Reimbursing generics in the UK: is there a better way?

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Article commissioned by Scrip Magazine.

8 Feb. 01

For years British generic suppliers were seen by the Department of Health (“DH”) and politicians as model students in the class. They supplied unbranded generic medicines in increasing quantities at low prices, and required minimal attention from government. It was widely accepted that market forces were sufficient to ensure that supply and demand were held in balance through price signals, thus ensuring that the NHS was getting good value for money.

The British way of reimbursing multi-source medicines seemed so much better than systems devised in other countries. Germany invented reference pricing in 1989 using a complex formula to determine the prices that the health funds would pay for multi-source products. The Dutch took reference pricing a stage further in 1991 when they clustered in-patent medicines with generics in setting reference prices. Other countries, notably Sweden and now France, Italy and Spain, have introduced varied approaches, but so far no EU country has copied the British system of simply leaving it all to market forces.

The British system seemed to work well, not least because it resulted in generic products coming to the market using their international non-proprietary names (“INN”). In the other countries mentioned, generic products frequently use fantasy names. This adds nothing to their therapeutic value but something to their price. Supposedly brand names for generics make it easier for doctors to write prescriptions. Certainly it makes it harder for pharmacists to substitute one generic for another generic, or indeed for an original, assuming that they are allowed to do so.

British medical students are taught to write prescriptions using the INNs even if the molecule is still in patent. This, together with continuing pressure on doctors from the DH and area health authorities for “rational” prescribing, has raised the percentage of prescriptions dispensed as generics. In 1999 in England 66 per cent of prescription items

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1 Ian Senior is a special adviser in the London office of National Economic Research Associates (NERA). The views expressed in this article are his own. They develop a paper that he gave to a Management Forum conference on “The reimbursement of generic medicines in the UK and Europe”, London 16 November 2000. He wishes to thank his colleagues John Dodgson and Edward Bramley-Harker for most helpful comments on the draft.
were written generically and 48 per cent were dispensed as generics. The remaining 18 per cent were dispensed as branded originals because they were still in patent.2

Everything seemed fine, yet out of the blue 1999 was the year that the system appeared to fail. Shortages of some lines of generics occurred, their prices went up sharply and there were reports of hoarding in the distribution chain. Politicians reacted swiftly. The House of Commons’ Health Committee produced a report, “The cost and availability of generic drugs to the NHS”3. It concluded among other things that “We are not convinced that market manipulation, hoarding and collusion are limited to the short-line wholesalers”, and it recommended that the OFT should investigate the system.

In parallel the DH hired the consultancy OXERA in 1999 to carry out a “fundamental review” of the market and the causes of the turbulence. The report has not been published but the DH has stated that a factual summary will be made available at some date in the future.4 However the government made references to being “ripped off” and further action was inevitable. After hurried consultation with the suppliers, the government imposed price caps on a significant number of generic lines and said it would review the situation in 2001. Unsurprisingly, the concept of price capping was resisted by generic suppliers who pointed out that there had been no complaints about the system over the period 1994-1998 when the prices of the top 65 generic products had fallen in real terms by about 15 per cent.5

But did the system fail in 1999; and if so why did it fail and could failure recur? In the remainder of this article I shall argue that the market failure, if any, was not that perceived by the government, but rather that the flaws lay and lie in the reimbursement system itself.

The generic market is a cluster of mini-commodity markets

The generic market has often been described as a “commodity market”. This is inexact. A commodity market is one in which the item being traded — say copper or cocoa — is nearly or completely homogenous. Two copper bars, if of the same purity, are perfect substitutes for each other. The differences between cocoa from different sources are much less important than the similarities. Commodity suppliers therefore compete very largely on price, with peripheral forms of competition taking the form of speed of delivery or credit terms.

About 40 world commodities are traded in London and other exchanges ranging from various metals, through energy, pulp and paper to lean hogs and pork bellies. By contrast in the UK there are about 1,500 generic lines derived from perhaps one quarter that number of

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5 Health Committee report, op cit, p44
active ingredients. Unlike traditional commodities, generic products cannot move freely across borders even within the EU because of strict licensing laws imposed by national authorities. Marketing authorisations of course can be obtained, but this takes time. Packaging, the number of pills per pack, patient information leaflets and trade dress all form impediments to cross-border trade.

Within a national market such as the UK, medicines with the same active ingredient and strength should therapeutically be perfect substitutes for each other, but once a doctor has written a prescription for one active ingredient, they are completely non-substitutable for those with different active ingredients. Therefore each group of generic products with the same active ingredient constitutes a mini-commodity market. The British generics market as a whole is a cluster of mini-commodity markets. This fact is the key to understanding what occurred in 1999.

What triggered the turbulence of 1999?

In 1999 three separate events happened at the same time:

- Regent, a UK based supplier with a 10 per cent share of the market, was closed down following a factory inspection;
- the supply of generic medicines to pharmacists in bulk packs was being replaced unsystematically by the supply of the same medicines in individual patient packs; and
- two major UK-based suppliers of generics were in the process of transferring production abroad.

