

NHS Greater Glasgow and Clyde Guidance on the Use of Specials in Primary Care

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Definitions

- **Unlicensed medicines:** Medicines without a Marketing Authorisation from MHRA.
- **Off-label/off-licence medicines:** Licensed medicines with full Marketing Authorisation to be prescribed for unlicensed indications or in unlicensed dosages or used outwith the terms of their Marketing Authorisation.
- **‘Specials’:** A pharmaceutical ‘special’ as defined by law is a medicine made to satisfy the needs of an individual patient.
- **Extemporaneous preparations:** These preparations are not defined in law as ‘specials’ and are exempt from the usual requirements of the Medicines Act 1968 for quality, safety and efficacy (sometimes referred to as ‘Section 10-exemptions’).
- **Special order products:** This term currently is generally attributed in community pharmacies to all products not held routinely by Wholesalers e.g. unusual licensed product which has to be ordered through a ‘special order’ process.
- **Special requests:** This term is generally attributed in general practices to patient requests for medicines not currently on their repeat prescription record.

NB: Please note that information is correct at time of writing but may be subject to change.

This guidance should be read in conjunction with Royal Pharmaceutical Society “Prescribing Specials: Guidance for the Prescribers of Specials” and “Guidance for pharmacists on the procurement and supply of Specials”

1. Background to ‘Specials’

What is a ‘Special’?

Most drugs prescribed for patients are licensed medicinal products. Very rarely a patient will need a medicine which is not already available on the market; it then has to be specially made. This might be because a liquid is needed and only tablets that are unable to be crushed are available, perhaps for a child who needs an unusual dose, or to overcome swallowing difficulties in a stroke patient. Sometimes a patient is allergic to an ingredient, they cannot tolerate it or it is unsuitable e.g. alcohol is an ingredient in some liquids needed for infants. To address these needs, many specially prepared products are produced by specialist manufacturing units which have obtained a specials manufacturing licence from the Medicines and Healthcare Products Regulatory Agency (MHRA). This means the facilities of the supplier have reached a minimum standard. It does not mean the product is licensed.

A pharmaceutical ‘special’ as defined by law is a medicine made to satisfy the needs of an individual patient. These so-called ‘specials’ are unlicensed and, unlike licensed medicines, are not assessed for safety or efficacy by a regulatory body. Therefore, the prescriber may have to accept greater responsibility for the safety and effectiveness of the product. ‘Specials’ are made under a ‘specials’ manufacturing license from the MHRA, according to many different formulations by different companies (the exact contents can differ every time) and may have no safety, stability or efficacy testing.

‘Specials’ differ from unlicensed products that can be prepared in a registered pharmacy through a process usually referred to as ‘extemporaneous dispensing’. The latter are not defined in law as ‘specials’ and are exempt from the usual requirements of the Medicines Act 1968 for quality, safety and efficacy (sometimes referred to as ‘Section 10-exemptions’). The volume of extemporaneous dispensing undertaken in community pharmacies is now very small.

When are ‘Specials’ used?

MHRA advice and NHS Circular PCA(P)(2015)17 recommends that ‘specials’ and imported unlicensed medicines should only be used where there is no suitable licensed alternative, and that unless there is a specific clinical reason, clinicians should not continue to use an unlicensed preparation when there is a licensed product available. Before prescribing a ‘special’, prescribers should consider alternative strategies. To aid in these circumstances, the UK Medicines Information service (UKMi) produced guidance regarding patients unable to take solid dosage forms (Appendix 1). This guidance suggests taking a stepwise approach, and first considering licensed and off-licence/off-label alternative options prior to prescribing an unlicensed ‘special’.

Where do they come from?

“Specials’ are unlicensed products prepared under a “special’ manufacturing license from the MHRA, by licensed manufacturing units that have reached a minimum standard under the Medicines Act 1968. Such units may be small specialist manufacturers, NHS manufacturing units e.g. Pharmacy Production Unit (PPU), Western Infirmary, Glasgow or Tayside Pharmaceuticals, Dundee, or large companies who produce “specials’ in a similar way to their licensed products. “Specials’ will not have been assessed for safety, quality and efficacy by the licensing authority; however, the manufacturer must ensure that the process is carried out under the supervision of appropriately qualified staff. As the companies only require adherence to minimal standards, this means the facilities of the supplier have reached a minimum standard. It does not mean the product is licensed and the amount of information provided with these products varies significantly, as does the level of stability testing.

It is usually difficult to determine when ordering a product if it is going to be manufactured as a 'special' batch or as an extemporaneous product and the quality can vary.

How do I know if it's unlicensed?

If a medicine is not listed in the British National Formulary (BNF) then it is likely to be unlicensed (the BNF does list some unlicensed products but they are clearly identified as needing to be obtained from a 'specials' manufacturer). This NHS Greater Glasgow and Clyde (NHS GGC) Guidance on the Use of 'Specials' in Primary Care document and NHS GGC 'Specials' A to Z can also help.

