importance of stating the formulation and strength on prescriptions
- › The discharge letter should contain comprehensive prescribing information:
 - For both licensed and unlicensed medicines, the following information is required:
 - Drug name, dose, and frequency
 - Duration of treatment

Case study 2: A case of incomplete information

A 4-kg neonate was discharged from hospital on phenobarbital 20 mg three times a day (tds) prescribed as 2 ml tds of 50 mg/5 ml alcohol-free phenobarbital suspension. The general practice prescribing system included a British Pharmacopoeia (BP) suspension of 15 mg/5 ml, and the GP prescribed and the pharmacy dispensed 6.8 ml (20 mg) tds of this suspension.

Four days later, the child was taken to hospital with lethargy and increased fitting. The 15 mg/5 ml preparation contains 38% alcohol and the volume of 6.8 ml administered was similar to giving the neonate a glass of wine three times a day. As a neonate cannot metabolise alcohol as efficiently as an adult, this would have resulted in lethargy and decreased their seizure threshold, which explained the increased fitting.

To avoid this, the GP simply needed to specify on the prescription that the suspension should be ‘alcohol-free’.

Incomplete information can lead to pharmacists dispensing inappropriate products

- Strength
- Dosage form (e.g. tablet, capsule, or liquid)
 - For an unlicensed medicine or formulation, the additional following information is needed:
 - Source of supply (e.g. named specials manufacturer)
 - Specific formulation needs (e.g. alcohol-free)
- › Figure 1 (page 7) provides an example of a discharge letter for an unlicensed medicine with incomplete and complete information
- 2. If complete information is not available, then the patient’s current medicine should be examined or the original dispensing pharmacist contacted
- 3. The GP should ask the parent/carer to contact them or the primary care pharmacist if they are unsure that the medicine dispensed is the same as that originally prescribed
- 4. To ensure that future prescribing is more straightforward, the medicine should be added to the practice formulary, where possible
 - › The flow diagram in Figure 2 (page 8) shows how GPs can ensure continuity of care for patients referred from secondary care
 - › Case study 2 shows how an incomplete prescription can result in an inappropriate formulation being provided

Medicines review for children

- › The following questions may be helpful during a medicines review with the parent/carer and child:
 - Are there any problems with the medicine?
 - Does the medicine taste ok?
 - Is it easy to swallow?
 - Is the parent/carer finding administration of medicines a battle?

Figure 1: Complete and incomplete discharge summary for an unlicensed medicine

**Somewhere Hospital
Somewhere
Somewhereshire
SO1 2ME**

Dr General
Nearby General Practice
Nearby
NE4 3BY

Joe Bloggs (DOB 15 February 2005; Hospital no. 10111213)

Following the attendance of the above patient at Somewhere Hospital, please find below an outline of action taken that may be relevant for further consideration of the patient’s medical condition.

Date of attendance: 20 June 2008
Name of consultant in charge: Dr Secondary
Final diagnosis: Epilepsy
Details of medication:

Follow-up arrangements: To be continued until next hospital review
Hospital review in 3 months

Yours sincerely
Dr Secondary
cc Mrs Bloggs

Incomplete information
Started on phenobarbital 2 ml tds

Complete information
Started on phenobarbital 50 mg/5 ml (alcohol free) (XYZ Company/ABC Brand) 2 ml (20 mg) tds

- Is the parent/carer having to manipulate the formulation (i.e. are they mixing crushed tablets or the contents of capsules with food)?
 - If so, explain that this is rarely appropriate as it can affect the medicine’s properties and efficacy. NB there are some exceptions as some capsules are designed to be opened
- > An example of how manipulation of a medicine can result in dosing errors is highlighted in Case study 3
- > If the child has found it difficult to take the medicine, the GP should:
 - Contact the original prescribing physician, pharmacist or manufacturer for advice and to find out whether an alternative is available—e.g. a liquid medicine licensed for use in children
 - Consider referring the child to the local speech and language therapist for a swallowing assessment if it is suspected he/she has a clinical swallowing problem
- > The child should be reviewed regularly to ensure that the medicine is still appropriate as he/she grows:
 - If in doubt, the child should be referred back to secondary care to ensure appropriate prescribing as he/she grows

