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MANUFACTURE, DISTRIBUTION AND REIMBURSEMENT OF GENERIC MEDICINES IN THE UK

Report for the British Generic Manufacturers Association

Prepared by NERA

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EXECUTIVE SUMMARY

Terms of reference

On 23 March 2000 NERA was retained by the British Generics Manufacturers' Association ("BGMA") to advise on the fundamental review of the generic medicines market currently being undertaken by Oxford Economic Research Associates ("OXERA") on behalf of the Department of Health ("DH"). In particular, we were asked to consider whether the current system for reimbursing generic medicines was satisfactory from an economic point of view and, if not, to assess alternative systems.

Method

We reviewed the report of the House of Commons Health Committee, "The cost and availability of generic drugs to the NHS"[1], and other background material provided by BGMA. We then prepared a set of detailed headings for use as postal questionnaires or at personal interviews with generic manufacturers/suppliers, wholesalers (full-line and short-line), retail pharmacists and the Pharmaceutical Services Negotiating Committee ("PSNC"). Interviews were obtained with selected manufacturers/suppliers, all of whom were members of BGMA, with selected short-line wholesalers, the PSNC and with an authoritative pharmacist. They took place in April. Interviews were sought with major full-line wholesalers and with chain pharmacies but were not obtained.

Data were collected from BGMA members. In order to contain compliance costs, these consisted of the data already provided to OXERA. However, whereas the latter asked for data only for the period May – December 1999, NERA asked for the same data sets going back to January 1998 and forward to March 2000. We felt that this was necessary to avoid the risks of analysing seven exceptional months in isolation of normal trading conditions.

This report was drafted in May and submitted to BGMA on 19 May 2000.

Conclusions

Chapter 1. Background issues

Between generic products with the same active ingredient substitutability is very high, possibly perfect. Between those with different active ingredients, substitutability is zero at pharmacy level. Within the first group generics display many of the features of commodity markets. However, because the total generics market consists of 1,500 presentations it would be wrong to describe it in general as a single commodity market.

Patient demand for most generics is quite stable, but demand at individual manufacturer level is volatile.

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Chapter 2 Market entry

For existing manufacturers, the barriers to obtaining a market authorisation ("MA") and bringing new products to market are not large and do not act as a significant barrier to entry. Barriers are more significant if a manufacturer is the first supplier of a particular generic and encounters patent difficulties, or if there are data exclusivity problems. After the first generic entrant to the market, entry by followers does not seem problematic.

Within existing facilities, provided there is spare capacity or flexibility to adjust the mix of production, the capital costs of manufacturing a new product are relatively modest. A switch to manufacturing a product that has been made in the factory before can be undertaken within 12 – 24 hours providing materials are available. Under these circumstances, entry barriers are not high.

Chapter 3 Production

Generics plants have considerable flexibility in their production possibilities providing there is suitable equipment and know-how to produce the required lines. The costs of switching are not a major impediment, but it is clear that if the market becomes turbulent, as happened in 1999, the costs of frequent switching to chase short-term market shortages result in less efficient production. If changes to the system for reimbursing generic medicines had the effect of reducing market instability and hence the frequency of switching production, there would be efficiency gains in manufacture that could be shared with distributors and the NHS.

Chapter 4 Pricing

Price is the overriding form of competition in the supply of generics. Printed price lists are still prominent in the market but more as promotional material than the basis of transactions. The rapidly increasing sophistication of suppliers and wholesalers in maintaining electronic databases of transaction prices in a real-time market mean that the supplier-to-wholesaler sector has many characteristics of a dispersed electronic exchange. It is possible that within a year or two printed price lists at this level will be redundant.

Drug Tariff prices, being based on printed price lists, bear little relationship to transaction prices.

Chapter 5 Distribution

Distribution is done partly by suppliers as well as by full-line and short-line wholesalers. Boots, as a self-distributor is a special case, but there is also vertical integration between some major wholesalers and the pharmacies they own. All suppliers and wholesalers give discounts in order to win business. Some give loyalty rebates in addition. Discounts at

[1] The Stationery Office, printed 9 December 1999.

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each level of the chain mainly reflect the purchasing power of individual firms. Higher stock turn combined with far fewer lines enable short-line wholesalers to offer bigger discounts.

The market has developed naturally in this way in the UK and constitutes a level playing field because no statutory obligation exists for wholesalers to carry a full range of medicines.

Some short-liner wholesalers are also grey-market traders who in 1999 exploited the opportunities offered by the Category D system.

Chapter 6 Dispensers

For community pharmacists the differences between reimbursement prices and market prices provide scope to benefit financially from movements in these prices. Some pharmacists who entered the grey market in 1999 are now having to sell surplus stock at low prices.

In the hospital sector, medicines are generally procured and financed directly by NHS Trusts through contracts with manufacturers. The pricing strategy of generics in this market depends on their desire to be included on hospital formularies and on the pricing strategy of the branded equivalents. The use of formularies and contracts places hospitals in a strong position to purchase at low prices. There is little scope for hospitals to speculate on prospective changes in market prices, and the incentive is for stockholdings to be small, allowing stock to be used up if better prices become available.

Dispensing doctors obtain discounts on generics and branded medicines alike, which are clawed back by the DH. We have not studied this part of the system.

Chapter 7 Reimbursement: the current system

The current system for defining reimbursement prices for generic medicines and reimbursing pharmacists has worked uncontroversially for a number of years but there are inherent weaknesses. In particular there is scope for reducing disparities between list prices and the prices at which medicines are actually traded. This tightening could eliminate the need for recouping discounts through the claw-back mechanism.