Occasionally, medicines that are licensed in other countries, but unlicensed in the UK can be considered as an alternative to an unlicensed 'special'.

What does it mean for the prescriber and dispensing pharmacist?

The responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine off-label/off-licence may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label/off-licence. These risks may include adverse reactions, product quality, or discrepant product information or labelling e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use.

General Medical Council (GMC) 2015 guidance recommends that prescribers should usually prescribe licensed medicines in accordance with the terms of their licence. However, prescribers may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.

Prescribers are often unaware of the costs of 'specials'. The prescribing costs of 'specials' to GP practices have been increasing significantly for the past few years, and were until recently unregulated in Scotland. With the development in February 2013 of Scottish Drug Tariff Part 7S, a limited list of 'special' preparations is now included in the Scottish Drug Tariff. This reduces variation in cost. However, they are still generally more expensive than licensed medicines and remain unregulated, with a wide variation in quality of different Specials depending on the manufacturer. 'Specials' that can be obtained from NHS Pharmacy Production Units e.g. at the Western Infirmary, Glasgow or Tayside Pharmaceuticals, Dundee are often the most cost effective options.

Pharmacists, when dispensing, also have professional responsibilities and can incur liability if their actions or omissions have contributed to the harm of patients. It may be necessary for the community pharmacist to discuss this and the appropriateness of the 'special' prescription with the prescriber so that both are fully aware of the implications, status and cost of an unlicensed product being supplied. It is recommended that the community pharmacist document this. NHS Circular PCA(P)(2015)17 also requires community pharmacy contractors to seek Health Board authorisation before ordering and dispensing 'specials' and imported unlicensed medicines which are not listed in Part 7S of Drug Tariff or available from an NHS manufacturing unit in Scotland, England or Wales.

Therefore, prescribers should expect to be contacted by community pharmacists to confirm if they really want to prescribe an unlicensed 'special' and to advise if there is a licensed alternative available. They may need some more information about the patient in order to help e.g. why do they need a liquid? Are they on a feeding tube? etc.

Within NHS GGC, the NHS Circular PCA(P)(2015)17, NHS GGC Unlicensed Medicines Policy, NHS GGC 'Specials' A to Z and the 'NEWT guidelines' (The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties, North East Wales NHS Trust) are the most common reference sources used locally for information on the use of 'specials', unlicensed and off-label/off-licence medicines. HSCP/Locality Prescribing Teams, NHS GGC Central Prescribing Team and local community pharmacists can provide further advice on using 'specials', unlicensed medicines and licensed products in an off-label/off-licence way.

2. Good Practice in Prescribing and Dispensing of 'Specials'

General Principles

- Medicines contained within a Health Board Formulary should generally be used in preference to any non-formulary agent. Although it is anticipated that Health Board Formularies will cover the vast majority of prescribing decisions for patients, it is recognised that in some cases, medicines outwith the formulary may need to be considered.
- When patients are unable to take medicines in solid oral dosage forms, this should prompt a medication review. The choice of medicine for these patients should be made on an individual basis taking into account clinical evaluation e.g. consider a swallowing assessment, medication review to assess if the medicine is still required, the patient's method of feeding, the practicalities of administration, product quality and cost. Regular review of the prescribing and dispensing of 'specials' should be undertaken.
- Licensed products with the appropriate Marketing Authorisation should be used to treat patients in preference to unlicensed medicines, off-label use or use of 'specials'. It may be the case that an alternative medication or formulation could be used in preference. One option should be to consider if it is appropriate to crush a solid formulation.
- When a previously unlicensed 'special' gains a Marketing Authorisation, MHRA advise that use of the unlicensed preparation should cease in preference for the newly licensed product.
- Use of unlicensed, off-label, or 'specials' may be necessary in order to provide the optimum treatment for patients. In some specialities, such as paediatrics, this may be accepted practice. As a result, some Health Board formularies may include unlicensed 'specials'.
- Use of off-label/off-licence products is recommended in preference to the use of 'specials'.
- All healthcare professionals involved in the treatment of a patient with a 'special' should be aware of its unlicensed status, be informed of any potential problems or risks and how to deal with them and be given sufficient information to administer or use the medicine safely.
- Use of 'specials' made as batch processes are recommended in preference to bespoke products as batches are more likely to have undergone some quality control testing. Use of 'specials' made as batch processes also tend to have a lower acquisition cost from a given manufacturer, compared to bespoke products of the same drug.
- Nurse and Pharmacist Independent Prescribers may prescribe unlicensed and off-label medicines on the same basis as doctors provided they are competent and take responsibility for doing so.
- Supplementary Prescribers may only prescribe unlicensed medicines under an agreed Clinical Management Plan.
- Patient Group Directions (PGDs) can be utilised for administration of medicines used off-label but are not allowed to be used for unlicensed products.
- Adverse drug reactions and medication incidents involving unlicensed medicines, 'specials' or medicines used off-label should be reported using the yellow card process as for licensed medicines, and recorded, as appropriate, in line with NHS GGC policies – Incident Management Policy and Policy on the Management of Significant Clinical Incidents or contractor Significant Event Analysis procedures.

