

Specials Supplement

July 2018

Healthcare professionals should explore all alternatives before deciding to prescribe a 'special'.

Use of 'specials' in Northern Ireland costs over £6 million a year. In many cases, the patients' needs could have been met with a licensed medicine or a more competitively priced 'special' could have been sourced. With increasing demands on the Health Service budget, money spent on 'specials' could be better invested in other areas of healthcare.



'Specials' are special-order unlicensed medicines made to meet the needs of an individual patient. Unlicensed medicines may be prescribed in clinical situations where it is judged that, on the basis of the available evidence, unlicensed use is in the best interest of the patient.

£ The cost of 'specials'

Last year over £6 million was spent on 'specials' in Northern Ireland.

'Specials' can be very expensive and may not represent a cost effective treatment to the Health Service. Prescribers may not know the cost of a 'special' when it is prescribed.

A 'special' may be expensive if it involves high-cost ingredients and complicated manufacturing processes. Additionally, a distributor may levy charges that increase the total cost paid by the Health Service for the 'special'.

The price of an individual 'special' can vary greatly from one 'specials' manufacturer to another. This price variation depends on which supply route is chosen by the community pharmacy. For example, the price of one bottle of omeprazole 10mg/5ml oral suspension can range from £28 to over £1600.

Prescribers should ensure that they know the cost of a 'special' before prescribing, and discuss with community pharmacy colleagues the costs associated with prescribing and supply of 'specials', including where they are concerned about variations in price.

Top 10 most costly 'specials' in Northern Ireland (Jan 2017 to Dec 2017)

	Drug	Cost
1	Omeprazole liquid	£761,495
2	Melatonin caps/tabs	£666,834
3	Melatonin solution	£620,853
4	Hepa-Merz sachets	£318,165
5	Levomepromazine tablets	£293,922
6	Sucralfate tablets	£225,297
7	Mexiletine capsules	£145,127
8	Tacrolimus suspension	£129,985
9	Liothyronine tablets	£120,015
10	Coal tar ointments	£107,943

See also section on 'Specials' manufacturers and suppliers on page 3

Legal issues in prescribing and dispensing 'specials'

'Specials' have not been assessed by the MHRA (regulatory authority) for safety, quality and efficacy in the same way as licensed medicines. Therefore they have no Summary of Product Characteristics (SPC) outlining the dose, contra-indications, storage and side effect profile. Patient information leaflets are not routinely available for 'specials'.



'Specials' can be obtained from a range of sources by pharmacists and are not all manufactured in the same way. This means that the quality, bioavailability, ingredients and consistency of 'specials' can vary, even where the same product is prescribed.

Prescribers: if a prescriber writes a prescription for a licensed medicine, in line with the licensed dose and indication, then any untoward effects that may occur to the patient as a result of the patient taking the medicine, are the legal responsibility of the pharmaceutical company. However, for unlicensed products / 'specials' the prescriber takes full responsibility in law for any adverse effect a patient suffers (unless it can be proven that the product was faulty).

Pharmacists: pharmacists have a professional responsibility to make prescribers aware of the unlicensed nature of any 'special' before procuring a 'special'.

Managing patients with swallowing difficulties and feeding tubes

Given the additional clinical and governance risks associated with prescribing and dispensing unlicensed medicines, doctors, pharmacists and nurses have a duty to consider carefully the need for a 'special' in the first place.

Patients with swallowing difficulties or patients with feeding tubes in place are often cited as a reason for prescribing of 'specials' in liquid form. However this is seldom needed if a **stepped approach** is followed:



STEP 0	Is the medicine needed? Review medications to ensure they are still needed.
STEP 1	Is there an alternative licensed product that could be used? E.g. consider changing sertraline tablets to an alternative SSRI available as a liquid (e.g. fluoxetine liquid 20mg/5ml) if swallowing problems likely to be long-term.
STEP 2	Could a licensed product be used off-label? E.g. are tablets suitable for crushing / opening capsule? Could a 1ml oral syringe be used to facilitate measurements other than 5ml?
STEP 3	If the answer is 'no' to steps (1) and (2), an unlicensed manufactured 'special' could be considered.

