How the NHS pays for drugs – and when the system fails

Steve Chaplin BPharm, MSc

The NHS in England spent £12.9 billion on medicines in 2010 – over two-thirds of it in primary care.1 Much of this enormous sum is voluntarily agreed between the DH and pharmaceutical manufacturers. The system has checks and balances and, overall, works reasonably well for the NHS. But anomalies do occur and can cause significant problems – the latest being a massive hike in the price of Epanutin (phenytoin) 100mg capsules.2

Pricing drugs for the NHS

There are two principal ways in which the NHS agrees with manufacturers the maximum prices it will pay for drugs, depending on whether they are branded or generic. The prices actually paid may, however, be lower when local contracts are negotiated.

Branded drugs

Branded drugs are subject to the Pharmaceutical Price Regulation Scheme (PPRS), which sets a framework for pricing drugs by controlling the profits of manufacturers from sales to the NHS.3 Agreed between the DH and brand manufacturers, the current scheme began in 2009 and will end in 2014. It aims to deliver value for money for the NHS while providing market stability and incentives for the industry. It covers a total of 167 companies; a further 64 that did not sign up to the scheme are subject to statutory price controls.4

The 2009 scheme included a commitment to reward innovation by increasing NHS uptake of innovative medicines. The concept of flexible pricing was introduced to allow increases to reflect new evidence (not taken up so far) and there was a more systematic approach to patient access schemes.

The price controls in the current scheme are summarised in Table 1. Manufacturers can deliver the price adjustments in different ways – through across-the-board cuts, variable price reductions over their product range, or with a cash payment to the DH of up to 2 per cent of the price cut. Companies seeking to increase prices must obtain the agreement of the DH.

Manufacturers are free to set any price for a new medicine but they do so within the constraints of a cash-strapped NHS and the power of NICE to withhold approval of drugs so expensive that they fall above the threshold for cost effectiveness.

Patient access schemes that link payment to clinical outcomes allow
the NHS and manufacturers to share the risk of using expensive drugs. They must be approved by the DH, then submitted to the NICE Patient Access Scheme Liaison Unit for review. As of February 2013, there were 28 such schemes in place.6

When the PPRS expires, the price of new drugs will be determined by a system of value-based pricing.7 The price of older drugs will continue to be regulated by a PPRS-like scheme.

Generic drugs
The DH does not directly regulate the prices of generic drugs but relies on market forces to keep them low. An agreement (Scheme M) with the British Generic Manufacturers’ Association provides for a degree of pricing freedom subject to allowing the DH to scrutinise a manufacturer’s accounts to ensure that its prices are reasonable.8 This states that if there are ‘any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure, then the Department may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned’.

As with the PPRS, manufacturers that do not sign up to Scheme M can have prices imposed on them, backed up by statutory penalties.

There is a corresponding scheme for wholesalers (Scheme W). Both schemes were introduced to maintain the continuity and transparency of the supply chain.

Against this background, the Drug Tariff defines three categories of generic drugs for pricing purposes (see Table 2).10 It is clear from the example of omeprazole that this mechanism is highly specific to different presentations of a product. The categories for each presentation are listed in the Drug Tariff.

Category M was introduced along with a new pharmacy contract in 2005. Its purpose is to provide pharmacy contractors with a certain level of profit on their purchases by an adjustment to prices. The DH estimates pharmacists’ profit margins on a quarterly basis from manufacturers’ prices and prescribing data, and makes adjustments to recover excess payments or reimburse underpayments. Approximately 500 Category M drugs currently provide about £500 million of the £2.5 billion in total NHS funding for community pharmacy services.

When the systems don’t work
On the whole the management of prices for branded and generic drugs works well but both systems can fail to provide the NHS with medicines at a reasonable price in a timely manner.

Cabazitaxel
NICE may conclude that what appears to be a significant new drug does not offer value for money for the NHS. One recent example is cabazitaxel (Jevtana) for castration-resistant prostate cancer, for which urologists had high expectations.11

In some cases an alternative funding stream is available, such as the Cancer Drugs Fund, but this may result in regional differences in access to treatment.12

Ranibizumab
For other new drugs, only what amounts to a price cut will get the product into the NHS and this results in further delay in access to new treatments. NICE did not recommend ranibizumab (Lucentis) for diabetic macular oedema in May 2012 because it did not agree with the manufacturer’s economic model. This ruling was very controversial (Diabetes UK commented ‘This decision means more people will needlessly lose their sight’). The company revised its patient access scheme and prepared new evidence and NICE now recommends the drug for a subgroup of patients.14

Phenytoin capsules
There may also be problems with long-established brands – the Drug Tariff’s Category C drugs. GPs mostly prescribe phenytoin as the 100mg capsule and they must do so by brand because differences in bioavailability between formulations may affect seizure control. It is an old drug that presumably has not generated large profits; consequently, it is only available as the brand Epanutin.