Prescribing Responsibilities

- Clinical and legal responsibility for use of unlicensed, off-label or 'special' medicines rests with the prescriber signing and issuing the prescription. It is therefore important that the prescriber understands the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur. The manufacturer is only likely to be found liable if harm results from a defect in the product.
- When prescribing an unlicensed medicine the GMC advises that prescribers 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 not following common practice, the reasons for prescribing an unlicensed medicine.
 - ⇒ give patients (or their parents or carers) sufficient information about the medicines proposed to be prescribed to allow them to make an informed decision.
- When the treatment is initiated in secondary care, there should be full consultation between hospital doctors and prescribers in primary care regarding clinical and prescribing responsibilities, rationale behind the treatment, the risks involved and any necessary monitoring arrangements. A decision on final responsibility should depend primarily on the best interests of the patient in terms of safety and convenience, and regular review is recommended. GPs are under no obligation to continue prescribing unlicensed treatment that is initiated in secondary care.
- When obtaining consent to treat it is good practice to discuss, where appropriate, with the patient/carer the status of the medicine, side effects and to make a record of this in the patient's notes.
- Community pharmacists can advise on the use of 'specials'. It is recommended that community pharmacists should be satisfied that the prescriber is aware that a prescription is for a 'special' and should contact them to confirm this. It is also good practice for the prescriber to discuss availability of supply with the community pharmacist.
- Resources are available on alternative strategies and options, including the locally developed and quarterly updated NHS GGC 'Specials' A to Z, and regular review of unlicensed, off-label and 'special' medicines prescribing is recommended.

Pharmacist Dispensing Responsibilities

- The supplying pharmacist shares responsibility for the suitability of the 'special' product for the patient. In supplying a 'special', the pharmacist must be able to provide reasons why the 'special' is necessary, take all reasonable steps to ensure that procurement is from an appropriate source, that the product is of appropriate quality, that the product meets the needs of the patient and that relevant records are kept.
- Community pharmacists can advise prescribers on the use of unlicensed, off-label and 'special' medicines. Resources are available on alternative options, including the locally developed and quarterly updated NHS GGC 'Specials' A to Z, and regular review of unlicensed, off-label and 'special' medicines prescribing is recommended.

- NHS Circular PCA(P)(2015)17 also requires community pharmacy contractors to seek Health Board authorisation before dispensing 'special' preparations and imported unlicensed medicines.
- It is recommended that NHS Pharmacy Production Units are used when possible by community pharmacists to ensure most cost effective, quality assured and consistent supply of the 'special' product.

3. Medicines for Patients Unable To Take Solid Oral Dosage Forms

Some patients are unable to take medicines in solid oral dosage forms because they have swallowing difficulties or feeding tubes. The choice of medicine for these patients should be made on an individual basis taking into account clinical evaluation e.g. consider a swallowing assessment, medication review to assess if the medicine is still required, the patient's method of feeding, the practicalities of administration, product quality and cost.

The following process is recommended (see Figure 1)

