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

Written By:	Specials SLWG
Approved by:	Prescribing Management Group: Primary Care
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Definitions

- **Unlicensed medicines:** Medicines without a Marketing Authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA).

- **Off-label/off-licence medicines:** Licensed medicines with full Marketing Authorisation to be prescribed for unlicensed indications or in unlicensed dosages or used out with 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. an 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 "Professional Guidance 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 required to overcome swallowing difficulties, or to facilitate administration of unusual doses. A patient may be allergic or intolerant to an ingredient in the licensed product, or it is unsuitable (e.g. alcohol is an ingredient in some liquids needed for infants). To address these needs, specially prepared products are produced by specialist manufacturing units which have obtained a specials manufacturing license from the 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. As 'specials' are made under a 'specials' manufacturing license, different companies may use different formulations (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 as this is largely sub-contracted to 'specials' manufacturers.

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) has produced guidance regarding patients unable to take solid dosage forms (see here). This guidance suggests taking a stepwise approach, and first considering licensed and off-license/off-label alternative options prior to prescribing an unlicensed 'special'.

Occasionally, medicines that are licensed in other countries, but unlicensed in the UK can be considered as an alternative to 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. 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; they do not have a marketing authorisation and are unlicensed. As the companies only require adherence to minimal standards, this means the

amount of information provided with these products can vary 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 (and therefore are more likely to have undergone some quality control testing) or as an individual bespoke extemporaneous product and the quality can vary.

How do I know if it's unlicensed?

The only way to truly know if a product is unlicensed is to check if the item has a marketing authorization. However, the British National Formulary (BNF) does provide some information for products where a formulation or a drug is unlicensed. These items are clearly identified as needing to be obtained from a 'specials' manufacturer). The NHS Greater Glasgow and Clyde (NHS GGC) 'Specials' A to Z available on the NHS GGC Community Pharmacy Development Team website can also help.

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-license may be greater than when prescribing a licensed medicine within the terms of its license. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label/off-license. 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) guidance recommends that prescribers should usually prescribe licensed medicines in accordance with the terms of their license. 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 development in February 2013 of the Scottish Drug Tariff Part 7S, a limited list of 'special' preparations, reduced the variation in cost of those products listed. However, 'specials' 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. 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 or Prescribing Support Pharmacist so that all parties 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 the prescription of an unlicensed 'special' and to advise if there is a licensed alternative available. Background information about the patient can help to facilitate these discussions e.g. why do they need a liquid? Do they have 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 NHS GGC Community Pharmacy Development Team website 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-license 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-license 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 out with 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 specialties, such as paediatrics, this may be accepted practice. As a result, some Health Board formularies may include unlicensed 'specials'.

- Use of off-label/off-license 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, that the product is the most cost effective choice, 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.

- From August 2020, the Health Board has agreed to continue to adopt the guide price principles for the commonly requested “specials” for authorisation. This is following learning and feedback as a result of the Covid-19 pandemic situation.

- Items listed on the guide price do not require authorization as long as the cost to obtain the item is equal or less to the price stated. The handling charge is applicable on these items.

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-license 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-license 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.

