



## Pharmacy and Medicines Management CPG Document Number: 001

### Primary Care Guidance: Prescribing medicines for adults who are unable to swallow oral solid dosage forms

<b>Date to be reviewed:</b>	June 2012	<b>No of pages:</b>	20
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<b>Date approved:</b>	Date approved		
<b>Endorsement by:</b>	DTG sub-group		
<b>Date endorsed:</b>	Date endorsed		
<b>Date activated (live):</b>	Date becomes live		

<b>Date EQIA completed:</b>	10 <sup>th</sup> August 2010
<b>Documents to be read alongside this policy:</b>	
<b>Review</b>	<p><b>Purpose of Issue/Description of current changes:</b> To provide guidance to prescribers, pharmacists and nurses administering medicines for adults with swallow problems in response to the increased demand, complexity and cost of some “specials”.</p> <p>Minor amendments made to version 1 following feedback from the All Wales Medicines Strategy Group and the Royal Pharmaceutical Society.</p>

<b>First operational:</b>	Date the procedure/guideline was first operational				
<b>Previously reviewed:</b>					
<b>Changes made yes/no:</b>					

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## 1. Introduction and Purpose

Some adults have difficulty swallowing oral solid dosage forms such as tablets and capsules and prescribers must work with the patient and/or their carers to address their needs. This may be through reviewing the patient's requirements, the use of licensed medicines off label; the unlicensed manipulation of medicines or the use of unlicensed medicines.

This guideline provides a framework for healthcare professionals to support their prescribing decisions in response to the increased demand, complexity and cost of some "specials"<sup>1</sup>. A definitive protocol is not possible as each patient's circumstances will differ and practitioners must consider the potential risks, safety and liabilities associated with both off-label dosage manipulation and with use of unlicensed specials

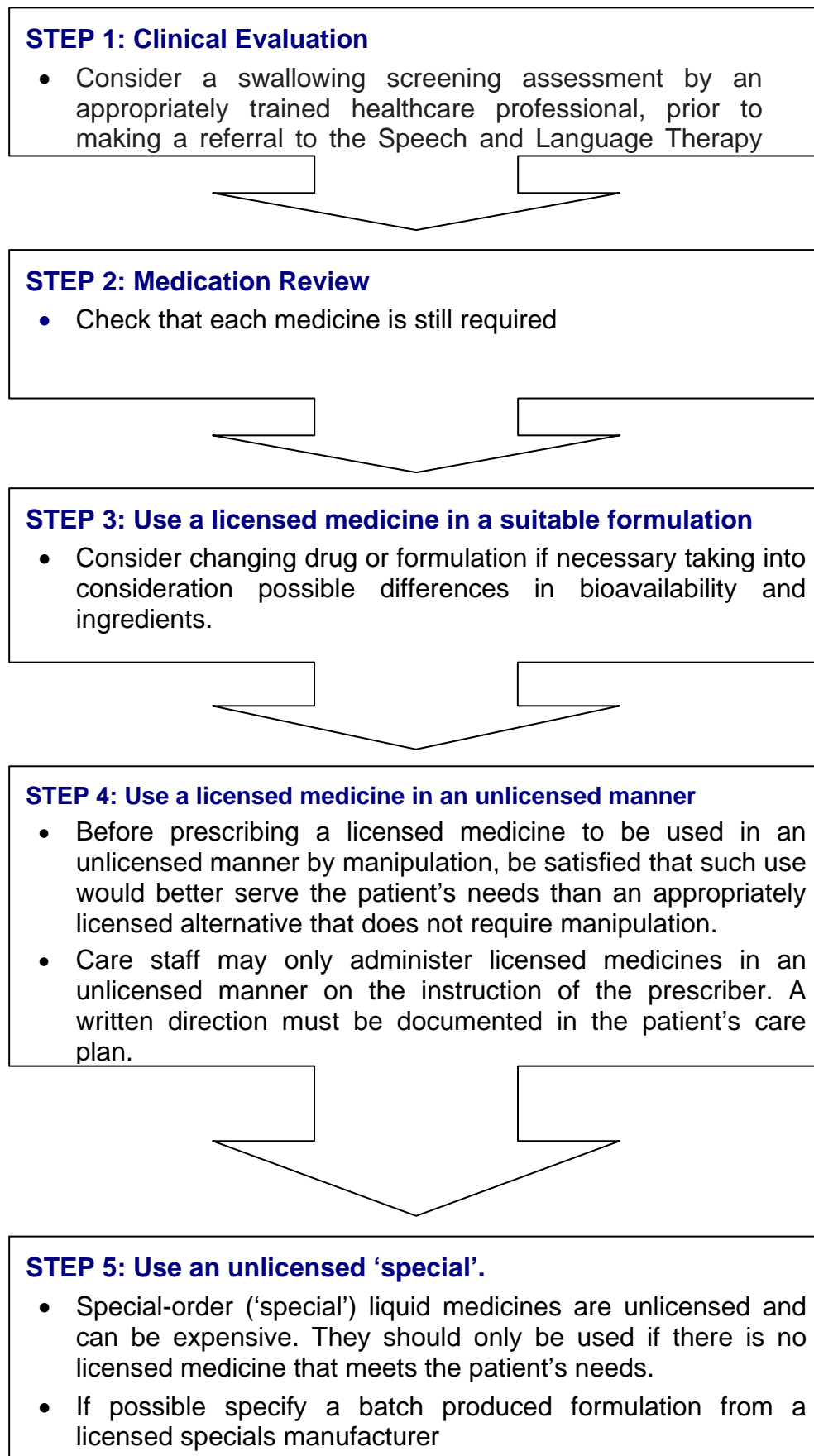
This document also seeks to clarify the individual professional responsibilities in the prescribing, supply and administration of medicines for this group of patients and aims to make an overall contribution to preserving the safety of patients whilst respecting their rights under the equalities legislation.