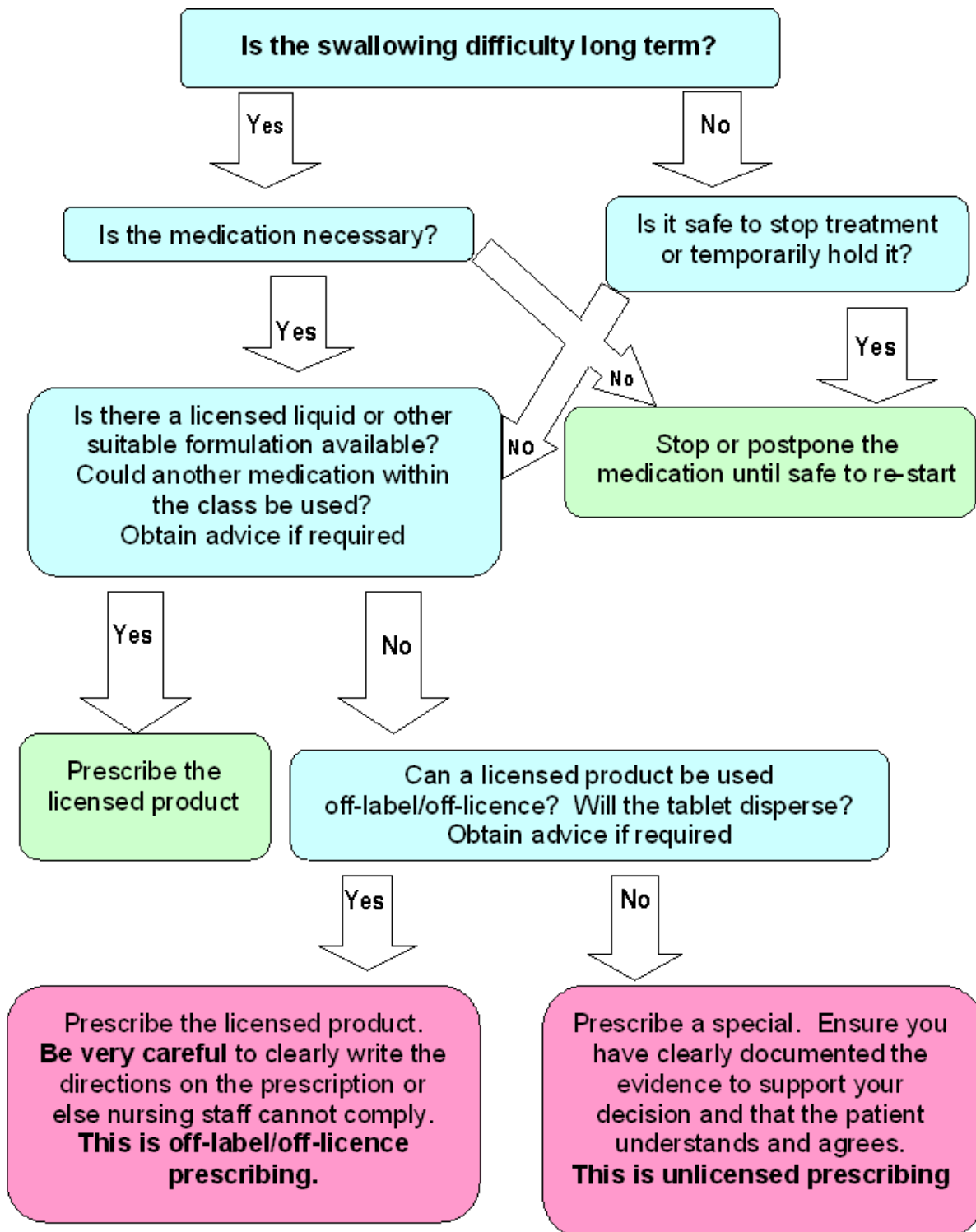
- Review the patient. Consider a clinical evaluation e.g. swallowing assessment and medication review as their condition may have changed. Do they still need the medicine?
- Licensed medicines should be used where possible. Have all licensed alternatives been considered? If possible, use a licensed medicine in a suitable formulation to meet the patient's needs (e.g. a dispersible tablet or licensed liquid medicine). Consider switching to a different agent in the same class, or to a different route of administration to allow a licensed medicine to be used. Please refer to NHS GGC 'Specials' A to Z, BNF and Summary of Product Characteristics.
- If switching medicines, make sure any dose changes are taken into consideration. Bioavailability can change between tablets and liquids, etc.
- Always consider that changes to a formulation may affect its absorption. Some formulations should not be altered or it may be dangerous to do so. Some medications/tubes/feeds interact.
- It is often safer to use a licensed product in an unlicensed manner, for example by crushing/dispersing tablets or opening capsules, rather than using a completely unlicensed product. This is off-licence or off-label prescribing. Not all medicines are suitable for use in this manner and it is important to check beforehand. Also, take into account the patient's and carer's ability to administer medicines in this way. Please refer to NHS GGC 'Specials' A to Z.
- If you decide to prescribe a licensed product to be used in an off-label/off-licence way e.g. opening a capsule, make sure the directions are very clearly written on the prescription. Nursing staff or carers will not be able to comply unless this is written clearly on the prescription and it appears on the label.
- Medicines that are licensed in other countries, but unlicensed in UK can also be considered as an option or as an alternative to a 'special'.
- Is the medicine chosen a cost effective option?
- If an unlicensed medicine or unlicensed 'special' is the best option for the patient, it is recommended that this is discussed with the patient so that they understand and agree.
- 'Specials' can have short expiry dates or may require fridge storage. Quantities prescribed and frequency of supply should be monitored to reduce waste. Only prescribe enough medicine to last until the expiry to avoid waste, this could be as short as 2 weeks.
- Advise your patient to use the same community pharmacy each time to enable consistency of supplier and manufacturer. Each manufacturer may use a different formula and the efficacy may vary. This is particularly important for drugs with a narrow therapeutic index. A

batch produced formulation from a licensed 'specials' manufacturer is preferred to bespoke preparations when possible.

- 'Specials' prescriptions take longer to be authorised, prepared and dispensed so when requesting, allow plenty of time for authorisation, manufacture and delivery.

Appendix 1 includes some useful advice on choosing and administering these medicines. For further advice please contact your HSCP/Locality Prescribing Team or NHS GGC Central Prescribing Team.