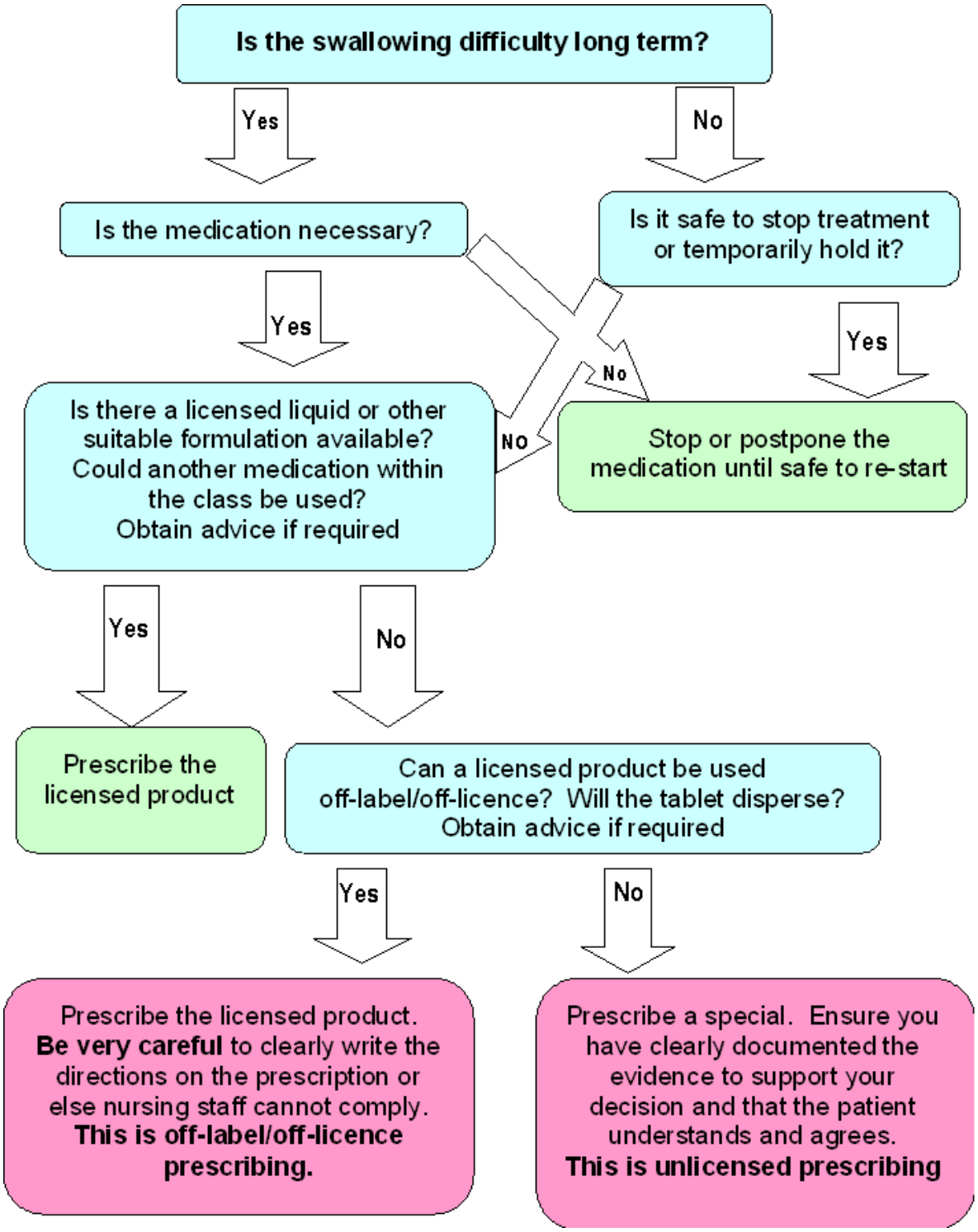
- Advise your patient to use the same community pharmacy each time to enable consistency of supplier and manufacturer. Each manufacturer may use a different formula and the efficacy may vary. This is particularly important for drugs with a narrow therapeutic index. A

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.

The UKMI Medicines Q&A: What are the therapeutic options for adult patients unable to take solid oral dosage forms available here includes some useful advice on choosing and administering these medicines. For further advice please contact your HSCP Prescribing Team or NHS GGC Central Prescribing Team.

Figure 1


Is the swallowing difficulty long term?
Yes
No
Is the medication necessary?
Is it safe to stop treatment or temporarily hold it?
Yes
Yes
No
Is there a licensed liquid or other suitable formulation available? Could another medication within the class be used? Obtain advice if required
No
Stop or postpone the medication until safe to re-start
Yes
No
Prescribe the licensed product
Can a licensed product be used off-label/off-licence? Will the tablet disperse? Obtain advice if required
Yes
No
Prescribe the licensed product. **Be very careful** to clearly write the directions on the prescription or else nursing staff cannot comply. **This is off-label/off-licence prescribing.**
Prescribe a special. Ensure you have clearly documented the evidence to support your decision and that the patient understands and agrees. **This is unlicensed prescribing**

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 available on the Community Pharmacy Scotland website 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 1 for the national framework.