Case study 3: Manipulation can lead to dosing errors

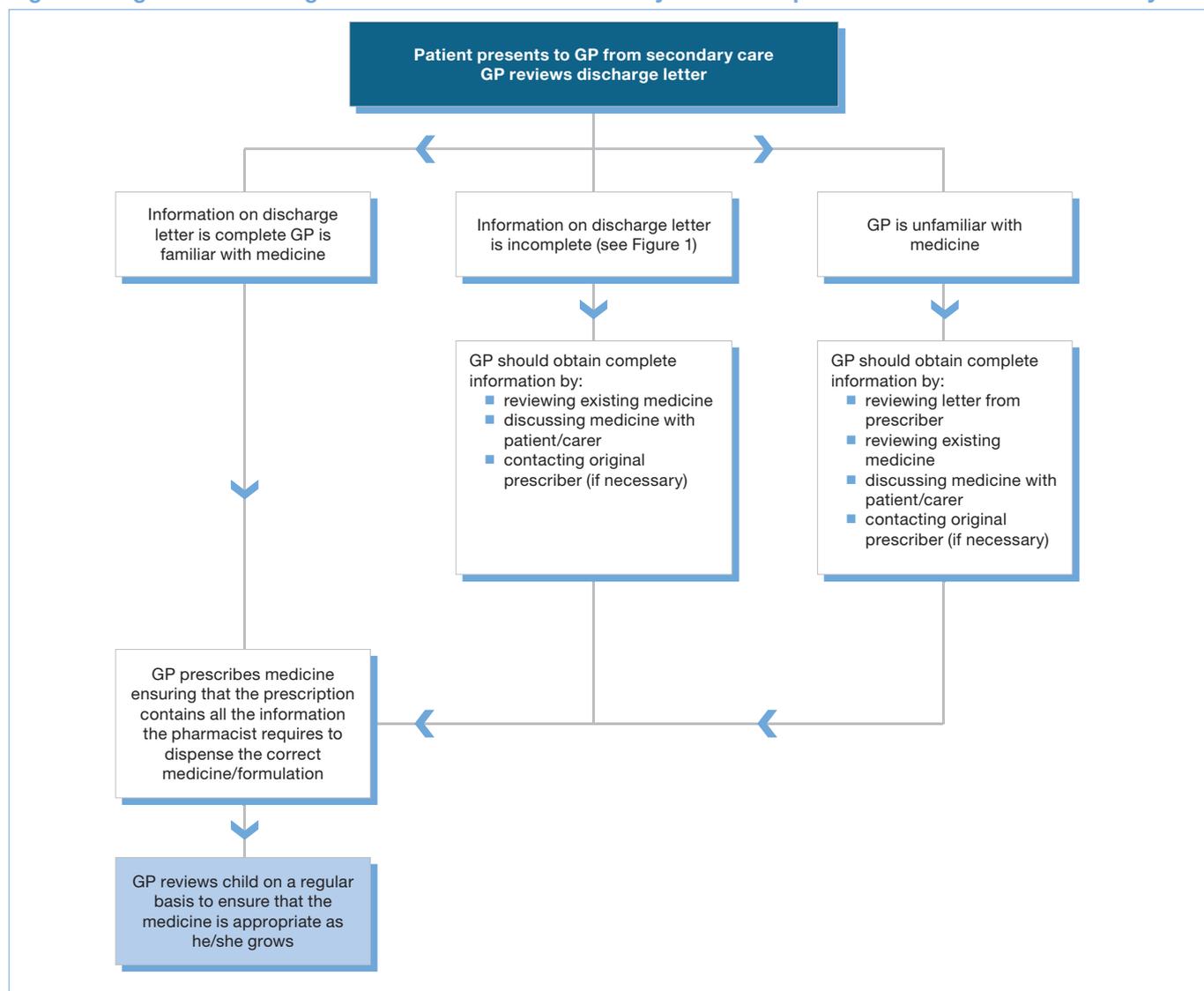
A GP prescribed diclofenac tablets for a child with arthritis. A week later, the mother returned to the GP as she was concerned that the child was still in pain despite the medicine being given as directed. The GP discovered that the child had been dispensed 50 mg dispersible tablets and that the instructions from the pharmacy were to dissolve one tablet in 5 ml of water and then give 1 ml of the liquid to the child, with the aim of providing a dose of 10 mg.