Figure 1



4. Processes for Prescribing and Dispensing of 'Specials' within Primary Care in NHS GGC

Prescribing

- The information included in this guidance and in NHS GGC 'Specials' A to Z should be used to help determine if an unlicensed 'special' is required to be prescribed following medication review, and whether a licensed alternative product or off-label/off-licensed medicine could be prescribed instead.
- If the requirement for a 'special' is via a request from secondary care, the prescriber in primary care should discuss the need for the 'special' product with the hospital specialist and agree if the prescription should be continued in primary care or if an alternative prescription would be appropriate.
- Prescriber responsibilities regarding clinical and legal responsibility for use of unlicensed or off-label/off-licence medicines as previously noted should be considered at this point. Details of the reasons for prescribing a 'special' follow up and monitoring should be documented.
- If an unlicensed, off-label/off-licensed or 'special' product is for administration, or there are specific instructions, the directions should be very clearly written on the prescription so that they appear on the dispensing label e.g. regarding crushing of tablets etc.
- Prescribers should expect to be contacted by local community pharmacists to confirm that an unlicensed 'special' is required to be ordered and supplied.

Dispensing

- Community pharmacists are asked to contact the prescriber to confirm that a 'special' has been requested, and discuss alternative options available, before ordering the product. NHS GGC 'Specials' A to Z resource should be accessed and considered for this purpose.
- Community pharmacy contractors should seek Health Board authorisation for those items detailed within NHS Circular PCA(P)(2015)17. It is vital that contractors comply with the Circular as failure to obtain prior Health Board authorisation may result in the additional costs incurred in obtaining these products not being reimbursed. See Appendix 2 for the national framework.
- When a 'special' is required to be ordered and dispensed, the community pharmacist should phone 0141 232 1777 for NHS GGC Central Prescribing Team advice or authorisation. In some instances, it may be possible to offer alternative options. Although the aim is to respond quickly to authorisation requests, there may be a delay if advice has to be obtained from other colleagues.
- It is important to ensure continuity of supply when children have been started on 'specials' in Royal Hospital for Children.
- If an unlicensed, off-label/off-licensed or 'special' product is for administration, or there are specific instructions, the directions should be very clearly written on the prescription and appear on the label so that nursing staff or carers can comply with instructions e.g. regarding crushing of tablets.
- All patients must be informed that the dispensed medication is unlicensed.

NHS GGC Prescribing Team will monitor the prescribing and dispensing of 'specials' across the Health Board on an ongoing basis to consider licensed and off-label/off-licence alternatives and promote and supportt safe, clinically effective and cost effective use of medicines via medication review. If more information or advice is required, please contact your local HSCP/Locality Prescribing Team or the Central Prescribing Team. Contact details are given in Appendix 3. Manufacturers/suppliers' contact numbers are given in Appendix 4.

5. References and Sources of Further Information

Royal Pharmaceutical Society Guidance on 'specials'

<http://www.rpharms.com/pharmacy-practice-resource/specials.asp>

Medicines and Healthcare products Regulatory Agency (MHRA) blog

<https://mhrainspectorate.blog.gov.uk/2015/10/09/supply-of-unlicensed-medicines-when-an-equivalent-licensed-product-becomes-available/>

The Scottish Government. NHS Circular: PCA(P)(2015)17 : Pharmaceutical Services: Amendment to Drug Tariff in Respect of 'special' preparations and Imported Unlicensed Medicines. 21st August 2015 [http://www.sehd.scot.nhs.uk/pca/PCA2015\(P\)15.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2015(P)15.pdf)

General Medical Council. Good practice in prescribing and managing medicines and devices. 25 February 2013. http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

GMC Hot topic: Prescribing unlicensed medicines. November 2015

http://www.gmc-uk.org/guidance/28349.asp?dm_i=OUY,3T89X,3F636G,DQDD4,1

Drug and Therapeutics Bulletin. The use of 'specials' in primary care. October 2010. Volume 48, Number 10: pages 110-112 <http://dtb.bmj.com>

Medicines and Healthcare products Regulatory Agency (MHRA). Drug Safety Update. Off-label or unlicensed use of medicines: prescribers' responsibilities. April 2009. Volume 2, Issue 9:6. <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990>

UKMI Medicines Q&A 294.3: What are therapeutic options for patients unable to take solid oral dosage forms? UK Medicines Information. July 2013.

http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Medicines%20Q%20&%20A/NW_QA294_3_Solidoraldosageformsalternatives.doc

Smyth J. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties, 3rd edition. Wrexham: Betsi Cadwaladr University Health Board; 2015

White R and Bradnam V. Handbook of drug administration via enteral feeding tubes, 2nd edition. Pharmaceutical Press. 2010.