- When a 'special' is required to be ordered and dispensed, the community pharmacist should contact the NHS GGC Central Prescribing Team advice or authorisation (PRESCRIBING@ggc.scotnhs.uk). 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, especially with respect to the strength of oral liquid medications

- 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 support 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 2. Manufacturers/suppliers’ contact numbers are given in Appendix 3.

5. References and Sources of Further Information

Royal Pharmaceutical Society Professional Guidance for the Procurement and Supply of Specials. Review date: December 2018. https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf

Medicines and Healthcare products Regulatory Agency (MHRA). Supply of unlicensed medicines when an equivalent licensed product becomes available. Blog published: 9 October 2015. 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: Amendments to Drug Tariff in Respect of Special Preparations and Imported Unlicensed Medicines. 21st August 2015. https://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf

General Medical Council. Good practice in prescribing and managing medicines and devices. 25 February 2013. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices

General Medical Council. Prescribing unlicensed medicines. Accessed July 2020. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines

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

Medicines and Healthcare products Regulatory Agency (MHRA). Drug Safety Update. Off-label or unlicensed use of medicines: prescribers' responsibilities. Published 11 December 2014. http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990

UKMI Medicines Q&A: What are the therapeutic options for adult patients unable to take solid oral dosage forms? UK Medicines Information. Date prepared: December 2019. https://www.sps.nhs.uk/articles/what-are-the-therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/

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 or http://www.newtguidelines.com/

White R and Bradnam V. Handbook of drug administration via enteral feeding tubes, 3rd edition. Pharmaceutical Press. 2015 or access via https://www.medicinescomplete.com/

NHSGGC Prescribing Support Teams. Document 9 – Covert Administration of Medication Provision of Pharmaceutical Advice. Version: 2. Review date: April 2018. http://www.staffnet.ggc.scot.nhs.uk/Acute/Division%20Wide%20Services/Pharmacy%20and%20Prescribing%20Support%20Unit/Prescribing/Documents/Document%2009%20-%20Covert%20Administration%20of%20Medication%20Provision%20of%20Pharmaceutical%20Advice.pdf

Mental Welfare Commission for Scotland. Good Practice Guide. Covert Medication. Reviewed February 2017. https://www.mwcscot.org.uk/sites/default/files/2019-06/covert_medication.pdf

British Association of Dermatologists. Specials Recommended by British Association of Dermatologists for Skin Disease, 2018. http://www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=6248

NHS Greater Glasgow and Clyde Formulary. http://www.ggcmedicines.org.uk/

NHS Greater Glasgow and Clyde Acute Division. Unlicensed Medicines Policy. October 2019. http://www.ggcprescribing.org.uk/media/uploads/policies/section_9/9.1_unlicensed_medicines_policy_-_final_1910.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. February 2017. http://www.staffnet.ggc.scot.nhs.uk/Applications/Datix/Documents/SCI%20Policy%20Final%202017.pdf

Appendix 1 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

The product is NOT 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)

The product is listed in Scottish Drug Tariff Part 7s

Health Board Authorisation Required

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.