## 2. Scope

This guideline is intended for use by:

Primary Care Prescribers  
Prescribing support teams  
Community Pharmacies  
Nursing Home managers  
Care Standards Inspectorate Wales

### 3. Summary



**Consent**  
As with any intervention the patient must give informed consent. Where necessary it is important that the patient's carers are involved in this process and where doses are manipulated ensure that they are happy and able to administer the medicine in this way

## 4. Recommendations

### STEP 1

#### Clinical Evaluation

If you have concerns about swallowing safety a suitably trained health care professional could undertake a swallowing screening assessment<sup>2</sup> (Appendix 1) prior to making a referral to the Speech and Language Therapy department.

The speech and language therapists may be able to recommend simple interventions to help patients swallow.

### STEP 2

#### Medication Review

There are many reasons why withdrawing a medicine might be beneficial, ranging from a serious adverse reaction to a lack of clinical response. A change in circumstances of a patient or their disease state may make the risk benefit profile unfavourable<sup>3</sup>.

Carry out a medication review (e.g. NO TEARS<sup>4</sup>) consider:

- **N**eed and Indication
- **O**pen questions to gauge concordance
- **T**ests and monitoring
- **E**vidence and guidelines
- **A**dverse events
- **R**isks of treatment
- **S**implification of existing regiment.

Some medicines should not be stopped abruptly following long term use, a pharmacist can advise on which medicines these are.

## STEP 3

### Use a licensed medicine in a suitable formulation<sup>5</sup>

For example:

Licensed liquid preparation

Soluble tablets

Powders or granules for suspension

Sublingual or buccal product

Transdermal products

Rectal products

Aim to use a licensed medicine, rather than an unlicensed dosage manipulation, consider switching to a licensed medicine that the patient can swallow such as a different agent in the same class, or to a different route of administration. As the bioavailability of products may vary between formulations care must be taken to ensure that the patient receives the same therapeutic dose e.g. Suspension of phenytoin 90mg in 15ml may be considered to be approximately equivalent in therapeutic effect to capsules or tablets containing Phenytoin sodium 100mg<sup>6</sup>. Some formulations may have significantly different ingredients and care must be taken to ensure that these are suitable for the patient e.g. Effervescent tablets often have a high sodium content.

