How Drug Tariff specials have reduced prescribing costs

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Steve Chaplin describes what specials are, who manufactures them and how the introduction of Drug Tariff specials in 2011 has led to a reduction in costs.

Specials – misunderstood, often expensive and a thorn in the side of many prescribing advisers – hit the headlines last year when The Daily Telegraph alleged fraudulent payments were made to pharmacists by two specials manufacturers. The story exposed an apparent invoicing scam that exploited weaknesses in the NHS reimbursement system.

One inference to be drawn from this episode is that there is little oversight of pricing for specials but, though it is not yet comprehensive, there is a system in place to control spending in what is a complex market.

What is a special?
The Drug Tariff defines specials as ‘unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned’. It may also be known as a Special Order Product.

The purpose of a special is to meet a patient’s clinical needs that cannot be achieved with a licensed product. Most are unlicensed formulations of a licensed drug, for example a solution, suppository or cream. They can be prepared to order by a pharmacist in a pharmacy, but this is time-consuming and the majority are supplied by companies specialising in manufacturing small quantities in response to a specific prescription.

Although individual pharmacists do not need a licence to prepare products for an individual prescription in a pharmacy, manufacturers require a Manufacturers ‘Specials’ Licence from the Medicines and Healthcare products Regulatory Agency (MHRA) that allows them to manufacture and also import unlicensed medicines.

Specials manufacturers
Licensed specials manufacturers are represented by the Association of Pharmaceutical Specials Manufacturers (APSM, http://apsm-uk.com). There are currently 15 members, including familiar names like Martindale, Moorfields and Rosemont (and one company implicated in The Daily Telegraph story), who have signed up to a code of conduct to ensure good manufacturing practice and ethical behaviour. The APSM says its members adhere to standards for quality assurance processes, batch testing, product labelling,
adverse event reporting and customer (ie the pharmacist) support lines.\(^3\)

The APSM acknowledges that ‘specials manufacturing is a less well-understood sector of the pharmaceutical industry’, pointing out that the licensing system prohibits it from talking about its products (other than publishing a price list). It ‘acknowledges that change is needed within the market’ and has been working with the DH on measures to regulate costs.\(^4\)

**Drug Tariff and non-Tariff specials**

From the prescriber’s point of view, there are no differences between specials in the way they are prescribed. They are, however, reimbursed differently.

In 2011, the DH decided that selected specials would in future be reimbursed according to Part VIIIIB of the Drug Tariff – in effect, setting the price that the NHS would pay. These products are listed in the Drug Tariff as Drug Tariff Special Order Products (DTSOPs). This list, which now includes 188 products, is updated quarterly to review prices and half-yearly to add or remove products. The APSM says that almost half of the top 100 specials by value are now DTSOPs and, since their introduction, the average cost per item has fallen by a quarter from £180 to £135.\(^3\)

The Drug Tariff price applies to a specific strength and a minimum volume of a product, with extra payments per additional unit. For example, the current price for metformin 10mg per 5ml oral suspension is £153.36 for 20ml, with each additional millilitre costing £0.45. Pharmacists endorse DTSOP prescriptions for reimbursement in the same way as for licensed medicines.

The price paid for a special not listed in the Drug Tariff is determined by a licensed manufacturer and the pharmacist endorses the prescription with this price. A pharmacist who prepares a product extemporaneously in the pharmacy is paid the cost of materials and a dispensing fee.

**Spending on specials**

Updates and developments in coding prescriptions for specials mean that prescribing data from different time periods are not directly comparable.

The latest data that have been collated by the DH for all specials are for 2011, when 614,834 items were prescribed at a total cost of £115.5 million;\(^3\) 399 drugs were dispensed in 17,484 different formulations with an average cost per item of £188 (compared with the average of £9.16 for all medicines).

In that year, the five top drugs by spending were melatonin (£13.8m), midazolam maleate (£7.6m), omeprazole (£6.0m), glycopyronium bromide (£5.1m) and colecalciferol (£5.0m). The extent to which possible fraud may have inflated costs is not known.

The NHS Business Services Authority publishes quarterly prescribing data for the top 500 products by volume and value.\(^6\) These data, derived from ePACT.net and limited to England, show that prescribing volume increased after the DTSOPs scheme was introduced but has remained at about the same level since, with DTSOPs accounting for an increasing share of prescribing. This is reflected in the overall costs, with a fall of about 20 per cent w ith the introduction of DTSOPs followed by a further steady decline (see Figure 1).

