



Newsletter Supplement: 'Specials'

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 NHS 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. As with any medicine, prescription of unlicensed medicines is the responsibility of the prescriber.

Additional considerations:

- 'Specials' have not been assessed by the regulatory authority (MHRA) 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.
- 'Specials' can be difficult to identify at the point of prescribing.
- The way that the supply chain operates for 'specials' means that costs for the same product can vary significantly. Prescribers will not know the cost of a 'special' when it is prescribed.



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

CONTENTS:

Legal issues
The cost of 'specials'
A need for 'specials'?
Local guidance
Newly licensed products
Common examples
COMPASS reports
Manufacturers / suppliers
Vitamin D
Dermatology list
Ophthalmology list
Action points

LEGAL ISSUES IN PRESCRIBING AND DISPENSING 'SPECIALS'



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 have a professional responsibility to make prescribers aware of the unlicensed nature of any 'special' before procuring a '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 community pharmacies.

e.g. omeprazole 10mg/5ml oral suspension price can range from £42 to £1664*

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.



THE COST OF SPECIALS

Last year approximately £6.4 million was spent on 'specials' in Northern Ireland.

'Specials' can be very expensive and may not represent a cost effective treatment to the NHS. There is no regulation of the pricing of 'specials'. 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 NHS for the 'special'.

The table shows the top 10 most costly 'specials' to the NHS in Northern Ireland 2014 / 2015

	Drug	Cost*
1	Omeprazole oral susp.	£791,242
2	Melatonin oral solution	£566,120
3	Glycopyrronium oral liquid	£164,708
4	Quetiapine oral susp.	£141,733
5	Spiroonolactone oral susp.	£91,094
6	Tacrolimus oral solution	£75,403
7	Clonidine oral solution	£71,942
8	Zonisamide oral susp.	£69,375
9	Naltrexone 3mg, 4.5mg caps	£69,102
10	Bisoprolol oral solution	£61,970

* based on BSO prescription data

LOCAL GUIDANCE

Managing patients with swallowing difficulties and feeding tubes

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. The Regional Medicines and Poisons Information Service (RMPIS) have produced a local guideline to aid prescribers to consider alternative strategies to manage patients unable to take solid dosage forms. This is available on the [Northern Ireland Formulary](#) website.

ACTION FOR PRESCRIBERS, NURSES AND PHARMACISTS:

Where a patient has been prescribed a 'special', treatment should be reviewed regularly with a view to prescribing the licensed product.

A NEED FOR 'SPECIALS'?

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.

A STEPPED APPROACH to choosing a suitable medicine should be adopted.



STEP 1	Is there an alternative licensed product that could be used? E.g. sertraline tablets: consider changing to an alternative drug 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 an 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.



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?:

- ◇ Many vitamin D preparations, e.g. Desunin[®] 800IU tablets, Fultium D3[®] 2740IU/ml drops, Plenachol[®] 20,000IU capsules, InVita D3[®] oral solution 25,000IU/ampoule
- ◇ Glycopyrronium 1mg and 2mg tablets (Morningside Healthcare)
- ◇ Magnaspartate[®] (10mmol of magnesium per sachet)
- ◇ Midodrine 2.5mg and 5mg tablets (Bramox[®])

COMMON EXAMPLES

In many cases, the use of ‘specials’ can be avoided. However, ‘specials’ can be difficult to identify at the point of prescribing.

The following are examples of medicines that are sometimes prescribed as ‘specials’ but where **a licensed medicine would be more appropriate**. Example prices are shown for the ‘special’ product (note: there is wide variation between suppliers — see next page) and the alternative licensed product.

‘Specials’ and alternative licensed products

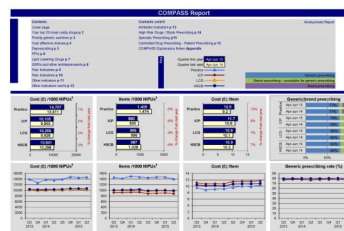
‘Special’	Alternative licensed product
<p>Ranitidine 5mg/5ml</p> <p>Prices can be up to £474 (200ml)*</p>	<p>Ranitidine 150mg/10ml (Zantac[®] syrup)</p> <p>is the licensed product. Price: £8.29 for 300ml</p>
<p>Omeprazole suspension 10mg/5mL</p> <p>Prices can be up to £1664 (300ml)*</p> <p>* price examples as per BSO prescription data May / June 2015 for third party ‘specials’ suppliers</p>	<p>Omeprazole and lansoprazole orodispersible tablets</p> <p>are licensed products. They are the preferred choice for patients (both children and adults) who cannot swallow the oral capsules. Price: £7.75 and £3.18 for 28 day supply. Refer to Medicines Management Newsletter Supplement August 2013 for further information on the use of anti-secretory agents in children</p>
<p>For further examples see RMPIS documents ‘Choosing medicines for patients unable to take solid oral dosage forms’. This will be uploaded to the Primary Care and HSCB websites in Oct 2015.</p>	

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).

COMPASS REPORTS

A section on ‘specials’ has been added to the COMPASS report for each practice for 2015.