Over the past decade the price of Epanutin 100mg capsules changed little but a weakness in the system has now allowed a price increase from £2.83 for 84 capsules to £67.50. Thanks to the blog of a persistent GP, the case has now received national exposure.15

How could this happen? Pfizer sold the marketing authorisation

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage Cut/Cut</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>3.9% cut</td>
</tr>
<tr>
<td>Year 2</td>
<td>1.9% cut</td>
</tr>
<tr>
<td>Year 3</td>
<td>0.1% increase</td>
</tr>
<tr>
<td>Year 4</td>
<td>0.2% increase</td>
</tr>
<tr>
<td>Year 5</td>
<td>0.2% increase</td>
</tr>
</tbody>
</table>

Table 1. Price controls in the 2009 PPRS3

---

3 The PPRS, or Price Control Scheme, is a framework for setting prices for new drug treatments in the UK. It is administered by the Department of Health (DH) and is designed to ensure that the NHS pays a reasonable price for medicines, while providing incentives for manufacturers to invest in research and development.

5 As of February 2013, there were 28 such schemes in place.

6 The PPRS expires, the price of new drugs will be determined by a system of value-based pricing. The price of older drugs will continue to be regulated by a PPRS-like scheme.

7 The DH estimates pharmacists’ profit margins on a quarterly basis from manufacturers’ prices and prescribing data, and makes adjustments to recover excess payments or reimburse underpayments. Approximately 500 Category M drugs currently provide about £500 million of the £2.5 billion in total NHS funding for community pharmacy services.

10 It is clear from the example of omeprazole that this mechanism is highly specific to different presentations of a product. The categories for each presentation are listed in the Drug Tariff.

12 This ruling was very controversial (Diabetes UK commented ‘This decision means more people will needlessly lose their sight’). The company revised its patient access scheme and prepared new evidence and NICE now recommends the drug for a subgroup of patients.

14 There may also be problems with long-established brands – the Drug Tariff’s Category C drugs. GPs mostly prescribe phenytoin as the 100mg capsule and they must do so by brand because differences in bioavailability between formulations may affect seizure control. It is an old drug that presumably has not generated large profits; consequently, it is only available as the brand Epanutin.

15 How could this happen? Pfizer sold the marketing authorisation for Epanutin 100mg capsules.

---

The DH does not directly regulate the prices of generic drugs but relies on market forces to keep them low. An agreement (Scheme M) with the British Generic Manufacturers’ Association provides for a degree of pricing freedom subject to allowing the DH to scrutinise a manufacturer’s accounts to ensure that its prices are reasonable. This states that if there are ‘any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure, then the Department may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned’.

As with the PPRS, manufacturers that do not sign up to Scheme M can have prices imposed on them, backed up by statutory penalties.

There is a corresponding scheme for wholesalers (Scheme W). Both schemes were introduced to maintain the continuity and transparency of the supply chain.

Against this background, the Drug Tariff defines three categories of generic drugs for pricing purposes (see Table 2). It is clear from the example of omeprazole that this mechanism is highly specific to different presentations of a product. The categories for each presentation are listed in the Drug Tariff.

Category M was introduced along with a new pharmacy contract in 2005. Its purpose is to provide pharmacy contractors with a certain level of profit on their purchases by an adjustment to prices. The DH estimates pharmacists’ profit margins on a quarterly basis from manufacturers’ prices and prescribing data, and makes adjustments to recover excess payments or reimburse underpayments. Approximately 500 Category M drugs currently provide about £500 million of the £2.5 billion in total NHS funding for community pharmacy services.

When the systems don’t work
On the whole the management of prices for branded and generic drugs works well but both systems can fail to provide the NHS with medicines at a reasonable price in a timely manner.

Cabazitaxel
NICE may conclude that what appears to be a significant new drug does not offer value for money for the NHS. One recent example is cabazitaxel (Jevtana) for castration-resistant prostate cancer, for which urologists had high expectations. In some cases an alternative funding stream is available, such as the Cancer Drugs Fund, but this may result in regional differences in access to treatment.