Further information

- HSC Guideline - Advice for Health Professionals: Choosing medication for patients unable to take solid oral dosage forms in **'specials'** section of NI Formulary.
- PrescQIPP info bulletin 188: Care Homes — Assisting people with swallowing difficulties.
<https://www.prescqipp.info/>.

Newly licensed products

The continued need to prescribe or dispense a 'special' should be routinely reviewed, to take account of newly licensed products. 'Specials' may become superseded by commercially available licensed products, which were not available at the time of first prescribing.



Did you know the following are now available as licensed medicines?:

- ◇ Epistatus[®] (midazolam) 10mg oromucosal solution
- ◇ Sialanar[®] (glycopyrronium) 320mg/ml oral solution
- ◇ Magnaspartate[®] (magnesium) 10mmol per sachet
- ◇ Bramox[®] (midodrine) 2.5mg and 5mg tablets

'Specials' manufacturers and suppliers

'Specials' are available directly from 'special-order' manufacturers (NHS and non-NHS), or via third party distributors or specialist-importing companies. Details of companies are available in the BNF under '[Special-order Manufacturers](#)'. Prices for a 'special' vary considerably from one manufacturer / supplier to the next.



NHS manufacturing units

NHS manufacturing units are 'special-order' manufacturers/suppliers that are attached to NHS hospital pharmacy departments. 'Specials' from NHS manufacturing units are usually supplied at more competitive prices than those supplied by non-NHS manufacturing units or suppliers. 'Pro-File' (www.pro-file.nhs.uk) is a database that lists the 'specials' that are made by NHS manufacturing units. Access is restricted to NHS pharmacy staff and is available via the Regional Medicines and Poisons Information Service (Tel 028 9504 0558 or email: nirdic.nirdic@belfasttrust.hscni.net).

Victoria Pharmaceuticals (based in the Belfast Trust) is the NHS manufacturing unit for Northern Ireland (Tel 028 9063 0070) and products available are detailed at <http://niformulary.hscni.net>.

Standardisation of the most common liquid medicines in paediatrics

A project has recently been undertaken to improve the safety regarding the prescribing of liquids as children make the transition between secondary and primary care.

The five Trust Pharmacy departments in Northern Ireland will be standardising the oral liquids that they stock for **captopril, colecalciferol, furosemide, glycopyrronium bromide, melatonin, omeprazole, sodium chloride, spironolactone**. For further details of the agreed products see '[specials](#)' section of NI Formulary. This includes both licensed and unlicensed liquids. This guidance will be focused on prescribing for new patients.



This will ensure continuity of supply between primary and secondary care, helping to reduce the likelihood of errors occurring due to incorrect dosing / strengths (enhancing patient safety) and will also ensure that Health and Social Care Northern Ireland secures good value from its expenditure.

Cost-effective supply via Victoria Pharmaceuticals

For the unlicensed liquids on the agreed HSC list, Victoria Pharmaceuticals (ordered via Movianto Northern Ireland) will hold stock for access by community pharmacists at a competitive price. The current prices (July 2018) to community pharmacies are:

1. Melatonin 1mg/ml Oral Solution SF and Alcohol Free (Kidmel) £17.63 for 200ml
2. Omeprazole 10mg/5ml Oral Suspension (Quzole powder and diluent for oral suspension) £28.65 for 100ml (when reconstituted)
3. Sodium chloride 5mmol/ml Oral Solution (St Mary's) £8.13 for 100ml
4. Spironolactone 25mg/5ml Oral Suspension SF (Birchwood) £37.63 for 100ml

Orders should be sent to: Movianto Northern Ireland Customer Service,
Sandyknowes Business Park, 605 Antrim Road, Newtownabbey, BT36 4RY
Telephone: +44(0) 2890795799; Fax: +44(0) 2890794004
Email: orders.nireland@movianto.com

Action for prescribers:

- Refer to the [agreed HSC list](#) when prescribing oral liquid medicines for captopril, colecalciferol, furosemide, glycopyrronium bromide, melatonin, omeprazole, sodium chloride, spironolactone or ergocalciferol. Prescribe these products generically, exactly as described on the list, with particular attention to the formulation and strength specified.

Action for pharmacists:

- Check suppliers for cost-effective prices to ensure value for money for the Health Service.
- Consider ordering the unlicensed liquids on the [agreed HSC list](#) from Victoria Pharmaceuticals.