'SPECIALS' MANUFACTURERS / 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'.

NHS MANUFACTURING UNITS

NHS manufacturing units are 'special-order' manufacturers 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.

Victoria Pharmaceuticals (Belfast Trust) is the Northern Ireland NHS manufacturing unit (Tel 028 9063 0070). Community pharmacies in Northern Ireland can however order directly from any of the NHS hospital manufacturers in the UK.

'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).

Example price comparison

Special	NHS manufacturing unit	Non-NHS manufacturing unit / supplier
Glycopyrronium oral liquid (strengths differ)	St. Mary's Cardiff (5mg/5ml) 100ml x £28.70	Third party distributor (1mg/5ml) 300ml x £304
	Preston Pharm. (5mg/5ml) 100ml x £41	Third party distributor (2mg/5ml) 400ml x £1840
	Huddersfield (1mg/5ml) 150ml x £43	
Omeprazole 10mg/5ml oral suspension	Newcastle Specials 125ml x £42	Martindale Pharma 150ml x £99
		Third party distributor 300ml x £1664

The table shows a price comparison example between NHS and non-NHS 'specials' manufacturers / distributors for glycopyrronium and omeprazole oral liquids. Prices shown are either supplied by the 'specials' manufacturers or taken from prescription invoices for third party suppliers paid by BSO in May / June 2015 against prescriptions in Northern Ireland.

PRICE VARIANCE

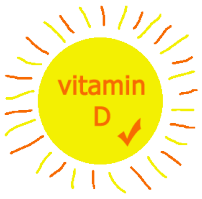
Prices for a 'special' vary considerably from one manufacturer / supplier to the next.

NHS manufacturing units usually supply 'specials' at more competitive prices than those supplied by non-NHS manufacturing units or third party distributors.

There can also be huge differences in price between non-NHS suppliers. For example, melatonin 1mg/ml oral liquid is a 'stock line' at the pharmaceutical wholesalers Sangers and costs £22 for 200ml. However, some 'specials' suppliers charge over £500 for this.

ACTION FOR PHARMACISTS:

Please consider checking alternative suppliers for cost-effective prices.



VITAMIN D

Until recently, few licensed vitamin D products existed and there was a reliance on unlicensed medicines and nutritional supplements to meet prescribing needs. However, **licensed vitamin D products are now emerging on the UK market and should be chosen instead of nutritional supplements or ‘specials’ in patients requiring treatment doses.**

ACTION FOR PRESCRIBERS AND PHARMACISTS:

A licensed product should be prescribed and dispensed where one is available.

Prescribers are asked to 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.

CMO LETTER

Recommendations for “at risk groups”

In a joint letter in February 2012, the four Chief Medical Officers (CMO) in the UK recommended that some population groups (e.g. pregnant women) would benefit from daily vitamin D. Full details can be found at:

<https://www.gov.uk/government/publications>

Advising individuals to purchase over-the-counter is the preferred option. For those on low-income, Healthy Start Vitamins are available via a voucher scheme see:

www.healthystart.nhs.uk

If a prescription is issued, licensed drops (see table) or nutritional supplements (brand names include ProD3[®]) should be supplied, rather than ‘specials’. Food supplements are however not subject to the same assessments for quality, safety and efficacy as licensed medicines. They are reasonably low-cost depending on brand.

Licensed vitamin D products (at time of publication)	
Products	Strength
Desunin [®] tablets, Fultium D3 [®] capsules	800IU
InVita D3 [®] oral drops	2400IU/ml (6 drops = 400IU)
Fultium D3 [®] drops	2740IU/ml (6 drops = 400IU)
Fultium D3 [®] capsules	3200IU
Aviticol [®] capsules, Fultium D3 [®] capsules, Plenachol [®] capsules	20,000IU
InVita D3 [®] oral solution (1 ampoule)	25,000IU/ml
Plenachol [®] capsules	40,000IU
Thorens oral solution (one 2.5ml bottle)	25,000IU/ 2.5ml

For patients who require therapeutic doses of vitamin D, a number of licensed vitamin D products are now available and should be selected (see table).

BRITISH ASSOCIATION OF DERMATOLOGY (BAD) PREFERRED LIST



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.

OPHTHALMOLOGY LIST

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.

Where a licensed product is not available, standard Drug Tariff products are preferred e.g. hypromellose 0.3%w/v or 0.5%w/v rather than 0.25%w/v. 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.



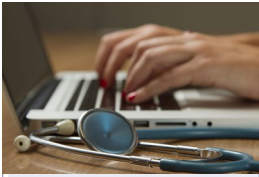
ACTION FOR PRESCRIBERS:

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

ACTION FOR PRESCRIBERS:

Prescribers should 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.

SUMMARY OF ACTIONS FOR PRESCRIBERS



- 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.
- Prescribers should 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.
- Prescribers should refer to the British Association of Dermatology (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.

SUMMARY OF ACTIONS FOR PHARMACISTS



- 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 Health and Social Care Northern Ireland 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 BSO 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. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

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