Special measures — time for a healthy debate on specials procurement

The way pharmacists source and supply specials is under intense scrutiny as the NHS looks to root out the specials spendthrifts, reports Ailsa Colquhoun

Information and guidance on the prescribing and use of unlicensed pharmaceutical specials makes clear that the days of the specials spendthrift are over. Noting the budget-busting near tripling of NHS spend in this area over the past four years, the guidance, published by the East of England NHS Collaborative Procurement Hub in January 2010, recommends a number of measures designed to curb inappropriate specials supply by pharmacies. According to the EECPH's procurement project manager Stephanie Sprakes, this guidance has been widely welcomed by primary care and other trusts, which are now working to implement its recommendations. She says: "The market has got to the stage where something has to happen. This growth in spend cannot continue at this rate." (Panel 1.)

Importantly, these principles are also supported by commercial specials suppliers, which welcome a healthy debate on the market forces at play in specials procurement. Karol Pazik, managing director of Mandeville Medicines, said: "I know that specials represent value for money, but I am not convinced that pharmacists who supply those specials add value."

Cost-effective support

The EECPH guidance is primarily designed to act as refresher guidance for healthcare professionals on the individual responsibilities and the risks involved in prescribing unlicensed medicines, but it also makes no bones about the need to improve the cost effectiveness of specials used in the NHS. Specifically raising the subject of commercial procurement policies, the document states that "pharmacists should avoid manufacturers offering excessive levels of discount . . . and intermediaries . . . to avoid excessive handling costs and mark ups."

Reference is also made to the new professional guidance from the Royal Pharmaceutical Society on supplying specials, which was published in June (Panel 2).

For prescribers, there are also guidelines, such as regularly reviewing the patient's ongoing need for a special, and the document gives explicit examples where specials prescribing could be improved. Among the "worst offenders", the EECPH cites the volumes recently prescribed for phenytoin 90mg/5ml, and tacrolimus solutions, despite the important bioavailability issues (Panel 3).

Finally, for PCTs, the guidance documents a set of practical actions to support the management of specials prescribing in the areas. Noting that "no one option will deliver complete control but a range may have an effect", the guidance spells out a range of demand-side initiatives such as GP incentive schemes that reduce specials prescribing, specials prescribing authorisation schemes and post payment verification. On the supply side it mentions a best value list and new arrangements with secondary care. Ms Sprakes says: "NHS acute trusts can manufacture some of these medicines at a fraction of the price. In this current financial situation, we have to question why we are not using that option."

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PANEL 1: SPECIALS PRESCRIBED IN ENGLAND AND DISPENSED IN THE COMMUNITY

	Items (numbers)			Net ingredient cost		
	Tagged*	Other specials	Total	Tagged	Other specials	Total
2006/2007	284,881	693,453	978,334	£18,427,807	£43,791,968	£62,219,776
2007/2008	389,208	775,064	1,164,272	£40,145,337	£41,848,800	£81,994,137
2008/2009	461,578	1,183,379	1,644,957	£67,288,325	£59,289,454	£126,577,779
2009/2010	649,682	971,867	1,621,549	£120,060,578	£53,307,922	£173,368,500

*Specials tagged as expensive. Caution is needed when comparing year-on-year growth in tagged items, because this list is extended each year as new medicines meeting the criteria are included

Source: PACT data analysis by the NHS Information Centre

The guidance also provides comprehensive instructions on using the specials reporting functionality of ePACT software. Ms Sprakes says this could help trusts "drill down" into their specials spending hot-spots, at specific drug and individual practice levels. It is the EECPH's opinion that the costs of specials have been escalated by "commercial complexities in the market", which include the price inflation that can occur during the passage of the product through the supply chain.

She says: "The fact is that specials have been allowed to slip under PCTs' financial radar and, as a result, the market has attracted a large number of companies which have realised its lucrative potential. But, the fact is that specials are now on the radar both at national (prescription pricing authority level) and PCT level."

She describes the response to the guidance as "overwhelming and very well received. Trusts are showing a clear demand for support in the management of specials." Such is the demand for support with the management of specials that the work of the specials sourcing group continues as a priority.

Ms Sprakes says that among the specials initiatives also develop ed by her organisation is the online publication of PCT-level spend data on specials. Preliminary work is also under way with the School of Pharmacy at East Anglia University, which aims to build good practice in the supply of specials into the pharmacy undergraduate curriculum.