Dispersible tablets are usually licensed to aid administration of the whole dose. The content of dispersible tablets is not necessarily dissolvable, however, and if a proportion of the whole dose is required, the volume measured is unlikely to contain the amount of medicine prescribed. Indeed, the dose actually dispensed could vary dramatically with each dose that they take—from as little as 2 mg up to 8 mg—and will rarely amount to the intended 10 mg. As a result, this child was not receiving a clinically effective dose and, therefore, had suboptimal pain relief.

The GP wrote a new prescription on which it was specified that a special was required. This ensured that the child received the intended dose, as the concentration of a special is more uniform and thus the amount of drug given in each dose is more consistent.

If you have any doubts, contact the original prescriber

Figure 2: Algorithm showing how GPs can ensure continuity of care for patients referred from secondary care



Legal guidance for prescribing unlicensed medicines for children

When prescribing unlicensed products, there are a number of legal issues that prescribers need to be aware of:

- Prescribing an off-label or unlicensed medicine carries a greater risk of legal liability to the prescriber if any harm occurs to the patient (*Davis v Jacobs* [1999] *Lloyds Rep Med* 72)¹² and products should be prescribed according to their manufacturing authorisations whenever possible (Human Medicines Regulations 2012¹³ and Consumer Protection Act 1987¹⁴)
- In summary, the law requires that the:
 - Right medicine is given to the
 - Right patient, at the
 - Right time, using the
 - Right dose, in the
 - Right formulation

- If prescribing an unlicensed medicine, prescribers minimise their liability by:
 - Clearly documenting the reason for giving the medicine by:
 - Following up-to-date, evidence-based practice that stands up to logical analysis ('You will not be exonerated because others are negligent or practice is generally slack')
 - Providing sufficient information to administer safely
 - Following available accepted published evidence for the medicine's use (e.g. from the *BNF for Children*⁷)
 - Prescribing a special rather than an extemporaneous medicine or advising manipulation because of the increased quality assurance with specials^{4,15}
 - Checking for common errors (e.g. dose/volume)
 - As with any treatment, obtaining valid consent that includes informing the parent/child of material risks (for further advice see the General Medical Council's *Good prescribing practice*, particularly paragraphs 71–73⁸)

- › Prescribing, dispensing, and administrative decisions that fall below the accepted standard can lead to:
 - Civil liability
 - Criminal liability
 - Professional liability
 - Breach of employment contract
- › If a GP continues prescribing an unlicensed medicine that was originally initiated in hospital and an error occurs:
 - Liability for continued prescribing will generally shift to the prescriber and/or community pharmacist depending on the error involved (*Prendergast v Sam and Dee* [1989] 1 Med LR 36)¹⁶
 - Where there is an error in transition of care from primary to secondary care, liability for negligence can rest both with the hospital prescriber and the GP depending on the circumstances of the case

Frequently asked questions

Many parents/carers will have particular concerns about the suitability of their child’s medicine. Listed below in bold are examples of questions that parents/carers may ask their GP followed by useful information that will help the GP provide an answer.

Q. I am trying to restrict the amount of sugar my child consumes. Does this medicine contain sugar and is there a sugar-free alternative?

A. The amount of sugar in children’s medicines is very small but there are sugar-free alternatives of some medicines available. The GP should reassure the parent/carer and highlight good dental care and healthy living rather than making this a reason for poor compliance.

Q. My child reacts to artificial additives. Does this medicine contain any of these?

A. Many medicines contain components other than the active drug to improve their shelf life and taste. Manufacturers of medicines are regulated by strict guidelines and should only use additives that are absolutely necessary—for example, to improve flavour. These generally have no effect on the child taking them, although some should be avoided in children with particular clinical conditions. The initial prescriber will be aware of this and will have prescribed appropriately. If the patient’s GP has particular concerns, they should contact a pharmacist to help decide on the best course of action. The GP should encourage the parent/carer to inform them immediately if unexpected side-effects occur.