For example, consider:

- Fluoxetine liquid (licensed preparation) as an alternative to sertraline tablets.
- HRT patches instead of tablets.

In exceptional circumstances, where there is an evidence base for its use, a licensed product may be manipulated and used in an unlicensed way in preference to another licensed form. Where this best meets the needs of the patient this is regarded as reasonable practice<sup>7</sup>.

## STEP 4

### Use a licensed medicine in an unlicensed manner

For example by crushing / dispersing tablets in water or by opening capsules<sup>5</sup>

In some cases it may be deemed preferable to give a licensed product via an unlicensed route (e.g. an injection given orally), rather than to use an unlicensed product<sup>7</sup>.

Local or regional Medicines Information services can provide advice on administration of medicines and additional drug information to help prescribers determine the best option for the patient. Appendix 2 provides further sources of information.

Practical guidance on drug administration is given in Appendix 3.

#### Legal and ethical aspects

- Before prescribing a medicine off-label, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative.
- As with any intervention the patient must give informed consent, where necessary it is important that the patient's carers are involved in this process and ensure that they are happy and able to administer the medicine in this way.
- The supply and administration of a medicine in an unlicensed manner may only be carried out on the specific written instruction of an independent prescriber<sup>8</sup>.
- Care staff may only give licensed medicines in an unlicensed way if there is a written direction in the patient's care plan.
- Further professional considerations are discussed in Appendix 4.

## **STEP 5**

### **In the few situations where there is no licensed option, consider using an unlicensed 'special'.**

Medicines legislation requires that medicinal products are licensed before they are marketed in the UK. However, some patients may have individual clinical needs that cannot be met by licensed medicinal products. In order that these needs may be met, the law allows manufacture and supply of unlicensed medicinal products (commonly known as 'specials') subject to certain conditions<sup>9</sup>.

Special-order ('special') liquid medicines are unlicensed and often expensive. Medicines and Healthcare products Regulatory Agency (MHRA) guidance<sup>7</sup> states that before prescribing an unlicensed medicine ensure that an alternative, licensed medicine would not better meet the patient's needs.

Special-order medicines may be produced as batch-prepared products or individual bespoke preparations. Batch prepared products are preferred as they have a higher level of assurance and have a known shelf life, which may be longer than bespoke medicines. It is recommended that the prescriber discussed with the supplying pharmacy which products are available and specifies the manufacturer's name on the prescription. This will also make it clear that the prescriber is aware that an unlicensed medicine is being requested and ensure consistency of subsequent supplies. Specials manufacturers may now publish price lists.

Manufacturers of specials must hold a Manufacturer's Specials Licence (MS) granted by the licensing authority and their manufacturing sites are inspected for compliance with Good Manufacturing Practice<sup>8</sup>. Products made by these manufacturers will have a MS number on the label<sup>6</sup>. Where an unlicensed drug is included in the BNF, this is indicated in square brackets after the entry<sup>6</sup>.

Guidance on the key professional responsibilities for pharmacists when providing advice about or supplying specials, and support in making appropriate choices for their patients is available from the Royal Pharmaceutical Society<sup>10</sup>.

## Appendix 1: Swallow Screening Assessment

The standardized bedside swallowing assessment (SSA) remains an important early screening tool for dysphagia and aspiration risk. It has variable sensitivity and specificity depending on the method used<sup>11</sup>.