In all commodity markets, supply and demand are brought into balance by the mechanism of price. Prices are set by what the market will bear. This is exactly how generic mini-commodity markets work in the UK and 1999 was no exception. However, because each mini-commodity market is small, quite sharp fluctuations of price can and do occur even in non-turbulent times.

The difference between indexed price fluctuations in traditional commodity markets and generic market is seen in Figures 1 and 2. In Figure 1 it took nearly two years for the price of maize to double before falling back. Price changes in the other commodities were less bumpy.

By contrast, consider the indexed price movements of three generics in 1998, a normal year. The price of captopril halved and the price of amoxycillin increased to 164 in December, both with bumps along the way. The price of thyroxine remained steady for the first four months, rose briefly to about 127 in August, fell to 49 in October, and finished the year at 90. In 1999 the fluctuations were much more pronounced.
Figure 1. Quarterly changes in six world commodity prices, 1994-1997

Changes in quarterly six different commodity prices 1994-97

Figure 2. Monthly changes in ex-supplier prices of three generics, 1998 – 2000

Source: NERA from data supplied by BGMA members
The shortages of products in 1999 caused by the three events noted above had the inevitable result of increasing generics’ prices. However, these in turn were fuelled unintentionally by an aspect of the reimbursement system itself.

For many years the DH had a system known as Category D. This allowed any generic medicine that was found (temporarily) to be in short supply to be placed in Category D of the monthly Drug Tariff and to be reimbursed at the price of the branded original. The result in 1999 was that pharmacists who could buy stocks of generics listed in Category D had them reimbursed by the NHS at branded prices several times higher. Faced with shortages on the one hand and the potential for windfall profits on the other, pharmacies increased their orders.

The same opportunities were exploited by short-line wholesalers too. They bought extra stocks in a rising market firstly to ensure continuity of supply but also in the expectation of being able to stock-pile and sell at greater profit later. In commodity markets these practices are normal and fully accepted as a way that enables market to clear. They are commonly described as “taking a view”. Unfortunately the politicians simply failed to notice that the generic mini-commodity markets were working in an entirely predictable way.

Yet despite the market turbulence in 1999 which was amplified by the Category D system, the market itself did not fail. The vast bulk of generically written scrips were filled with generic products. Rising prices (which fell back later) were a sign of the market working, not failing.

**Deep flaws in the current reimbursement system**

The prices at which pharmacists are reimbursed by the NHS for the generics they dispense are published monthly by the DH in the Drug Tariff. These prices are based on the price lists of three “manufacturers” and two wholesalers. A weighting system is then applied which, whatever its original concept may have been, has no rational basis today. The prices used to calculate Drug Tariff prices are taken from printed price lists, which are always significantly higher than transaction prices.

The result is that the prices at which pharmacies are reimbursed by the NHS leave a large discount in pharmacists’ pockets. To “claw back” these discounts, the DH has an annual survey based on a sample of 350 pharmacies, which generate about 200 usable responses. The inherent flaw in the discount survey is that it is based on comparing the wholesalers’ list prices, and not transaction prices, with those of the Drug Tariff. Yet substantial discounts below list prices are normal at wholesaler level. Thus, the discount survey does not claw back the full amount of discounts but leaves the balance with pharmacists or the wholesalers who own pharmacy chains.

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6 Many products sold by “manufacturers” are actually bought in from other sources including imports
A better system for reimbursing generic medicines

Even if the discount survey was perfect and was able to claw back the full discounts on generic medicines from the distribution system, the fundamental question remains: why put excessive public cash into the system in the first place only to claw it back a year later?

A more practical system would be the following. Each month, every supplier of generic medicines would submit electronically to the DH or to a trusted third party a statement of the volumes of every line sold and the total sales value. The latter would take account of discounts below list price and is standard, essential management information that all generic suppliers have. Any generics company that does not know on a monthly basis (if not weekly) its sales volume and value will not remain in business long.

The data would be submitted in a defined electronic template so that collating the results of the 1,500 lines across the industry’s suppliers would be extremely simple. The result would be the real average ex-supplier prices of each line for the previous month. To each price thus calculated would be added a mark-up of a suitable amount for the wholesaling function. The resulting prices would be published electronically on a web-site and would be available within, say, two days of the end of each month. These would be the new reimbursement prices. The paper-based Drug Tariff would become redundant.

Punctual returns would be critical, so the DH could apply a rule that the products of any supplier that did not submit a return on time would not be reimbursable in the following month.

The attractions of the system are clear and significant. The NHS would reimburse generic medicines at real market prices. If there were shortages for any reason, suppliers would increase their prices in a given month according to market forces. Next month, higher prices would be reflected in higher reimbursement prices to pharmacists, and vice versa. Thus market forces would prevail and direct intervention by government on prices could and should be abandoned.

Would it be possible for suppliers to cheat the system, say, by colluding to put in inflated data and thus drive up the pharmacy reimbursement prices? Though this is theoretically possible, it would constitute a breach of competition law for which heavy fines are already available.