PANEL 2: NEW RPS PRACTICE GUIDANCE ON SPECIALS RESPONSIBILITIES

Practice guidance from the Royal Pharmaceutical Society outlines the key professional responsibilities for pharmacists providing advice on, or supplying specials, and provides support in making appropriate choices for their patients.

The document covers:

- General information about specials
- Key professional responsibilities
- Assessing clinical need
- Choosing a suitable product
- Choosing a suitable supplier and placing an order
- Good record keeping

Additionally, this guidance encourages community, hospital, primary care and industrial pharmacists to engage with one another and with prescribers to discuss the issue of specials.

Prescribers are not always aware they are prescribing a special and therefore will not be aware that as a bespoke special it is likely to be more expensive to procure than a licensed product. This can lead to a more efficient procurement of specials within the locality

An NHS-wide focus

East of England is far from alone in making a stand on specials, and the Quality, Innovation, Productivity and Prevention (QIPP) initiative — postponed from June to September — has already earmarked specials spending as an area ripe for specific investigation. Launching the £20bn medicines management and procurement efficiency drive earlier this year, pharmacist Peter Rowe said that some £50m is currently spent each year on specials when a licensed alternative could be prescribed in its place. The QIPP medicines workstream lead said: "I cannot see how you could conceivably justify prescribing a special when there are licensed products which, on the face of it, do the same job."

Specials come in for special attention in project one of the QIPP primary care medicines management project. Under the terms of this workstream, QIPP recommends that if drugs bill inflation is to be curbed, there needs to be:

- General awareness raising on prescribing "specials"
- General guidance for prescribers and commissioners highlighting the costly nature of specials and guidance on appropriate prescribing
- Recommendations on any national/structural changes that may be required to minimise inappropriate use

Taking forward the QIPP workstream, at the beginning of August NHS chief executive

PANEL 3: SUMMATIVE REPORT OF PRESCRIBING VOLUMES OF SPECIALS MEDICINES AND PRICES (PACT DATA, ENGLAND, SEPTEMBER 2009)

Formulation	No of prescriptions	No of different quantities prescribed	Total cost of all volumes prescribed	Most common volume prescribed	No of scripts for common volume	Average cost	Maximum cost	Minimum cost
Co-Dydramol_Liq Spec 10mg/500mg/5ml	207	21	£36,298.90	150	58	£112.26	£342.86	£89.97
Diazepam_Oral Soln 10mg/5ml	188	24	£20,011.14	200	95	£95.35	£602.41	£7.17
Ferr Sulph_Liq Spec 60mg/5ml	183	18	£31,638.07	100	29	£128.72	£409.33	£7.89
Omeprazole_Liq Spec 10mg/5ml	1,034	39	£215,895.27	150	188	£220.55	£812.62	£13.87
Paracetamol Susp 500mg/5ml.	470	23	£62,359.76	500	268	£107.64	£493.67	£6.36
Phenytoin_Sod Liq Spec 90mg/5ml	425	32	£43,967.43	500	247	£120.83	£453.63	£3.96
Tacrolimus_Liq Spec 2.5mg/5ml	77	10	£55,961.68	100	22	£382.37	£579.94	£177.85

Source: Appendix 7: Information and Guidance on the Prescribing and Use of Unlicensed Pharmaceutical Specials.
Full list online at www.eoecph.nhs.uk/Pharmaceutical_Specials.pdf

David Nicholson wrote to English trusts asking for boards to consider how QIPP's recommendations can be implemented at trust level. Trusts are also asked to give feedback ahead of the publication of the latest NHS Operating Framework in the autumn. Calling for local trusts to react proactively to the challenges laid down by QIPP, Mr Nicholson said: "Alongside pandemic flu, this is the most important challenge facing the NHS for the foreseeable future."

Financial planning

QIPP, of course, is just part of an ongoing NHS workstream to curb the spiralling drugs bill — said to be inflating by 14 to 22 per cent a year in secondary care — and plenty has already been done to improve procurement efficiency across the NHS.

In May 2009, the Department of Health unveiled plans to boost the commercial and procurement skills across the NHS in the form of a new commercial operating model. Among the products of this model is the network of commercial support units (CSUs), designed to support NHS health care providers and service commissioners to help them improve their skills, gain better value from procurement and respond more effectively to commercial challenges. Launching the new commercial model, the Department of Health director general of commissioning and system management Mark Britnell said: "The new commercial operating model will deliver a step change in commercial capability, raising the standard of commercial knowledge at all levels across the NHS. . . . In a colder economic climate, a new commercial operating model is a necessity, not a nicety or an optional extra."