Mental Welfare Commission for Scotland. Good Practice Guide. Covert Medication – for consultation. July 2013.

http://www.mwcscot.org.uk/media/140485/covert_medication_finalnov_13.pdf

Barking and Dagenham, Havering and Redbridge Clinical commissioning Groups, 'Specials Information Pack' January 2015.

http://www.barkingdagenhamccg.nhs.uk/downloads/For-health-professionals/Medicines-management/Guidance/BHR_Specials_Information_pack%20Sept%202014.pdf

NHS East of England Collaborative Procurement Hub 'specials' Sourcing Group. Information and Guidance on the Prescribing and Use of Unlicensed Pharmaceutical 'specials'.

http://www.eoecph.nhs.uk/Pharmaceutical_'specials'.pdf

British Association of Dermatologists. Specials Recommended by British Association of Dermatologists for Skin disease, 2014

<http://www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=1848>

NHS Greater Glasgow and Clyde Formulary <http://www.ggcprescribing.org.uk/>

NHS Greater Glasgow & Clyde Acute Division. Unlicensed Medicines Policy. December 2010.
[http://www.ggcprescribing.org.uk/media/uploads/policies/section_9/9.1_ulm_policy - 1206.pdf](http://www.ggcprescribing.org.uk/media/uploads/policies/section_9/9.1_ulm_policy_-_1206.pdf)

NHS Greater Glasgow and Clyde. Incident Management Policy. June 2014
<http://www.staffnet.ggc.scot.nhs.uk/Applications/Datix/Documents/Incident%20Management%20Policy.pdf>

NHS Greater Glasgow and Clyde. Policy on the Management of Significant Clinical Incidents.
January 2011.
<http://www.staffnet.ggc.scot.nhs.uk/Applications/Datix/Documents/SCI%20Final%20Version%20Jan%202011.pdf>

Choosing medicines for patients unable to take solid oral dosage forms

Selecting suitable formulations for adult patients with swallowing difficulties or feeding tubes

A stepped approach is suggested:

STEP 1

Use a licensed medicine in a suitable formulation.

For example:

- Licensed liquid preparation
- Soluble tablets
- Powders or granules for suspension

In order to use a licensed medicine, consider switching to a different agent in the same class, or to a different route of administration.

For example, consider:

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

Consider the patient's method of feeding:

Patients on liquid feeds may take oral liquid medicines, dispersible tablets or solid preparations dispersed in water. For patients on thickened fluids, liquid medicines can be mixed with products like *Thick and Easy*.

Patients on soft-food diets may be able to swallow crushed tablets or the contents of capsules given with food.

Patients with enteral feeding tubes may have oral medicines given by this route.

Why licensed status matters

To be granted a licence a medicine must meet quality standards and be shown to be safe and effective. Licensed medicines usually come with a patient information leaflet and are considered the safest choice.

Special-order medicines are unlicensed and are not required to meet the same standards as licensed medicines. Prescribers take greater responsibility when using them.

In many cases a licensed preparation will be available that meets the patient's needs.

Cost

Special-order medicines are often considerably more expensive than licensed medicines. They may have short shelf-lives compared to licensed alternatives and may need fridge storage.

For example, bendroflumethiazide liquid is 80 times more expensive than tablets:

- 28 doses of 2.5mg tablets costs about £1,
- 30 doses of 2.5mg/5ml liquid (150ml) costs more than £80.

Bendroflumethiazide tablets can be dispersed in water for administration orally or via feeding tubes.

STEP 2

Consider using a licensed medicine in an unlicensed manner, for example by dispersing tablets in water or by opening capsules.

For example:

- Clindamycin capsules can be opened and the contents mixed with water.
- Bendroflumethiazide tablets can be dispersed in water.
- Both examples are suitable for administration orally or via a feeding tube.

Not all medicines are suitable for administration in this way and it is important to check beforehand. See over for where to get advice.

As before, consider switching to a different agent or route of administration in order to use a licensed product.

Is it needed?

If the patient is taking medicines that aren't needed or aren't working, stop or change them.

Care staff should only give licensed medicines in an unlicensed way if there is a written direction in the patient's care plan.

Practical directions are overleaf.

STEP 3

In situations where there is no suitable licensed option, consider using a 'special'.

Special-order ('special') liquid medicines are unlicensed and expensive. They should only be prescribed if there is no licensed medicine that meets the patient's needs.

Licensed medicines should be used where possible.
Special-order medicines are unlicensed and expensive and should only be prescribed if necessary.

Practical directions

Always check beforehand if a tablet is suitable for dispersing or crushing, or if a capsule is suitable for opening.

- Crushing or dispersing tablets**

Many immediate-release tablets can be dispersed in water without crushing; some medicines need to be crushed first. Some tablets (e.g. modified-release) are not suitable for crushing.

For medicines that are suitable for crushing, crush using a tablet crusher, a pestle and mortar or between two metal spoons.

Only crush medicines one at a time; do not crush all the patient's medicines together. Crushing or dispersing should only be performed immediately before administration.

- Opening capsules**

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

- Giving medicines in liquids or soft food**

Some capsule contents or crushed tablets can be given with a small amount of cold liquid or cold soft food such as a teaspoon of yoghurt or jam. Use a small amount of food to ensure the full dose is taken; if taken with a meal, add medicine to the first mouthful of food.

Crushed tablets or capsule contents may taste very bitter to patients taking them orally. Mask the taste by giving with strong flavours such as blackcurrant.