Commonly prescribed 'specials'

Omeprazole / lansoprazole / ranitidine

Choosing a suitable formulation of omeprazole / lansoprazole / ranitidine for infants can be problematic. Clinical practice does not always reflect the licensed products available.

'Special'	Alternative licensed product
Ranitidine 5mg/5ml (prices up to £500)	<ul style="list-style-type: none">Ranitidine 150mg/10ml (Zantac® syrup) plus a 1ml oral syringe if necessary.
Omeprazole suspension 10mg/5ml (prices can be over £1600)	<ul style="list-style-type: none">Omeprazole tablets and lansoprazole orodispersible tablets are preferred for patients (both children and adults) who cannot swallow the oral capsules.If a liquid is necessary, refer to agreed HSC list of paediatric liquid formulations for the preferred choice.

Further information

- Refer to [Medicines Management Newsletter Supplement February 2017](#) for further information on omeprazole / lansoprazole / ranitidine in infants and
- Patient information leaflets on Administration of Lansoprazole / Omeprazole tablets to an infant or a child, available in the [Patient Zone](#) section of NI Formulary.

Oral syringes

Oral syringes are available from community pharmacies to facilitate measurements other than 5ml

- Community pharmacies can order 1ml, 3ml and 5ml oral syringes from local pharmaceutical wholesalers.
- 1ml and 3ml syringes are available in small packs or single packs to avoid bulk buying and cost less than £1 each.
- Only the 5ml size oral syringe is currently on NI Drug Tariff.



Vitamin D

The Department of Health (NI) issued updated [advice](#) to the public in 2017 on how much vitamin D they need and how to obtain it.

Some children aged up to four years and pregnant women will be entitled to free Healthy Start Vitamins (Healthy Start Vitamins are available via a voucher scheme see: www.healthystart.nhs.uk).

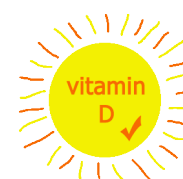
All other people should be **advised to purchase a vitamin D supplement** from their local community pharmacy, supermarket or other retail outlet. Vitamins should not be prescribed.

This advice relates to the general public and does not, for example, apply to those who are being treated for an underlying medical condition or deficiency with pharmacological doses as prescribed by their clinician.

There are now many licensed vitamin D products available and should be chosen instead of nutritional supplements or 'specials' in patients requiring treatment doses. Refer to vitamin D section of NI Formulary website for [table of licensed vitamin D products](#).

Action for prescribers and pharmacists:

- A licensed product should be prescribed and dispensed where one is available.
- Avoid generic prescribing of vitamin D to ensure expensive 'specials' are not dispensed.
- Pharmacists are asked to order vitamin D preparations via usual pharmacy wholesalers, rather than placing an order for a 'special' as this is associated with higher costs.



Guidance on rationalisation of 'specials'

Dermatology

For many common skin conditions, the range of licensed medicines is limited. As a result, Dermatology prescribing may rely significantly on unlicensed creams and ointments.

In order to rationalise the range of dermatology 'specials' prescribed, the British Association of Dermatology (BAD) has developed a 'preferred list' of 40 unlicensed dermatological preparations. The list is available to download from the BAD website <http://www.bad.org.uk/healthcare-professionals/clinical-standards/specials>, along with related prescribing guidance and quantities to prescribe.



It is hoped that adherence to the BAD List will allow patients easier access to these treatments, at less cost to the NHS. According to BAD, if the top 12 most commonly prescribed Dermatology 'specials' on the BAD list had been obtained from an NHS manufacturing unit (rather than a non-NHS manufacturing unit), this could have saved the NHS £683,000.

The BAD list has now been ratified and implemented by the hospital Trusts in Northern Ireland.

Dermatology 'specials' that do not appear on the BAD list should not be requested in primary care. Adherence to the BAD list is encouraged in order to address concerns around 'specials' and optimise quality of care.

Action for prescribers: Prescribers should refer to the BAD list and, for items not on the list, confirm with secondary care before prescribing.

Ophthalmology

The Royal College of Ophthalmologists and the UK Ophthalmic Pharmacy Group have produced guidance on ophthalmic 'specials'. This can be found at <https://www.rcophth.ac.uk>.