SIGN Guidelines (119): Management of patients with stroke: identification and management of dysphagia<sup>12</sup> recommends the following:

<b>2.2 SWALLOW SCREENING</b>
Patients with dysphagia should be monitored daily in the first week to identify rapid recovery. Observations should be recorded as part of the care plan.
<p>A typical swallow screening procedure should include:</p> <ul style="list-style-type: none"><li>▪ initial observations of the patient's consciousness level</li><li>▪ observations of the degree of postural control.</li></ul> <p>If the patient is able to actively cooperate and is able to be supported in an upright position the procedure should also include:</p> <ul style="list-style-type: none"><li>▪ observations of oral hygiene</li><li>▪ observations of control of oral secretions</li><li>▪ if appropriate, a water swallow test.</li></ul>



## Appendix 2: Sources of further information

### Using licensed medicines in an unlicensed manner

Dosage manipulation is generally outside a product's licence and consequently bioavailability data is limited. Unless specific data is available and it is established custom and practice, products must not be manipulated and used in an unlicensed way. Where the use of a licensed product in an unlicensed manner is necessary, further information can be obtained from the following sources:

1. Local Medicines Information Departments are recommended as the primary source of specific drug information; Local contacts are:  
(YGC) North East Wales Medicines Information Service: 01745 534097 and [drugs@wales.nhs.uk](mailto:drugs@wales.nhs.uk)  
(YG) North West Wales Medicines Information Service: 01248 384141
2. Standard reference texts include.
  - a. The NEWT Guidelines for the administration of medication to patients with enteral feeding tubes or swallowing difficulties<sup>13</sup>. This book provides drug-specific information to pharmacists and other healthcare professionals providing or administering medications to patients with swallowing problems. It also provides general information on the legal aspects of altering licensed medicine formulations, how to prepare solid dose formulations for administration to patients with swallowing problems, and contains formulae for the extemporaneous preparation of suspensions.
  - b. The Handbook of Drug Administration via Enteral Feeding Tubes<sup>14</sup>. This book provides the background knowledge to inform clinical decisions and contains guidance on the safe administration of specific drugs and formulations. Contents include: tube flushing, restoring and maintaining patency, drug therapy review, medication formulation choice, unlicensed medication use, health and safety and interactions.
3. The BNF for children <http://bnfc.org/bnfc/> also gives information on unlicensed uses e.g. Amlodipine: Tablets may be dispersed in water<sup>15</sup>.
4. Individual manufacturer's medicine information departments may be able to provide advice on their products.
5. Some websites are available but it is recommended that the information is checked as their validity cannot be assured and some information may be out of date.

### Using unlicensed medicines (specials)

East of England Collaborative Procurement Hub Specials Sourcing Group has recently published "A Web based information for prescribers, pharmacists and nursing care staff on the prescribing and use of unlicensed pharmaceutical specials"<sup>16</sup>. The objective of which is to highlight their individual responsibilities, the risks involved and to make an overall contribution to preserving the safety of patients.

## **Appendix 3: Guidance for medicines administration**

### **1. Administering medicines to patients unable to take solid oral dosage forms**

In all cases, first establish that a medicine is suitable for administration in the intended manner. Contact your medicines information centre for advice.

Care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber. A written direction to crush or disperse tablets or to open capsules must be documented in the patient's care plan. Form 1 could be used for this purpose.

#### **• Crushing or dispersing tablets**

For medicines that are suitable for crushing, crush using a pestle and mortar, a tablet crusher or between two metal spoons. Only crush medicines one tablet at a time; do not crush all the patient's medicines together. Crushing or dispersal, generally in a small amount of water, should only be performed immediately before administration.

#### **• Opening capsules**

Some hard gelatine capsules can be opened and their contents mixed with water or administered with food. Some capsules may be too small to manipulate. Capsules should only be opened immediately before administration.

#### **• Administering medicines in soft food**

Some crushed medicines or capsule contents may be administered with a small amount of cold soft food. Crushed tablets or capsule contents may taste very bitter; it can be helpful to mask the taste for patients taking these medicines orally by using strong flavours. A teaspoon of yoghurt or jam may be suitable but practitioners must be mindful of the patient's medical condition(s), beliefs and preferences. A small amount of soft food should be used to ensure the full dose is taken.