Scott Rothstein/Dreamstime.com

The contract conundrum

For specials manufacturers supplying secondary care, one of the most important ramifications of the new CSU model has been the recommendation that procurement chiefs identify "the opportunity to develop current mechanisms to achieve further efficiencies on providers' own third-party spend of some £20 billion a year."

According to Bath ASU, a specials company specialising in aseptic manufacturing, a manifestation of the new commercial model has been to increase the use of longer term contracts; for Bath ASU, over the past four years, this has grown its

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contract business from around 5 per cent when the company was formed in 2006, to around 60 to 70 per cent today.

It is the view of Bath ASU managing director Richard Wastnage that the offer of commercial security has undoubtedly secured price deflation in the specials market in secondary care. But in his mind, the question still remains whether, in the long term, this business model will prove more cost-efficient than simple market forces.

He says: "In the aseptic segment there are six major multinational manufacturers and competition is intense as a result. I believe that the Department of Health is already getting the best prices and that the contractual framework will not improve on this."

Furthermore, as contracts can be made on a product and price — rather than service-led model — he believes that the NHS is being encouraged to see specials as "stock commodities", which, he says, "threatens the essence of what a special should be – and that is a product that is produced on an individual patient basis".

A special future

Bath ASU is also sceptical about the EECPH's vision to see outsourced specials manufacture switch to in-house technical departments. The well documented, all-band vacancy rates in secondary care aside, Mr Wastnage says there are several factors at play that suggest, if anything, in the future there will be demand for more — not less — outsourcing in his market. These include:

- Environmental factors — better screening, treatment, increased use of second- and third-line chemotherapy options, more complex treatment schedules, and existing national strategies to centralise aseptic manufacturing are already putting pressure on technical unit capacity
- Regulatory capacity constraints
- Human resources — insufficient technical skills in the pharmacy workforce
- Product liability concerns
- Health and Safety concerns — risk to the health and safety of technical manufacturing staff

Manufacturers respond

Commercial specials manufacturers worked with the RPS on its practice guidance and the Association of Commercial Specials Manufacturers hopes that this will be the start of more collaboration to come. Alan Krol, managing director of Moorfields Pharmaceuticals and current ACSM chairman, says: "As an industry meeting a unique clinical need [there is] need to work together to ensure that doctors, pharmacists and patients are armed with the right information."

The ACSM says that over the past few years pharmacists have come to value and rely on the specials sector, and it is the ACSM's opinion that most pharmacists now order in their specials, rather than undertaking their own preparation. Each week Martindale Pharma says it is approached for between 20 and 24 new formulations — due to factors including growing awareness of the role of the delivery mechanism in compliance, the ageing population, and the increasing incidence of cancers, which are having an impact on the number of patients with dysphagia. PACT figures for the past three years (2007/08–2009/10) confirm that liquid specials now represent almost 60 per cent of all specials tagged by PACT as "expensive", up from 44 per cent, and 73 per cent of the total cost of this specials group (up from 68.7 per cent).

Mr Krol says this is not a reflection of the skill of the pharmacist: "Rather it is recognition that manufacture of even the simplest formulation takes time, resource and investment, together with all the requirements for quality and recording." For this reason, the ACSM says that most pharmacists will prefer to pick up the telephone and order the special. "This is true of NHS pharmacists as well as community pharmacy, with a significant number of orders coming from hospitals," he says.

Also stimulating demand for specials is the industry's total recent stated investment of

THE LEGAL AND ETHICAL ISSUES OF TABLET CRUSHING

There are several important legal and ethical implications that become relevant when the form of a medicine is changed by crushing a tablet or emptying a capsule.These can render the person administering the medicine liable for any harm that is caused to the patient's health.

The main statutory framework for the regulation of medicines is the Medicines Act 1968. The Act requires that all medicinal products for human use are manufactured and used in accordance with a product licence or manufacturing authorisation. The Act states that "a medicine with a product licence would be used in an unlicensed manner if the dose, route or form were outside the licensed terms".

Statutory protection against harmful products is provided by the Consumer Protection Act 1987 that implements the Product Liability Directive (Directive 85/374/EEC) from the EU. Strict liability (liability without fault) makes a producer accountable for damage caused by a defective product and this includes medicines. Unless it is designed to do so, changing the form of medication by crushing a tablet or emptying a capsule removes the protection afforded by the Consumer Protection Act 1987 and renders the person administering the altered medicine liable for any harm caused.