This was published in response to concerns over the suitability and cost of some unlicensed ophthalmic preparations prescribed and dispensed in primary care: in the first 9 months of 2013, 30,000 prescriptions for unlicensed eye preparations were dispensed in England and Wales at a cost of £3m.



When clinically appropriate and available, licensed products should always be prescribed and dispensed in preference to unlicensed products.

Often there is no clinical advantage to prescribing an ophthalmic 'special' over existing licensed ophthalmic medicines.

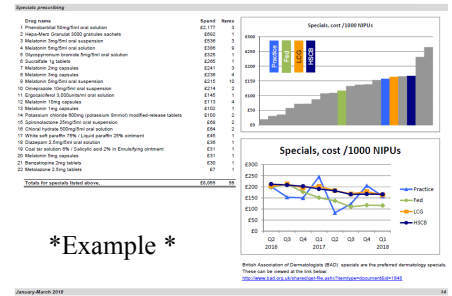
For example, check whether hypromellose 0.25%w/v eye drops are required, or if hypromellose 0.3%w/v or 0.5%w/v eye drops (which are on the Drug Tariff) could be used. Ophthalmic 'specials' are often selected inadvertently from the GP computer system, with the prescriber unaware that it is a 'special', and hence the legal and cost implications of prescribing.

Action for prescribers: refer to the ophthalmic list and, for items not on the list, confirm with secondary care to ensure that a transcription error has not occurred.

COMPASS reports

A section on 'specials' was added to the COMPASS report for each practice from 2015. The table details the 'specials' prescribed by each GP practice and the associated costs.

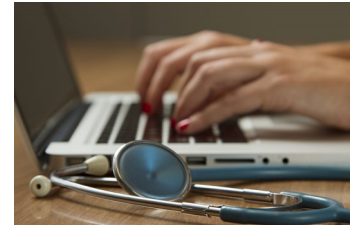
The two graphs show how each practice compares to the Federation, the LCG and the HSCB average in terms of overall spend on 'specials'.



Example

Actions for GP practices

- When clinically appropriate and available, licensed products should always be prescribed and dispensed in preference to unlicensed products / 'specials'.
- Ensure there is sufficient evidence / experience of using an unlicensed 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.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.
- Review patients regularly who have 'specials' on repeat to ensure that they are still required, that the patient is benefiting from it, that a licensed product does not exist and that the dose / formulation is still appropriate for the patient:
 - Doses in a child may need to be changed as the child gets older
 - Check to see if the patient is receiving other medicines in solid dosage form, i.e. the patient is in fact able to swallow tablets.
- Refer to the ophthalmic list and, for items not on the list, confirm with secondary care to ensure that a transcription error has not occurred before prescribing.
- Refer to the BAD list and, for items not on the list, confirm with secondary care before prescribing.
- A licensed vitamin D preparation should be prescribed where one is available, and avoid generic prescribing of vitamin D.
- Given the potential for inadvertent prescribing of 'specials', practice based pharmacists may wish to audit prescribing, e.g. of omeprazole or melatonin, to identify the type of scripts generated and how this happens.



Actions for community pharmacies

- Alert the GP to the unlicensed nature and cost of any prescribed 'special' before it is procured (GPs are often not aware from GP clinical systems that a product is a 'special') and advise on alternative licensed products where available.
- Pharmacists are encouraged to ensure that the Health Service secures good value from its expenditure, and pharmacists should bear this in mind in the procurement of 'specials'.
- The price of an individual 'special' can vary greatly from one manufacturer to another. Pharmacists should be aware of this when placing an order for a 'special'.
- If in doubt about ordering a 'special', contact a HSCB Pharmacy Advisor before ordering.
- Vitamin D nutritional supplements should be ordered via usual pharmacy wholesalers, rather than placing an order for a 'special' as this is associated with higher costs.
- A written Standard Operating Procedure (SOP) should be in place, detailing the steps involved in the ordering of 'specials' including risk assessments of the different options available.



This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team.

HSCB Pharmacy Advisors in your local HSCB office:

Belfast Office: 028 9536 3926

South Eastern Office: 028 9536 1461

Southern Office: 028 9536 2104

Northern Office: 028 9536 2845

Western Office:

028 9536 1010

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