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

- Giving medicines via feeding tubes**

Feeding tubes should be flushed with water before and after each medicine is administered. If a liquid medicine is thick or syrupy, dilution may be required. Some patients are fluid restricted and that needs to be taken into account.

When administering crushed tablets or opened capsules via a feeding tube, add the powder to 15-30ml water and mix well. Draw into a 50ml oral syringe and administer. If you have used a mortar or tablet crusher, rinse this with water and administer the rinsings also.

Suggested protocol for administering medicines via feeding tubes:

1. Stop the feed (leaving a feeding break if necessary).
2. Flush the tube with 30ml water.
3. Prepare the first medicine for administration, and give it.
4. Flush with 10ml water.
5. Repeat stages 3 and 4 with subsequent medicines.
6. Flush with at least 30ml water.
7. Re-start the feeding (leaving a feeding break if necessary).

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 should be documented in the patient's care plan.

Where can I get advice?

- Local Prescribing Support and Community Pharmacies**

For advice on choosing appropriate dosage forms or to check if tablets or capsules can be dispersed, crushed or opened and dispersed, please refer to NHS GGC Specials A to Z, or contact your local Community Pharmacist, your HSCP/Sector Prescribing Team or NHS GGC Central Prescribing Team.

- UKMi medicines information centres**

Contact details for UKMi medicines information centres are available at www.ukmi.nhs.uk. Click on the map then search for your local or regional centre.

- Medicines Q&A**

This leaflet accompanies a *Medicines Q&A* document which provides further information and lists options available in several therapeutic areas for adult patients with swallowing difficulties or feeding tubes. Access it online via the link at the bottom of the page.

- Reference texts**

Details of two respected texts are at the bottom of the page.

Only prescribe special-order medicines if there is no suitable licensed medicine available that meets the patient's needs.

It may be appropriate to use a licensed medicine in an unlicensed way.

References:

- UKMi. Medicines Q&A 294.3. What are the therapeutic options for patients unable to take solid oral dosage forms? July 2013. Available online via www.evidence.nhs.uk.
- White R and Bradnam V. Handbook of drug administration via enteral feeding tubes. Pharmaceutical Press. 2010 Available via www.medicinescomplete.nhs.uk (subscription required).
- Smyth J. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Available at www.newtguidelines.com (subscription required).

Date of preparation: July 2013

**Appendix 2 Generic Framework for Specials authorisation Process across Scotland
(An authorisation is required for every individual patient)**

Patient presents with a prescription at the community pharmacy. The GP practice system (EMIS / INPS) if used may have informed the prescriber that the product is unlicensed. This does not exempt the community pharmacist from undertaking the appropriate clinical checks. The pharmacy proceeds to secure supply unless the pharmacist when undertaking the clinical check deems it necessary to first contact the prescriber.

**No Health Board
Authorisation Required**

**Health Board
Authorisation Required**

The product is NOT listed in
Scottish Drug Tariff Part 7s

The product is listed in Scottish
Drug Tariff Part 7s

- a. Authorisation obtained for patient prescription within last 12 months with less than 20% price variation from original authorisation
- b. Preparation is available from an NHS manufacturing unit within Scotland/ England/ Wales.
- c. Endorse the fixed non part 7s handling charge as a handling charge (hc)
- d. If other OOP expenses apply (including wholesaler handling charges) endorse as postage and packing costs (pp)

- a. The product is not listed on Scottish Drug Tariff Part 7s.
- b. One quote to be sourced including postage & packing, handling charges, shelf life etc.
- c. Reauthorisation for the same patient and product if price varies > 20% from the original authorisation prescription
- d. Reauthorisation required after 12 months for clinical validation
- e. Endorse prescription electronically and on paper with invoice price, less any rebate plus any additional cost authorised e.g. OOP expenses (including wholesaler handling charge) should be endorsed as postage and packing costs (pp)
- f. Endorse the fixed non Part 7s handling charge of £30 as a handling charge (hc)

Recovery by Health Boards of unauthorised expenditure e.g. where the full amount has not been authorised or the contractor has purchased at a higher price than was pre-authorised

1. If a contractor sources a product at a greater price than agreed the Health Board may reclaim the difference between the agreed price and the final invoice price.
2. If the contractor has not obtained authorisation the Health Board may reclaim the difference between the price that would have been approved and the invoiced price.
3. If the Health Board intends to reclaim monies they will inform the contractor giving them 28 days to appeal any decision.
4. All appeals will be considered on an individual basis by Health Board with a written response within 28 days.