Medicines should only be administered in food with the patient's knowledge and consent. Hiding medication in food is considered 'covert administration' and is only condoned in certain circumstances.

### **2. Administering medicines via feeding tubes**

Care workers administering of medicines via feeding tubes in care homes and those providing domiciliary care must be trained to Health and Social Care National Occupational Standard skill level 3. Care workers who agree to give medicines via feeding tubes must receive training from a healthcare professional and there must be a written record of this training<sup>17</sup>.

The choice of drug and/or formulation to be administered via a feeding tube requires specialist knowledge; advice must be sought from local medicines information departments to ensure suitability, compatibility with the feed and to establish an appropriate enteral tube flushing regiment.

The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties<sup>13</sup> and the Handbook of Drug Administration via Enteral Feeding Tubes<sup>14</sup> provide the following advice regarding formulation selection:

- Solutions or soluble tablets are the formulations of choice.
- Do not assume that liquid formulation will be suitable.
- Do not crush tablets or open capsules unless an appropriate alternative formulation or drug is unavailable.

They also provide specific guidance on the administration of liquids (solutions and suspensions), solid dosage forms (soluble, effervescent, dispersible, buccal/ sublingual, compressed tablets and soft and hard gelatin capsules) and injectable products.”

The British Association for Parenteral and Enteral Nutrition known generally as BAPEN provides useful information including patient information leaflets on drug administration via enteral feeding tubes ([http://www.bapen.org.uk/res\\_drugs.html](http://www.bapen.org.uk/res_drugs.html)).

For further advice contact your local Medicines Information Department.

<b>Form 1</b>	<b>Request for medicine adjustments for patients unable to swallow oral solid dosage forms</b>								
Patient Name:									
Patient Address:									
Home Manager/ Matrons Name:									
Does the patient have a PEG or NG Tube:				Y/N					
Has a swallow assessment been completed:				Y/N if Y what was the date:					
Step 1: Clinical review :									
				Recommendation (Practice use)					
Required medicines				1 & 2	3	4	5	GP	Actioned
Name of Medicine	Strength	Dose form	Dose	Need reviewed	Licensed Product	Unlicensed use	Unlicensed product	Initial	Date
Requested by:				Pharmacist Signature:			Date:		
Date:				Prescriber Signature:			Date:		
Designation									
Plan discussed with Patient /Carer/ nursing staff? Please specify.....									

## Appendix 4: Professional guidance on the off-label use of licensed medicines and the use of unlicensed medicines

Unless the Summary of Product Characteristics (SPC) for a licensed medicine specifically allows the possibility of crushing or other manipulation, then doing so produces an unlicensed product or is off-licence use of the product. When a product is unlicensed or used off-licence the prescriber, pharmacist and a nurse or carer administering the medicine are responsible for any manipulations that they carry out. The following guidance is best practice:

### A) Prescribing

The MHRA has issued the following advice for prescribers<sup>18</sup>:

#### *Consider...*

- Before prescribing an unlicensed medicine, be satisfied that an alternative, licensed medicine would not meet the patient's needs
- Before prescribing a medicine off-label, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative
- Before prescribing an unlicensed medicine or using a medicine off-label:
  - Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy
  - Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up
  - Record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine; you may wish to record that you have discussed the issue with the patient.

#### *Communicate: best practice is that...*

- You give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision
- Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant.
- You explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative.

#### *Report suspected adverse reactions...*

Use the Yellow Card Scheme. Such reporting is equally important for unlicensed medicines or those used off-label as for those that are licensed.

The General Medical Council (GMC) guide to Good Practice in Prescribing Medicines 2008<sup>7</sup> reflects the advice of the MHRA; additionally the GMC advises that it is the responsibility of every prescriber to make efficient use of the

resources available and to consider the impact of their actions, such as prescribing, on resources available to other patients<sup>19</sup>.