Ranibizumab
For other new drugs, only what amounts to a price cut will get the product into the NHS and this results in further delay in access to new treatments. NICE did not recommend ranibizumab (Lucentis) for diabetic macular oedema in May 2012 because it did not agree with the manufacturer’s economic model. This ruling was very controversial (Diabetes UK commented ‘This decision means more people will needlessly lose their sight’). The company revised its patient access scheme and prepared new evidence and NICE now recommends the drug for a subgroup of patients.

Phenytoin capsules
There may also be problems with long-established brands – the Drug Tariff’s Category C drugs. GPs mostly prescribe phenytoin as the 100mg capsule and they must do so by brand because differences in bioavailability between formulations may affect seizure control. It is an old drug that presumably has not generated large profits; consequently, it is only available as the brand Epanutin.

Over the past decade the price of Epanutin 100mg capsules changed little but a weakness in the system has now allowed a price increase from £2.83 for 84 capsules to £67.50. Thanks to the blog of a persistent GP, the case has now received national exposure.

How could this happen? Pfizer sold the marketing authorisation for Epanutin 100mg capsules.
for Epanutin capsules to Flynn Pharma but continued to manufacture it. Flynn Pharma renamed it Phenytoin Sodium Flynn Hard Capsules and wrote to GPs to assure them that ‘the Flynn Pharma product is identical to Epanutin. There are no differences in formulation and the site of manufacture remains unchanged. The capsules continue to contain the same identicode markings as Epanutin, including the word Epanutin.’ Confusingly for patients and prescribers, the product must now be prescribed as ‘Phenytoin Sodium Flynn xmg Hard Capsules’.

The price rise has been possible because the NHS uses a single formulation of phenytoin capsules. Flynn Pharma now have the best of both worlds: they are marketing the renamed product as a generic, which is free of price controls, while making it clear that it is essentially Epanutin. In 2011, GPs in England spent £1.3 million on Epanutin 100mg capsules. Next year this will be £31 million.

Category M

Much of the criticism about pricing generic drugs relates to Category M. If manufacturers’ prices fall, the DH will reduce the Category M price. However, wholesalers may not respond as quickly, leaving pharmacists unable to obtain supplies at the price they will be paid.

There is also the risk that the Category M price for a common generic may rise disproportionately. For example, the price of phenytoin 100mg tablets has increased substantially in recent years. According to NHS statistics, the mean cost per item dispensed in England in 2004 was approximately £6.00. By 2006 it was £85 and in 2007 it rose to £231. Following an intervention by the DH in 2008 the price declined, reaching £91 in 2011. The 100mg tablet now accounts for only 12.5 per cent of all presentations prescribed but eats up 85 per cent of spending on phenytoin by GPs in England.

Category M pricing also created the paradox of branded generics. These are supplied at lower cost than the Category M price, leading prescribing advisers to encourage brand prescribing of specific drugs that are readily available as generics – at a stroke making a nonsense of their efforts to promote generic prescribing and undermining community pharmacy remuneration.

Implications

Imperfections in the pricing systems for drugs may have a relatively small effect on NHS finances overall but they probably have a substantial impact on specific services and patient groups.

While manufacturers and NICE squabble about the price of new drugs, patients do not have access to potentially valuable treatments. Value-based pricing, under which a price will be set before marketing and adjusted in light of clinical experience, should prevent such delays.

Exploiting loopholes to inflate the price of formerly cheap drugs enriches the coffers of quick-witted manufacturers but denies resources to patients who need other treatments. The DH should consider new regulations to enable it to tackle this problem more quickly.

References


15. Brunet M. Epanutin scandal picked up by The Daily Telegraph – now MPs need to know. (http://binscombe.net/blog/?p=494).


Table 2. Drug Tariff pricing categories for generic drugs9

<table>
<thead>
<tr>
<th>Category</th>
<th>Availability as generic</th>
<th>Price</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>readily available</td>
<td>the average of the price calculated for the pack size listed in the Drug Tariff weighted by 4 manufacturers and suppliers</td>
<td>omeprazole 10mg gastroresistant tablets</td>
</tr>
<tr>
<td>C</td>
<td>not readily available</td>
<td>based on a particular proprietary product, manufacturer or supplier</td>
<td>omeprazole 20mg dispersible gastro-resistant tablets</td>
</tr>
<tr>
<td>M</td>
<td>readily available</td>
<td>based on information submitted by manufacturers</td>
<td>omeprazole 10mg or 20mg gastro-resistant capsules</td>
</tr>
</tbody>
</table>

Declaration of interests

None to declare.

Steve Chaplin is a pharmacist who specialises in writing on therapeutics.

---

www.prescriber.co.uk