

# THE TABLET

## Specials Formulations

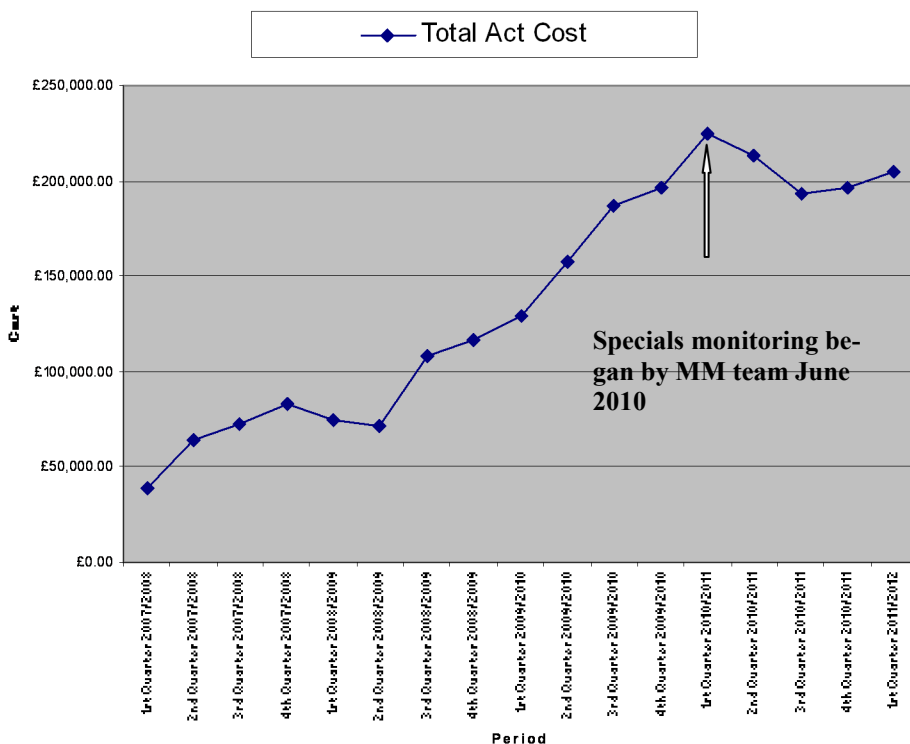
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### Did you Know?

- Dudley PCT spent over £800,000 on specials formulations during the financial year 2010-2011.
- Specially formulated medicines are unlicensed which increases legal liability for the prescriber and the dispensing pharmacist.
- Supplying a special when an alternative licensed product exists is in breach of the Pharmacist Code of Ethics. An example of such supply locally includes: Hypromellose 0.3% p/f eye drops when minims exist (e.g. Hydromoor® 30 x 0.4ml costing £5.75).
- Analysing prescribing of specials formulations during the last financial year, the Medicines Management (MM) team believes that there is available a more cost-effective licensed alternative in many cases.
- The cost of identical specials varies considerably between different local pharmacies i.e. 300ml Omeprazole 10mg/5ml liquid has cost anywhere between £146 and £714.
- The cost of identical specials varies considerably between branches of the same pharmacy i.e. 28 Melatonin 5mg capsules has cost between £47 and £135.
- Since June 2010, the MM team have supplied the practice pharmacists and their GP surgeries, details of monthly specials costs identifying the supplying pharmacy contractor for individual items. This has contributed to reversing the previous rapidly escalating cost trend being observed.

**Specials Cost for Dudley PCT**



### What has happened locally so far?

The MM team began the "Specials" campaign in June 2010. Each month specials (unlicensed) prescribing data is sent to practice based pharmacists for review and discussion within individual practices. The graph on the left demonstrates that the campaign initially had a positive impact on reversing the previous rising cost-trend. The MM team would like to extend its appreciation to the LPC & those community pharmacies that have supported GP practices & the practice pharmacists to procure cost-effectively &/or contact the GP to flag an alternative licensed preparation. Whilst, savings have been achieved, community pharmacies need to remain vigilant with their in-house dispensing systems (or SOPs) to ensure unlicensed specials are avoided where possible. For example, this can be achieved by the community pharmacist clinically screening the prescription prior to another member of staff ordering a special inadvertently when a licensed product exists.