Whilst it is generally outside the scope of this guideline the GMC advises that where some medicines are routinely used outside the scope of their licence, for example in treating children. Where current practice supports the use of a medicine in this way it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients, or those authorising treatment on their behalf, require or which they may see as significant.

As other healthcare professionals will be responsible for the supply and administration of the medicine it is important to involve them as well as the patient and carers in the decision to use an unlicensed medicine or the manipulation of a licensed medicine that is off license. Their professional responsibilities are set out below:

The supplying pharmacist should:

- Ensure that there is no licensed alternative,
- Where there is no licensed alternative the pharmacist should ensure that there is a sufficient evidence base that the proposed dosage manipulation is safe.
- That the unlicensed use is in the patient's best interests.

The nurse (or carer) administering the medicine should:

- Assure themselves by consulting the supplying pharmacist (or another pharmacist) that the proposed dosage manipulation is safe.
- Ensure that the dosage manipulation is written into the patients care record by the prescriber' this may be in the form of a prescription.
- Prior to administration obtain the patients informed consent.

## **B) Supplying**

The Royal Pharmaceutical Society of Great Britain provides the following guidance<sup>20</sup> to pharmacists.

### **Off-label use of medicines**

Reasonable steps should be taken to ensure that the prescribing doctor knows that he has prescribed a product for use outside its marketing authorisation and the possible consequences of this. Pharmacists should liaise with the prescriber and in the light of the available data make a decision as to whether or not to make a supply. Data on the use of the product for the particular indication may be available from the manufacturer, drug information services and possibly the Information Pharmacists at the Royal Pharmaceutical Society. It may be that the prescriber has had substantial experience of using this product in this way.

Principle 1 of the Code of Ethics, “Make the Care of Patients your First Concern”, states that:

- “The care, well-being and safety of patients are at the centre of everyday professional practice. They must be your primary and continuing concern when practicing.”
- You must “consider and act in the best interests of individual patients and the public.”

Generally speaking it is not appropriate to deviate from a prescriber’s directions, but this must be balanced against the pharmacist’s professional duty to ensure that every prescription is appropriate for the patient. If the pharmacist feels that a significant risk to the patient’s health is likely if the supply is made, then the option of refusing to supply should be given due consideration.

A pharmacist should bring to the attention of the patient that the product does not have a marketing authorisation or is being used outside the terms of its marketing authorisation, as the case may be. As far as possible this should be done without undermining the patient’s confidence in either the prescriber or the prescribed medicine.

Pharmacists should not feel that they discharge all their potential liability where the prescriber is prepared to sign a declaration to the effect that he or she is accepting full responsibility for any adverse effects of the prescribed medicine. The potential liability would be shared with the prescriber in any event<sup>24</sup>.

### **Unlicensed Medicines**

Pharmacists are reminded that it is a professional requirement that where a product is ordered on a prescription, a pharmacist must supply a product with a marketing authorisation, where such a product exists and is available, in preference to an unlicensed medicine or food supplement. Guidance on the key professional responsibilities for pharmacists when providing advice about or supplying specials, and support in making appropriate choices for their patients is available from the Royal Pharmaceutical Society<sup>10</sup>.

The Good Practice Guidance on: The procurement and supply of pharmaceutical specials<sup>21</sup> published by the Pharmacy Professional in July 2010 reiterates the importance of only supplying a special where no clinically appropriate licensed product is available. Pharmacists should challenge prescriptions for unlicensed products and suggest alternatives when they are prescribed<sup>22</sup>. E.g. paracetamol 500mg/ 5ml suspension; a licensed paracetamol 250mg/5ml suspension or a soluble 500mg paracetamol tablet may be suitable alternatives.