Taken from The Scottish Government NHS Circular: PCA(P)(2015)17

Appendix 2 HSCP/Locality/Prescribing Support Team Contact Details

CH(C)P	Pharmacist		email address	Work No	Mobile No
North East Locality–Glasgow City HSCP Templeton Business Centre, Building 2 62 Templeton Street Glasgow, G40 1DA	**Andrew Beattie** *Admin* *Paula Marshall*	Lead Clinical Pharmacist	andrew.beattie3@nhs.scot Paula.Marshall@ggc.scot.nhs.uk	0141 277 7452	 07805 758 808
North West Sector–Glasgow City HSCP Glasgow City HSCP North West Locality HQ, William Street Clinic, 120-130 William Street, Glasgow, G3 8UR	**Sheila Tennant** *Admin*	Lead Clinical Pharmacist	stennant@nhs.net	0141 314 6235 Fax 0141 314 6233	07812 600 974
South Sector – Glasgow City HSCP 1st Floor, Pavilion One Rowan Business Park 5 Ardlaw Street, Glasgow, G51 3RR	**Raj Sabharwal** *Admin* *Frances Butler*	Lead Clinical Pharmacist	raj.sabharwal@ggc.scot.nhs.uk frances.butler@ggc.scot.nhs.uk	0141 451 7123 0141 451 7111	07825 935 645
East Dunbartonshire HSCP Kirkintilloch Health and Care Centre 10 Saramago Street, Kirkintilloch Glasgow, G66 6BF	**Andy Christopherson** **Carolyn Fitzpatrick** Working Days: Tues-Thurs *No Admin*	Lead Clinical Pharmacist	Andrew.christopherson@nhs.scot carolyn.fitzpatrick@ggc.scot.nhs.uk	0141 232 8292 0141 304 7433	07903 680 752 07780 708 100
East Renfrewshire HSCP Eastwood Health & Care Centre Drumby Crescent, Clarkston East Renfrewshire, G76 7HN	**Susan Galbraith** Working Days: Tues-Thurs and Friday mornings *No Admin*	Lead Clinical Pharmacist	susan.galbraith2@ggc.scot.nhs.uk		07779 983 497
West Dunbartonshire Vale Centre for Health and Care Main Street Alexandria, G83 0UA	**Gillian Calderhead** *Admin* *Fiona Anderson*	Lead Clinical Pharmacist	gillian.calderhead@ggc.scot.nhs.uk fiona.anderson4@ggc.scot.nhs.uk	01389 828 293	07970 045 860
Renfrewshire HSCP Renfrew Health & Social Work Centre 10 Ferry Road Renfrew, PA4 8RU	**Susan Robertson** *Admin* *Allen O'Neill*	Lead Clinical Pharmacist	susan.robertson4@ggc.scot.nhs.uk allen.oneill@ggc.scot.nhs.uk	0141 207 7752	07500 608 726
Inverclyde HSCP Port Glasgow Health Centre 2 Bay Street Port Glasgow, PA14 5EW	**Margaret Maskrey** *Admin*	Lead Clinical Pharmacist	margaret.maskrey@ggc.scot.nhs.uk	01475 506142 Ext 66142	07742 014 420
Whitevale Medical Group 30 Whitevale St Glasgow, G31 1QS	**Dr Roger Hardman**	Medical Prescribing Adviser	roger.hardman@nhs.net	0141 554 4536	

Central Prescribing Team Clarkston Court 56 Busby Road Clarkston Glasgow, G76 7AT	**Specials**		prescribing@ggc.scot.nhs.uk	0141 201 6023	
	Elaine Paton	Senior Prescribing Adviser	Elaine.Paton@ggc.scot.nhs.uk	0141 201 6038	07815 586 327
	Mairi-Anne McLean	Senior Prescribing Adviser	Mairi-Anne.McLean@ggc.scot.nhs.uk	0141 201 6030	07824 569 798
	Heather Harrison	Senior Prescribing Adviser	Heather.Harrison@ggc.scot.nhs.uk	0141 201 6035	
	Carol Smart	Prescribing Support Adviser	Carol.Smart@ggc.scot.nhs.uk	0141 201 6037	
	Karen Liddell	Prescribing Support Adviser	Karen.Liddell@ggc.scot.nhs.uk	0141 201 6039	
	Alison McAuley	Prescribing Support Technician	Alison.McAuley@ggc.scot.nhs.uk	0141 201 6023	

Appendix 3 'Specials' Suppliers Contact Numbers

NHS GGC Central Prescribing Team
Please email form to prescribing@ggc.scot.nhs.uk for advice or authorisation using the agreed form.