Duty of care

The law places a duty of care on health professionals (Kent v Griffiths [2001]). They are required to prescribe and administer medicine to others to a standard consistent with a responsible body of professional opinion (Bolam v Friern HMC [1957]). The Court of Appeal has held that the duty of care includes giving advice to patients, carers and nurses about the risks inherent in treatment, safe methods of administration and, even, the standard of handwriting used to convey instructions (Prendergast v Sam and Dee [1989]). In terms of supplying specials, Royal Pharmaceutical Society guidance states that the pharmacist who supplies the product to the patient remains accountable for its quality. Pharmacists should, therefore, take all reasonable steps to assure it. All holders of a manufacturer's specials licence should supply products with a certificate of conformity. A certificate of analysis should be available for any batch manufactured special.

Care with crushing

If a healthcare professional advises that a tablet is crushed or a capsule opened to assist with swallowing difficulties and harm results then liability in negligence might arise and the injured party could seek damages for the harm caused.

Furthermore, it is insufficient defence to say that tablet crushing is common practice. Unless it can be shown that the practice is a safe, evidence-based, well-reasoned intervention then the court has the right to reject the professional standard (Bolitho v City & Hackney Health Authority [1998]). A healthcare professional will not to be exonerated because others too are negligent or common professional practice is slack (Reynolds v North Tyneside Health Authority [2002]).

Ethics

The Human Rights Act 1998 incorporates into UK law the main rights and freedoms set out in the European Convention on Human Rights by regulating the relationship between individuals and public authorities. When deciding on appropriate methods of medication management and administration, it is now necessary to focus on the patient's wishes and interests as these closely echo the requirements of the Human Rights Act.

The Equality Act, which comes into force from October 1, incorporates the Disability Discrimination Act 1995. This makes it is unlawful for a contractor to discriminate against a disabled person by failing to comply with a duty in which the effect of that failure is to make it impossible or unreasonably difficult for a disabled person to make use of any services provided. This may make it necessary for pharmacists to provide easy-open closures or large print labels, remove tablets from blister packs, supply non oral formulations or provide monitored dosing systems.

Source: Rosemont Pharmaceuticals

Guidance for contractors on implementing the DDA is available from PSNC at www.psnc.org.uk/

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around £150m in recent years in facilities and products. At Martindale Pharma, for example, delivery times have been a core area for business development, and over the past six months, the company claims to have reduced order-to-door delivery times down from 48 hours, to around 24 hours for 85 per cent of the company' product portfolio. This has been achieved through the identification of items most suited to batch manufacture and manufacturing capacity improvements, says company chairman Thomas Engelen. He adds: "Patients ultimately don't distinguish between licensed [products] and specials, they just want it in their hands as quickly as possible after leaving the doctor's surgery. The challenge for us is to consider how we can make our supply chain mirror that of the licensed product manufacturer."

Mr Krol confirms that Martindale is not alone in this approach: "Specials manufacturers are investing heavily in new products, facilities and human resource, leading to faster delivery times, and more comprehensive customer support services. Many ACSM members are now specialising — some in therapy areas such as ophthalmics, others in delivery systems such as liquid formulations. This specialisation will result in tailored products for specific clinical needs, faster response, wider choice, higher levels of patient compliance and, of course, patient safety."

SUPPLYING A SPECIAL — A DECISION GUIDE FOR PHARMACISTS

Preferred choice — **Lowest net risk**

UK licensed medicines
Off-label use of a UK-licensed medicines
An imported product licensed in the country of origin
A UK manufactured "special" made in MHRA licensed facilities
Crushing UK-licensed tablets or opening capsules
An extemporaneously dispensed medicine
An imported product not licensed in the country of origin
A non-UK-made unlicensed medicine or food supplement

Last choice — **Highest net risk**

Source: RPS practice guidance on supplying specials

Victim of success

As part of its collaborative approach to the ongoing investigation in the market, the ACSM is readily accepting of some less desirable developments in the specials industry, namely, the burgeoning presence of parties, variously described by some ACSM members as "quick-buck, cherry-picking merchants", or "happy-slappy specials houses offering too-good-to-be-true rebates".

Summarising, these views, the ACSM identifies the core problem as the specials resale sector, a distribution chain over which it says: "neither the manufacturer nor the NHS has control". Mr Krol says: "This, unfortunately, has had a negative effect on the reputation of the industry."