<p style="text-align: center;"><b>Medico-Legal Implications for Pharmacists and Staff</b></p> <p>The pharmacist/dispenser assumes a greater degree of liability than normal when they request a special to be manufactured. Under normal circumstances, a pharmacist is not liable for harm caused to a patient if:</p> <ul style="list-style-type: none"> <li>• A licensed medicine is dispensed against a valid prescription.</li> <li>• No error is made during dispensing.</li> <li>• Storage requirements of the license were observed.</li> <li>• No factors present that would cause a pharmacist to intervene during dispensing process.</li> </ul> <p>However in the case of a special, the pharmacist has a responsibility to:</p> <ul style="list-style-type: none"> <li>• Ensure that <b>both</b> the prescriber and patient are aware of the unlicensed status of the medicine and to recommend a licensed alternative if one exists.</li> <li>• Specify the exact formulation requirements to the manufacturer, including non-active ingredients so that the right medicine for the patient is prepared. Most pharmacists would seek professional advice from the manufacturer but again, the quality may vary depending upon the manufacturer.</li> </ul> <p>In the event of a medicine harming the patient, especially if it was determined to be of sub-standard quality, then the pharmacist would share liability (with prescriber) of any such harm caused.</p> <p>Further details available at: <a href="http://www.eoeceph.nhs.uk/Pharmaceutical_specials.pdf">http://www.eoeceph.nhs.uk/Pharmaceutical_specials.pdf</a></p>	<p style="text-align: center;"><b>Q &amp; A's for Community Pharmacists</b></p> <p><b>Q: Am I sure a special formulation is required by the prescriber?</b>  A: Many GP practice systems do not clearly identify when a special formulation product has been selected. We would expect our community pharmacists to <b>confirm</b> that this is what the prescriber intended <b>before</b> ordering a special. For example "Preservative free" eye drops are often selected when Minims® brand is intended.</p> <p><b>Q: Is there a suitable licensed alternative?</b>  A: In many cases there is—either of the same drug (i.e. Losec® MUPs as opposed to Omeprazole liquid specials), or one from the same therapeutic class (i.e. Dosulepin HCL 75mg/5ml liquid special can be substituted with licensed liquid amitriptyline). As per the code of ethics, we would expect our community pharmacists to use their expertise to contact and advise prescribers when there is a suitable licensed alternative formulation available.</p> <p><b>Q: Is my supplier pricing specials competitively and am I obtaining good value for money for the NHS?</b>  A: Possibly not. Analysis of prescribing data for quarter 1 2011-12 showed:</p> <ul style="list-style-type: none"> <li>• 300ml omeprazole 10mg/5ml cost between £146 and £714.</li> <li>• 150ml Melatonin 10mg/5ml liquid cost between £93 and £1320.</li> </ul> <p>These were not isolated instances.</p> <p><b>Q: Can I source direct from the specials manufacture rather than procuring via a wholesaler or third party?</b>  A: Often, YES and this then avoids "mark ups" that appear with additional steps of the supply chain (i.e. wholesaler). Remember, pharmacists have a professional duty to source medicines cost-effectively providing value for money for the NHS.</p>	<p style="text-align: center;"><b>Are you breaching your code of ethics?</b></p> <p>Under the key professional responsibilities section of the pharmacist's code of ethics, <u>standard 3.7</u> clearly states that:</p> <p><i>"a product with a marketing authorisation is supplied where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement"</i></p> <p>Prescribing data for quarter 1 2011-2012 identifies that unlicensed specials are consistently being supplied contrary to the above standard. We would expect our pharmacists to contact the prescriber and suggest equivalent <b>licensed</b> alternatives from a patient safety, quality, accessibility and cost perspective.</p> <p>Some examples include (list not exhaustive):</p> <ul style="list-style-type: none"> <li>• Amitriptyline 10mg/5ml liquid (top cost of £82 for 150ml). <i>What should have been supplied?</i> <b>A:</b> Amitriptyline 25mg/5ml SF or 50mg/5ml SF.</li> <li>• Hypromellose 0.25% eye drops (top cost of £87 for 10ml). <i>What should have been supplied?</i> <b>A:</b> Hypromellose 0.3% eye drops 10ml (£1.40 per 10ml).</li> <li>• Hypromellose 0.3% P/F eye drops (top cost of £50 for 10ml). <i>What could have been supplied?</i> <b>A:</b> Hydromoor® 0.3% minims (£5.75 for 30 x 0.4ml).</li> <li>• Methadone 30mg capsules (top cost of £792 for 60 capsules). <i>What could have been supplied?</i> <b>A:</b> Physeptone 1mg/1ml liquid SF or Methadone 5mg tablets.</li> </ul>
<p style="text-align: center;"><b>Local GP Feedback on Specials</b></p>		
<p>A pertinent question for all pharmacists is: do you <b>always</b> contact the prescriber to check their awareness of the unlicensed status &amp;/or licensed alternatives? This is important since several GPs have fed-back that they have selected an unlicensed special (a) in error or (b) as they didn't realise that the product was unlicensed. Given that one of the roles of pharmacy is to provide a back up for prescribers, the absence of the check is a cause for concern from both a safety and financial perspective. Generally, GPs and practice staff are very welcoming and appreciative to being contacted to discuss issues around specials. Good practice would recommend that any interventions made are documented from both a clinical governance perspective as well as providing evidence of community pharmacy role in supporting GPs to realise cost savings whilst promoting quality. This potentially could support future cost-saving initiatives to be commissioned locally to community pharmacy when the new clinical commissioning groups take over PCT function.</p>		

**Sodium Chloride 5% Eye Drops 10ml**

ePACT data for Qtr 1 2011-2012 demonstrates a range of prescribing costs for sodium chloride 5% eye drops x 10ml. The range at the lowest end was £9.04 whereas the greatest observed cost was £101.38 with an average cost for 10ml of £42. This is typical of the cost variations with specials locally observed. Please note that recently sodium chloride 5% eye drops have appeared under **part IXA** (appliances) of the drug tariff (Sept 11) and this will ensure greater regulation of costs. Sodium chloride 5% eye drops x 10ml (Alissa Healthcare) will be reimbursed at £25.25.

**Important:** The prescription must be endorsed with "Alissa Healthcare" to ensure payment is received. The PPD have confirmed that any other endorsement will result in the item being disallowed.