Q. The volume of liquid medicine I give my child has changed—does this mean that the dose has also changed?

A. As a child grows, their dose may well change. The GP should reassure the parent that the dose will be unchanged from prescription to prescription unless the GP tells them otherwise. To avoid confusion, the GP should always

Quick reference checklist

Optimising the transition between primary and secondary care

- › Clarify the indications and dosing for any medicines or formulations that you do not recognise, as this will help identify any unlicensed medicines
- › Always prescribe exactly the same medicine as was initiated in secondary care by carefully transferring all instructions from the discharge summary/letter
- › If the information required is not included on the discharge summary/letter, contact the original dispensing pharmacist or examine the patient’s current medicine
- › Ask the parent/carer to contact you if they are unsure that the medicine dispensed is the same as that prescribed originally (for example, in terms of taste, strength, symptom control or side-effects)

Medicines review

- › Before issuing repeat prescriptions, find out whether the child has been having problems with their prescribed medicine
- › If the child has been having problems:
- › Explain that the parent/carer should not mix crushed tablets or the contents of capsules with food or drinks to achieve adherence
- › Contact the original prescribing physician or pharmacist or the manufacturer to find out if a suitable alternative is available
- › Refer to the local speech and language therapist if you suspect a *clinical* swallowing problem
- › Review the child regularly to ensure that the medicine is still appropriate as he/she grows

If you have any doubts, contact the original prescriber

ask the pharmacy to provide the same strength of liquid from the same supplier. If changes are necessary for some reason—such as a different volume or different strength—the GP should ask the pharmacist to explain exactly what has changed to the parent/carer and ensure that the parent/carer is confident that they are giving the correct dose.

Q. What should I do if I feel my child is having an adverse reaction to the medicine?

A. The GP should encourage the parent/carer to report any unexpected side-effects that occur to them immediately.

Q. My child cannot swallow their tablets/capsules. Can I crush the tablets/open the capsules and put the contents into their food or drink?

A. If this is a long-term issue, the GP should try to find an appropriate alternative (unless the medicine is designed to be manipulated). If crushing tablets or opening capsules is the only option for initial supply, the GP should ask the

pharmacist to confirm whether this kind of manipulation is acceptable. Medicines may not be stable with food and drinks, and if all the food and drink in which the medicine is mixed is not consumed, the dose will not be appropriate. If absolutely essential, the GP should tell the parent to mix the crushed tablet or capsule contents with one spoonful of food immediately before it is given to the child.

Q. As my child has grown, their dose has increased and I now have to give them four spoonfuls of medicine at each dose. Is it possible to change the medicine so they only need to take one or two spoonfuls?

A. Some medicines do come in different strengths, and it is occasionally appropriate to change strengths in order to decrease administration volumes. Clear communication is essential between the doctor, pharmacist and parent to avoid confusion and incorrect dosing.

Acknowledgements

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Are their medicines ending up where they should?

Swallowing difficulties may be one of the major causes of non-compliance amongst older patients. This could lead to tablets and capsules being left unused, thrown away or hidden (sometimes in the most unlikely places). Every year, drug wastage and treating the adverse outcomes associated with non-compliance costs the NHS over a billion pounds.¹

For patients with swallowing difficulties, Rosemont produces a wide range of liquid alternatives to solid formulations, which can be swallowed more easily. So if you want to be sure your patient's medicine ends up where it should, make sure it's a Rosemont solution.

Reference 1. Greener M. *JME* 2006; 9: 27-44.

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The source of liquid solutions.

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Rosemont Pharmaceuticals Ltd. Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds LS11 9XE **T** +44 (0)113 244 1400 **F** +44 (0)113 245 3567
E rosemont.infodesk@perrigouk.com Sales/ Customer Service: **T** +44 (0) 113 244 1999 **F** +44 (0) 113 246 0738 **W** www.rosemontpharma.com

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