Over the past 12 months, the ACSM has been working with the Department of Health to create a system that more effectively

SOME EXAMPLES OF ALTERNATIVES TO LIQUID PHARMACEUTICAL SPECIALS

Drug	Formulation and administration advice
Amlodipine	Tablets will disperse in water — light sensitive so administer immediately.
Doxazosin	Tablets can be dispersed in sterile (not tap) water.
Ferrous sulphate	Change to equivalent dose of sodium feredetate (55mg/10ml = ferrous sulphate 200mg)
Phenytoin	Convert to syrup: 90mg syrup = 100mg capsules. Single daily dose is preferable. To avoid adsorption to the tubing mix with equal volume water and flush with 30ml water before and after administration. To avoid interaction with feeds it is necessary to stop feed two hours before and two hours after administering.
Pantoprazole	Not suitable for crushing. Consider changing to alternative proton pump inhibitor.

Source: Appendix 5: Information and Guidance on the Prescribing and Use of Unlicensed Pharmaceutical Specials. Full list online at www.eoecph.nhs.uk/Pharmaceutical_Specials.pdf

manages the cost of specials without compromising supply. For many suppliers, this workstream cannot deliver results fast enough. It is the view of Mandeville Medicine's Karol Pazik that safety, efficacy and quality should be at the heart of a specials industry, which in itself should be viewed as a "last chance saloon" procurement decision made for the patient. But, he says: "Many pharmacies, particularly those in the smaller chains, are under pressure to buy on price, particularly, because 80 to 90 per cent retrospective rebates are on offer." Calling for transparency, he argues for new measures to be implemented, including ex-factory pricing, and incentives for quality manufacturing, and disincentives — capped margins and even the introduction of Drug Tariff prices — for products supplied without a certificate of analysis.

At Martindale, Mr Engelen agrees that the industry needs to make a stand and stress its quality credentials. He says: "There needs to be a healthy debate — Martindale is a well-known name and we have an established relationship with primary and secondary care. Our pricing has to be defendable, and we don't want all specials manufacturers placed in the same basket."

The company is also keen to see issues such as compliance and medicines waste factored into the discussion. He says: "If a medicine is discontinued due to format issues, then that is simply wasted money."

For its part, the ACSM accepts the need for debate, and it is keen that specials should be seen as delivering value for money for the NHS. Checks already under way on the sector — for example, the Medicines and Healthcare products Regulatory Agency's informal review of unlicensed medicines — have already tabled suggestions such as improving patient information and, possibly, strengthening regulation of the sector. Provided clinicians remain able to prescribe freely and according to patient need, the ACSM has welcomed these proposals. It says: "ACSM members are confident that any new measures requested will be easily implemented into existing best practice. They can only have a positive impact on their sector – leading to a better understanding of the role and expertise of specials manufacturers."

PRICE PROBLEMS WILL CONTINUE

Specials suppliers fear that open price lists for specials will do nothing to crack the price problems that pervade their market, and they could disadvantage quality product manufacturers.

On August 19, regulations were published allowing the publication and dissemination of price lists for unlicensed medicines. The regulations are the Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010.

Although the Association of Commercial Specials Manufacturers (ACSM) has welcomed the move as providing greater transparency, some manufacturers fear that the initiative does not go far enough. Karol Pazik, of Mandeville Medicines, says: "It won't disclose the retrospective discounting arrangements of [manufacturers] in primary care who won't publish their lists. It will merely give the intermediaries better opportunities to get lower prices for the products which they already source." He added that controlling specials pricing needs something quite different."

Mr Pazik believes there are other reasons why open lists are a bad idea. First, they give the impression that all specials are equal, "and this couldn't be further from the truth", he says. "What would be of real benefit is if the lists were mandated to state the quality standard to which the special was manufactured, and whether shelf lives have been validated with supporting evidence."

Secondly, lists can pressure prescribers to fit the clinical need to the listed special, and not the other way round. Mr Pazik says: "Openly-published lists 'endorse' the use of specials and I don't think that is in the best interests of the patient. Unlicensed medicines are, after all, just that — totally untried and untested and, in many cases, of dubious clinical benefit."

The Pharmaceutical Services Negotiating Committee believes that the change has the potential "to ease the current problems pharmacy contractors face in procuring these products", although it recognises that such lists can not be comprehensive.

The ACSM says the publication of price lists "will lead to greater clarity within the marketplace".