## **C) Administration**

The Nursing & Midwifery Council (NMC) Standards for Medicines Management include two standards (number 16 and 22) that relate to the administration of off-label use of licensed medicines and unlicensed medicines<sup>23</sup>. These are:

**Standard 16: Aids to support compliance** gives the following guidance:

**Crushing medication**

“The mechanics of crushing medicines may alter their therapeutic properties rendering them ineffective and are not covered by their product licence. Medicinal products should not routinely be crushed unless a pharmacist advises that the medication is not compromised by crushing, and crushing has been determined to be within the patient’s best interest.”

**Disguising medication**

“As a general principle, by disguising medication in food or drink, the patient or client is being led to believe they are not receiving medication, when in fact they are. The NMC would not consider this to be good practice. The registrant would need to be sure what they are doing is in the best interests of the patient, and that they are accountable for this decision.”

**Standard 22: Unlicensed medicines** gives the following guidance:

**Unlicensed medicines**

“A registrant may administer an unlicensed medicinal product with the patient’s informed consent against a patient specific direction but not against a patient group direction.”

“An unlicensed medicine is the term used to refer to a medicine that has no marketing authorisation. If an unlicensed medicine is administered to a patient, the manufacturer may not have liability for any harm that ensues. The person who prescribes and dispenses or supplies the medicine carries the liability. This may have implications for you in obtaining informed consent.”

**Medicinal products used outside their licence**

“As a registrant, you should be satisfied that you have sufficient information to administer a medicine prescribed off-label safely and, wherever possible, that there is acceptable published evidence for the use of that product for the intended indication.”

The Advice Centre of the Nursing and Midwifery Council has also provided the following guidance<sup>24</sup>:

**Liability**

*“The crushing of a tablet before administration in most cases renders its use “off-label”. Consequently the manufacturer may assume no liability for any ensuing harm that may come to the patient or the person administering it. Careful consideration should be given to the person crushing the tablet and whether or not they have sensitivity to it. In such cases even minimal contact with the medication, could result in a serious reaction.*”



*When a medicine is authorised to be administered "off-label" by an independent prescriber, a percentage of liability for any harm that may ensue will still lie with the administering nurse. The balance of this liability would be assessed in a court of law on an individual case basis."*

### **Administration via a PEG tube**

*"Where medicines are required to be administered via a PEG tube, registrants are advised to discuss the situation with the independent prescriber and the pharmacist. Where there is one, an alternative should be prescribed. If there is no option but to crush the medication, then the manufacturer should be contacted to establish whether this is advisable.*

*Furthermore authorisation for "off-label" medication administration (crushing of tablets) should always be obtained in writing and not accepted verbally. The reasons why medication is being crushed must be clearly documented in the patient's notes and communicated to the patient and other members of the multi disciplinary team. A care plan should also be implemented to identify this intervention with the reasons clearly stated.*

*The issues surrounding the administering of medication via a PEG tube for nurses, when it involves the crushing of tablets are many and include concerns regarding blockages in the tube. In incidences where this has occurred, it is in the majority of cases, because of previously crushed tablets forming a blockage. There are potential risks to the patient, in that they could on removing the blockage, by flushing the tube, inadvertently administer a bolus of a previously administered medication, to the detriment of the patient's health."*

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## 6. Members of the Working Group

Name	Title
William Duffield	Head of Pharmacy and Medicines Management – Denbighshire
Rory Wilkinson	Prescribing Support Pharmacist

## 7. Consultation

Name	Title	Date Consulted
North Wales Medicines Management Group		March 2010
Dorothy Blythin	Nurse Reviewer/ Care home support, Denbighshire.	February 2010
Steve Farley	Lead Nurse Reviewer, Denbighshire.	February 2010
Conwy and Denbighshire Prescribing subgroup		April 2010
Nursing & Midwifery Council		July 2010
Welsh Medicines Partnership	Technical Editors	August 2010
All Wales Prescribing Advisory Group	Multidisciplinary group including GPs, hospital consultants, pharmacists, nurses, lay members and representatives of the pharmaceutical industry.	Final consultation 20 <sup>th</sup> October 2010
Royal Pharmaceutical Society		June 2011