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

• Working Party – Tomlin, Cockerill, Costello, Griffith, Hicks, Sutcliffe, Tuleu, Wong & Wright •

This guideline was developed by a multidisciplinary expert panel: Tomlin S et al with the support of a grant from Rosemont Pharmaceuticals Ltd.
See page 444 for full disclaimer.

Making unlicensed prescribing safer

- Although GPs most commonly prescribe licensed medicines, they will inevitably be involved in prescribing unlicensed products, particularly for children—around 1 in 10 children seen in general practice is prescribed at least one unlicensed medicine

- The GP should take the following steps:
  - step 1—check the *BNF for Children* to see if a suitable licensed product is available
  - step 2—consider a licensed product that may be used outside its licence (i.e. used off label), for example, a medicine licensed for an older child but used for a younger patient
  - step 3—consider whether an unlicensed medicine is appropriate
    - there are several methods of procurement, but all carry potential associated risks as well as benefits
    - 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

- Unlicensed medicines may take the form of:
  - '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 ('extemps')—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)

- General Medical Council guidance states that when an unlicensed medicine is prescribed, the prescriber must:
  - 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

- Further information on a product or formulation prescribed for children can be obtained from:
  - the local community pharmacist or secondary care pharmacist
  - the original prescriber
  - United Kingdom Medicines Information Pharmacists Group (www.ukmi.nhs.uk)
  - *BNF for children* (www.bnf.org/bnf)
  - the manufacturer

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 below on medicines review for children)

Optimising transition between primary and secondary care

- 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. These difficulties may arise because:
  - the pharmacist is unable to supply exactly the same medicine
  - the GP may lack the relevant expertise to prescribe the same product confidently
  - the GP may have concerns about the legal implications of unlicensed prescribing (see section on legal guidance below)

- 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

- There are several ways that pharmacists may procure the medicine prescribed by the GP and 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. These 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 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
       - 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)

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 algorithm below shows how GPs can ensure continuity of care for patients referred from secondary care

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?
  - is the parent/carer having to manipulate the formulation (i.e. 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

- 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

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, and products should be prescribed according to their manufacturing authorisations whenever possible

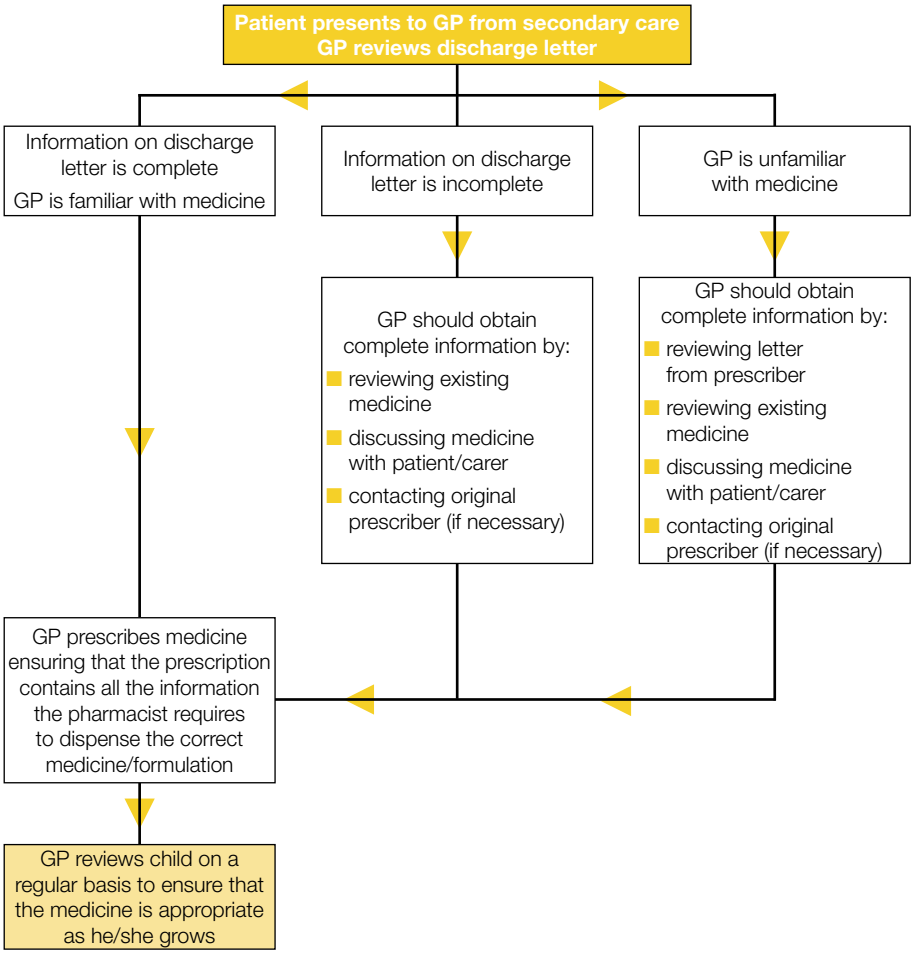
- In summary, the law requires that the:
  - right medicine is given to the
  - right patient, at the
  - right time, using the
  - right dose, in the
  - right formulation

- 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
    - providing sufficient information to administer safely
    - following available accepted published evidence for the medicine's use (e.g. from the *BNF for Children*)
    - prescribing a special rather than an extemporaneous medicine or advising manipulation because of the increased quality assurance with specials
    - checking for common errors (e.g. dose/volume)
    - as with any treatment, obtaining valid consent that includes informing the parent/child of material risks

- 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
  - 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

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



about this working party guideline...

sponsor – This guideline has been developed by MGP Ltd, the publishers of *Guidelines*, and the Working Party was convened by them. Rosemont Pharmaceuticals Ltd was able to recommend experts for the working party group and comment on the scope and title, with final decisions resting with the Chair. Rosemont Pharmaceuticals Ltd had the opportunity to comment on the technical accuracy of this guideline but the content is independent of and not influenced by Rosemont Pharmaceuticals Ltd.

working party members – Steve Tomlin (Chair, consultant pharmacist), Helen Cockerill (consultant speech and language therapist), Ian Costello (chief pharmacist), Richard Griffith (lecturer in healthcare law), Rob Hicks (general practitioner), Alastair Sutcliffe (reader in general paediatrics and honorary consultant paediatrician), Catherine Tuleu (reader in pharmaceutics and director), Ian C K Wong (professor and head of department of pharmacology and pharmacy), David Wright (professor of pharmacy practice)

further information – call MGP Ltd (01442 876100) for a copy of the full guideline November 2008, updated May 2013