Version 1
Agreed July 2015 Review July 2017

Appendix 3 HSCP/Locality/PPSU Prescribing Team Contact Details

CH(C)P	Pharmacist	Work No
North East HSCP Locality - Glasgow City HSCP Templeton Business Centre Building 2 62 Templeton Street Glasgow G40 1DA	Anne Thomson , Lead Clinical Pharmacist anne.thomson2@ggc.scot.nhs.uk	0141 277 7452
North West HSCP Locality – Glasgow City HSCP Glasgow City HSCP North West Locality HQ William Street Clinic 120-130 William Street Glasgow G3 8UR	Sheila Tennant , Lead Clinical Pharmacist stennant@nhs.net	0141 314 6235
South HSCP Locality – Glasgow City HSCP Clutha House South HSCP Locality Headquarters 120 Cornwall Street Glasgow G41 1AF	Graeme Bryson , Lead Clinical Pharmacist graeme.bryson@ggc.scot.nhs.uk	0141 427 8350
East Dunbartonshire HSCP Stobhill Hospital Old Trust HQ 300 Balgrayhill Road Glasgow G21 3UR	Carolyn Fitzpatrick , Lead Clinical Pharmacist carolyn.fitzpatrick@nhs.net	0141 201 3441
East Renfrewshire CHCP The Dickie Building 1 Burnfield Avenue Glasgow G46 7TL	Susan Galbraith , Lead Clinical Pharmacist susan.galbraith@nhs.net	0141 577 3391
West Dunbartonshire Vale Centre for Health and Care Main Street Alexandria G83 0UA	Pamela Macintyre , Lead Clinical Pharmacist pamela.macintyre@ggc.scot.nhs.uk	01389 828 293
Renfrewshire HSCP Renfrew Health & Social Work Centre 10 Ferry Road Renfrew PA4 8RU	Susan Love , Lead Clinical Pharmacist susan.love1@nhs.net	0141 207 7752
Inverclyde HSCP Port Glasgow Health Centre 2 Bay Street Port Glasgow PA14 5EW	Margaret Maskrey , Lead Clinical Pharmacist margaret.maskrey@ggc.scot.nhs.uk	01475 506142
Central Prescribing Team - PPSU 2nd Floor Main Building West Glasgow ACH Dalnair Street Yorkhill Glasgow G3 8SJ	Specials:	0141 232 1777
	Elaine Paton, Senior Prescribing Adviser	0141 232 1724
	Mairi-Anne McLean, Senior Prescribing Adviser	0141 232 1701
	Heather Harrison, Senior Prescribing Adviser	0141 232 1723
	Carol Smart, Prescribing Support Pharmacist	0141 232 1719
	Karen Liddell, Prescribing Support Pharmacist	0141 232 1723

Appendix 4 'Specials' Contact Numbers

NHS GGC Central Prescribing Team
Telephone 0141 232 1777 for advice or authorisation

Manufacturers/Suppliers Contact Numbers *(NHS units commonly used in NHS GGC in bold)*

Manufacturer / Supplier Name	Telephone No.	Fax No.
AAH Pharmaceuticals	0141 423 5888	0141 423 7662
AAH Retail	0845 607 8899	
Aclardian Specials	0844 5763180	0844 5763182
Arjun	01932 268 286	
Alliance Healthcare	01773 515599	0845 0518779
Archimedes Pharmaceuticals UK Ltd	0118 9315060	
BCM Specials	0800 952 1010	
Bristol Myers Squibb	01244 586 250	01244 586251
Durbin PLC	0208 869 6554	0208 869 6582
Eaststone	0800 678 3102	0800 678 3101
Eclipse	01355 598 300	
Ethigen	01355 598154	
Eldon Laboratories	0800 616 132	
Healthcare at Home	0800 783 2943	
Higher Nature	0870 066 4111	0870 0664010
Hospira	0208 838 5870	
Huddersfield Royal Infirmary	01484 342 788	
IDIS World Medicines	01932 824 000	
John Bell & Croydon	0207 935 5555	
Mandeville Medicines	01296 394 142	01296 397223
Martindale	0800 137 627	0800 393360
Moorefield Pharmaceuticals	0207 684 8561	
Nova Laboratories	01162 782 277	01162 230120
Novartis	0845 741 9442	
Oxford Pharmacy Store	01865 904 141	01865 337 550
Pharmacia (Pfizer)	01304 616 161	
Pharmacy Production Unit – NHS GG & C	0141 451 5820	0141 334 9064 0141 334 9137
Pharmalon	01708 379 000	
Pharma Nord	01670 534901	01670 534902
Phoenix Healthcare	01355 243091	01355 227075
Quantum Specials	0800 043 9372	01207279411
Rosemont	0800 919312	
SLA Pharmacy	01923 681 001	01923 681 221
St Mary's Hospital	0203312 6666	
Special Products Limited	01932 690325	01932 341091
Stockport Pharmaceuticals	0161 419 5657	0161 419 5426
Stoke Mandeville Hospital	01296 315000	
Tayside Pharmaceuticals, Ninewells Hospital	01382 632 052	01382 632 060
Thornton & Ross	01484 842217	
Torbay NHS Pharmacy Manufacturing Unit	01803 664 707	01803 664 354
UDG Link Pharmaceutical	01773 510 123	01773 810 644
Unichem	01506 434 211	01506 449 617
Unidrug Distributors	01773 510 123	01773 810644
Vitaline	01844 269 007	01844 269005