Manufacturers/Suppliers Contact Details

Manufacturer / Supplier Name	Telephone No.	Email
AAH Pharmaceuticals	0141 423 5888	
Aclardian Limited	01954 213 490	info@aclardian.com
Alium Medical	0208 238 6770	enquiries@aliummedical.com
Alliance Healthcare	0344 854 4998	specials.orders@alliance-healthcare.co.uk
Arjun Products	0800 015 7806	info@arjunproducts.co.uk
BCM Specials	0115 968 6464	Specials.bcm@fareva.com
Clinigen	01932 824 100	
Durbin PLC	0208 869 6555	imports@durbin.co.uk
Eaststone Limited	0800 678 3102	
Eclipse Generics (DE Group)	0800 328 7169	specials@de-group.co.uk
Ethigen	0800 019 7100	specials@ethigen.co.uk
Ethypharm	0800 137 627	unlicensed@ethypharm.com
Higher Nature	0800 458 4747	technicalsupport@highernature.com
Huddersfield Royal Infirmary	01484 355 388	hps.orders@cht.nhs.uk
John Bell & Croydon	0207 935 5555	jbc@johnbellcroyden.co.uk
Mandeville Medicines	01296 394 142	info@mandevillemedicines.com
Mawdsleys	0844 736 9016	info@mawdsleys.co.uk
Nova Laboratories	0800 975 4840	sales@novalabs.co.uk
Oxford Pharmacy Store	01865 904 141	ops.orders@oxfordhealth.nhs.uk
Pharma Nord	01670 534 900	info@pharmanord.co.uk
Phoenix Healthcare	0844 736 2287	customerservice@phoenixmedical.co.uk
Quantum Pharmaceutical	0800 043 9372	orders@quantumpharma.co.uk
Rayner (Moorfields Pharmaceuticals)	01903 854 560	orders@rayner.com
Rokshaw Laboratories	0800 1699 765	orders@rokshaw.co.uk
Rosemont Pharmaceuticals	0113 244 1999	rosemont.marketing@perrigouk.com
Solgar		productsupport@solgar.co.uk
St Mary's Pharmaceutical Unit	02920 748 120	contact@smpu.co.uk
Stockport Pharmaceuticals	0161 419 5666	sppu.orders@stockport.nhs.uk
Target Healthcare Limited	0845 618 0036	info@target-healthcare.co.uk
Tayside Pharmaceuticals, Ninewells Hospital	**01382 632 052**	**tpsales.Tayside@nhs.net**
Thornton & Ross	01484 842 217	customerservices@thorntonross.com
Torbay Pharmaceuticals	01803 664 707	torbaypharmaceuticals@nhs.net
Veriton Pharma (Special Products Limited)	01932 690 325	info@veritonpharma.com

and Clyde

NHSGGC Specials Authorisation Form

The Specials authorisation telephone line remains unmanned. The authorisation process is resuming via email as outlined below.

Authorisation is **not** required when:

- The product is a UK licensed medicine
- Products are:
  i) Listed in Scottish Drug tariff part 7s, part 7u
  ii) Listed on the pre-approved price list
  iii) Available from the NHS manufacturing unit, Pharmaceutical Specials Service (PSS) – formerly Tayside Pharmaceuticals
- The product is not a medicine e.g. stocking, dressing
- Authorisation has been obtained within last 12 months with less than 10% price variation from original authorisation

Where authorisation is required please complete all sections of this form and email to: prescribing@ggc.scot.nhs.uk

All communications must come from the Pharmacy Clinical mailbox (NHS Net), not a personal email due to GDPR.

Please ensure your email is correctly addressed. It is recommended that a statement regarding confidentiality is included in your email, suggested wording is noted below.

Information to wrong recipient

The information contained within this file is confidential and may be privileged. If you are not the intended recipient, please destroy this file, delete any copies held on your systems and notify the sender immediately; you should not retain, copy or use this file for any purpose, nor disclose all or any part of its content to any other person.

Specials authorisations will operate between 08:30 and 16:30 Monday to Friday, any requests out with this time will be responded to on the next working day.

Pharmacy contractor code	
Contractor phone number	
Pharmacy contact name	
Patient name	
Patient CHI	
Item requested (including strength, preparation and volume/quantity)	
Dose	
Patient's GP practice code (5 digit number beginning with 4, 5, 8)	
Quote from wholesaler (include quantity, pack size and name of wholesaler)	

Re-authorisations

Current or previous authorisation number	S-
Has the prescriber been advised it has been 12 months since last review?	
If the quantity /volume has changed, please supply details	
Current cost	
Any additional information	

Dispensing pharmacists have a responsibility to ensure that where Specials are prescribed they are the most appropriate choice and patients are supported to use them effectively. Please ensure all Specials have been clinically screened by a responsible pharmacist
Email to: prescribing@ggc.scot.nhs.uk