Data for 500 individual products are available for the quarter to March 2013 (the top 10 are listed in Table 1).\(^5\) These figures give some idea of the low volume of most products – the top product by volume (colecal capsules 20,000 units) is prescribed five times more frequently than the second. Eight of the top 10 products by volume are also in the top 10 by spending, suggesting similar costs per item for those most frequently prescribed.

These data also show how astonishingly expensive some specials are. For example, a total of only 11 items comprising theophylline suppositories 300mg (£4848 per item), arginine liquid 750mg per 5ml (£4199) and human insulin 500U/ml (£3522) cost nearly £47 000.

Some of this expense can be avoided and prescribing advisers regularly monitor specials prescribing to identify savings. In one audit, NHS Sheffield (then a PCT) cited the example of the special omeprazole liquid 20mg per 5ml, which costs £6.95 per dose compared 41p for Losec 20mg MUPS, which can be dispensed in water.\(^7\)

**Drawbacks of specials**

Other than cost, specials lack some of the assurances taken for granted with licensed medicines. There is no guarantee of bioequivalence or cost comparability for the same medicine sourced from different manufacturers, and shelf-life may be limited. The prescriber and the dispensing pharmacist are liable for harm that the patient might experience.

According to guidance from the General Medical Council, patients must be informed that they are being prescribed an unlicensed medicine and told why, and a record should be kept of the rationale for choosing this medicine.\(^8\)

### Table 1.

<table>
<thead>
<tr>
<th>Product</th>
<th>Items</th>
<th>Net ingredient cost (£)</th>
<th>Special or DTSOP</th>
<th>Cost per item (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. colecal cap 20 000u</td>
<td>40 698</td>
<td>812 152</td>
<td>special order</td>
<td>19.96</td>
</tr>
<tr>
<td>2. melatonin cap 3mg</td>
<td>8 079</td>
<td>744 731</td>
<td>special order</td>
<td>92.18</td>
</tr>
<tr>
<td>3. melatonin cap 2mg</td>
<td>7 247</td>
<td>641 898</td>
<td>special order</td>
<td>88.57</td>
</tr>
<tr>
<td>4. melatonin oral soln 5mg/5ml</td>
<td>6 570</td>
<td>796 576</td>
<td>DTSOP</td>
<td>121.24</td>
</tr>
<tr>
<td>5. midazolam oromuc soln 10mg/ml</td>
<td>6 261</td>
<td>834 132</td>
<td>DTSOP</td>
<td>133.23</td>
</tr>
<tr>
<td>6. diltiazem HCl crm 2%</td>
<td>4 577</td>
<td>401 958</td>
<td>DTSOP</td>
<td>87.82</td>
</tr>
<tr>
<td>7. mag glycerophos tab chble 97.2mg</td>
<td>4 027</td>
<td>371 178</td>
<td>special order</td>
<td>92.17</td>
</tr>
<tr>
<td>8. colecal cap 10 000u</td>
<td>3 808</td>
<td>94 685</td>
<td>special order</td>
<td>24.86</td>
</tr>
<tr>
<td>9. melatonin cap 5mg</td>
<td>3 580</td>
<td>290 587</td>
<td>special order</td>
<td>81.17</td>
</tr>
<tr>
<td>10. omeprazole oral susp 10mg/5ml</td>
<td>3 530</td>
<td>572 901</td>
<td>DTSOP</td>
<td>162.29</td>
</tr>
</tbody>
</table>

Table 1. Top 10 specials by prescribing volume (quarter to March 2013),\(^6\) DTSOP = Drug Tariff Special Order Product
Prescribing guidance
In 2011, the National Prescribing Centre (now part of NICE) published guidance on prescribing specials, identifying five guiding principles:9
• establish a clinical need
• identify medicines and preparations with the help of a pharmacist or local prescribing committee
• make a shared decision with the patient or carer
• ensure effective prescribing governance
• monitor and review on an ongoing basis.

Summary
Specials are more expensive than licensed products – in some cases, much more so – and lack their regulatory guarantees of safety and quality. Measures to control prices, agreed between the DH and manufacturers in 2011, are having an effect on both spending and volume. Guidance is available to help ensure patient safety when prescribing a special, which should be done in consultation with colleagues and the patient.

References
3. Association of Pharmaceutical Specials Manufacturers. The Specials Tariff is important to ensure confidence and best practice within the sector. 27 June 2013 (http://acsm blog.blogspot.co.uk).

Declaration of interests
None to declare.

Steve Chaplin is a pharmacist who specialises in writing on therapeutics