If just one supplier acted alone to submit inflated data, that firm would be unlikely to benefit. Wholesalers would continue to shop around among the several suppliers for each generic line and would choose the cheapest, as at present. Thus, the dishonest supplier would still have to offer at the going market price. Benefit from the inflated reimbursement

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7 This system was devised by a team of consultants in NERA’s London office
price would accrue to the distribution chain and to pharmacies but not to the dishonest supplier. Dishonesty, therefore, would not pay.

**Estimating the leakage of public cash into the distribution system**

There is wide agreement in the DH, generic suppliers and elsewhere that leakage of public cash into the distribution system occurs. Quantifying the leakage is less easy. The following table sets out two estimates.

The total net ingredient cost of all medicines in England that is paid to community pharmacies in 1999 was £5,026m. Of this the DH’s published figure ascribes 18 per cent to generics. The Pharmaceutical Services Negotiating Committee (“PSNC”) believes that the figure in 1999 was “between 12 per cent and 13 per cent”. Estimate 1 uses a figure of 12 per cent and Estimate 2 uses 18 per cent.8

These alternative estimates of £603 million and £905 million provide a range from which to estimate the total sum reimbursed to pharmacists by the NHS for generics.

Some of this is clawed back. The PSNC has estimated the claw-back on “pure generics” as “close to £157.9m”. This figure relates to the PSNC’s estimate that generics accounted for 12 per cent of total net ingredient costs, and so this figure is used in Estimate 1. In Estimate 2 the figure for the claw-back is increased by 50 per cent to £237 million to allow for the DH’s figure that generics account for 18 per cent rather than 12 per cent of total medicine costs.

We need now to estimate what pharmacists actually pay for generics. To do this we take a figure derived from data from BGMA’s members for sales of generics to the UK in 1999. From this we have an estimate of £286 million for generics supplied in England at ex-supplier prices.

To this we add an estimate to cover wholesalers’ mark-ups. I believe that a mark-up of 25 per cent is appropriate for generics. In the case of in-patent branded products, the wholesaler’s mark-up is about six per cent. The sale price of branded medicines is about 4.2 times higher than generics, but the operations needed to store, break bulk and deliver generics to pharmacies are much the same as for brands, so a higher mark-up is needed. A mark-up of 25 per cent represents our estimate of what an efficient wholesaler may require to distribute generics.

The leakage (£87 million in the case of Estimate 1) is therefore calculated as:

8 The PSNC considers that the difference between their figure and that of DH is explained by branded medicines sold under “brand equalisation schemes” plus parallel imported generics and proprietaries that have been (wrongly) classified as generics.
• The amount actually reimbursed to pharmacists on the basis of the Drug Tariff (£603 million in the case of Estimate 1);

• **minus** the estimated ex-supplier cost of generics including the mark up required by wholesalers (£286 million plus £72 million in the case of Estimate 1);

• **minus** the estimated claw back (£158 million in the case of Estimate 1).

In Estimate 2 we use the same method but start from the DH’s figure that generics account for 18 per cent of the total NIC. This means that generics including price-equalised brands etc are £905m. We increase the figures for the supply of generic, for wholesalers’ mark-up and for claw-back pro-rata.

The calculations give a range of estimates of the leakage, between around £90 million to £131 million, but even the lower figure can be considered a significant loss of public money. With better data the figures could be made more robust.

**Table. Two estimates of cash leakage into the distribution system (wholesalers and pharmacies), England 1999**

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<tr>
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<th>Estimate 1</th>
<th>Estimate 2</th>
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<tr>
<td>Total net ingredient cost reimbursed to community pharmacies</td>
<td>£5,026</td>
<td>£5,026</td>
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<tr>
<td>of which either 12% or 18% are generic dispensings</td>
<td>603</td>
<td>905</td>
</tr>
<tr>
<td>Generics supplied, ex-supplier prices</td>
<td>286</td>
<td>430</td>
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<tr>
<td>Estimated wholesalers’ required markup of 25%</td>
<td>72</td>
<td>107</td>
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<tr>
<td>Surplus remaining in distribution</td>
<td>245</td>
<td>368</td>
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<tr>
<td>Claw-back</td>
<td>158</td>
<td>237</td>
</tr>
<tr>
<td>Cash leakage remaining in distribution (wholesalers and pharmacies)</td>
<td>87</td>
<td>131</td>
</tr>
</tbody>
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**Sources and notes**
2. Estimate 1 uses PSNC’s figure of 12%, private communication, 2 Feb 2001. Estimate 2 uses DH’s published figure of 18%.
3. Author’s estimate from BGMA members’ data
4. Author’s estimate, see text
5. From above figures
6. Estimate 1 from PSNC private communication, 2 February 2001. Estimate 2, see text

**Conclusion**

Against a backdrop of a flawed claw-back system producing a significant leakage of public funds into distribution, the system of reimbursing generics developed by NERA has much to commend it. It would be transparent and fair to all parties. It would reinstate market forces in place of price caps as the means of ensuring the supply of generics to the NHS at competitive prices. It would enable the mini-commodity markets to continue to work. Not least, it would, at a stroke, eliminate the large and meaningless discounts that currently occur in the distribution system.
Under NERA’s system, suppliers of generic medicines in the UK could return to favour for what they are, namely suppliers of large volumes of cost-effective medicines to the NHS.

2830 words