The process for calculating the Drug Tariff's reimbursement prices appears to have little justification. The current system allows a small number of suppliers to have considerable influence over the determination of reimbursement prices. This influence is present even if the suppliers are only minor players in the supply of an individual product. These suppliers' stock levels are also influential in determining Category D entries, even though they may not have provided an accurate snapshot of supply in the market for the lines in question.

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The Discount Inquiry has recouped significant sums of money for the NHS. This shows that the levels of discounts given to pharmacies are large, but does not necessarily imply that the claw-back effectively recoups all discounts.

The structure of the clawback may disadvantage independent pharmacies relative to the larger chain pharmacies.

Chapter 8 The events of 1999

Given that the submarkets for generic medicines with the same active ingredient have the characteristics of commodity markets, sudden price increases are as normal as reductions. They are a market clearing mechanism and not a "rip-off". However, the large quantities of public money that lie in the distribution system waiting to be clawed back may increase instability in the market.

The events of 1999 — the closure or Regent, the transfer of production abroad by two major generic manufacturers and the change-over to patient packs — produced temporary shortages in a number of generic lines. The existence of Category D exacerbated the resultant price increases and offered attractive opportunities for grey market speculative trading. Despite this, patients seldom if at all were kept waiting for the prescribed medicines, which mainly were still generic products.

Some grey market traders made additional profits in 1999, but they may see these offset in 2000 as they try to unload their remaining stock at almost any price.

The events of 1999 did not represent a breakdown of the market, but rather the impact of unusual events coupled with a flawed reimbursement system.

Chapter 9 Review of alternative reimbursement systems

We review the following possible alternative reimbursement systems and discuss what we see as the merits and demerits of each system:

- co-operation between the generics supply industry;
- tendering;
- profit control;
- reimbursement prices based on manufacturers' average selling prices;
- reference pricing;
- direct price controls; and
- RPI-X.

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Some of the systems described above have clear merits and demerits compared with the existing scheme for reimbursing generics in the UK. The current system, in NERA's judgement, is seriously flawed and should be revised.

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1. BACKGROUND ISSUES

1.1. Defining a Market for Generics

The production of generic medicines in the UK consists of several hundred products (about 1,500 lines) which are characterised by highly varying degrees of substitutability between them.

- In most cases, where different manufacturers produce the same presentation (defined by e.g. strength, dosage route) of the same molecule, the products can be regarded as perfectly substitutable.
- Substitution between different presentations of the same molecule, or between different molecules of similar therapeutic effect is more difficult, requiring different prescriptions, but may be plausible at GP level.
- Substitution between molecules with significantly differing therapeutic effects is generally not possible.

Thus, although certain generic medicines may be interchangeable at will, the degree of differentiation between many products is such that the market for generic medicines could not be considered to be a single market on the demand side of the market.

On the other hand, the supply characteristics of the industry are such that it does seem sensible to talk about a "market for generics". Although technical factors make some forms of production switching impossible (e.g. a production line used for penicillin - containing products cannot subsequently be used for non-penicillin - containing products) in general production capacity can be switched to make a range of products using the same equipment. Although such changes are not costless, they do allow quite a high degree of supply side flexibility, which is explored in more detail in Chapter 3.

1.2. Why Have Economic Regulation in the Medicines Market?

Governments impose price or expenditure controls of various forms on medicines in the great majority of countries. In the case of branded medicines, this may partly be because patents offer their holders a degree of market power. More generally, sources of market failure in the market for medicines include:

- the fact that patients are often relatively uninformed about which medicines are suitable treatments for them;
- much of the cost of prescription medicines is met by the government, with patients paying a copayment unrelated to the price of the medicine. This offers few incentives for patients to seek lower priced treatments or make rational trade-offs between price and quality.

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As a response to these concerns, governments generally choose to intervene in the market for medicines. However, the need for different levels of such regulation depends crucially on the way in which the market is structured in an individual country. Where generic medicines are concerned, the close substitutability of products from different suppliers can reduce the need for interventionist regulation if the market is structured appropriately. This report considers ways of reforming the market for generic medicines in the UK, notably the reimbursement mechanism.

1.3. Are Generics a Commodity Market?

Generic medicines are often referred to as a commodity, and the generic medicines market as a commodity market. In our view there are similarities between generic medicines, and other markets commonly referred to as commodity markets.

We define a commodity market as one in which quality issues are unimportant and there is minimal scope for product differentiation. The result is a market in which a single market price is established. Such markets are likely to be characterised by significant amounts of price volatility, since any imbalance in supply and demand needs to be immediately reflected in market prices rather than absorbed in suppliers' pricing strategies.

The interchangeability of products from different suppliers at dispensing level is likely to make price differentiation difficult, and suggests that generic medicines have many of the normal characteristics of a commodity market. This does not imply that quality issues are unimportant for generic medicines. Rather, it reflects that product regulation imposes a high level of standardisation of product quality. This is similar to a number of other commodity markets, particularly exchange-traded commodities such as metals. While the physical commodity can take different forms or grades, the exchange-traded product is precisely defined.

Commodity markets are often characterised by speculative trading behaviour that is facilitated by high levels of product standardisation, and possibilities to buy, store and resell the commodity at issue. Since most, although not all, generic medicines can be stored fairly readily there is scope for such behaviour in the generic medicines market.

1.4. Volatility in Demand, Supply and Prices

1.4.1. Demand

When discussing volatility of supply and demand for generics, it is important to distinguish volatility at the level of the individual supplier compared to the industry as a whole. In general, respondents to our survey suggested that generics were not subject to strongly seasonal or fluctuating demand. There were exceptions, such as antibiotics whose use may display seasonal fluctuations. However, in general volatility of demand at pharmacy level was not viewed as an important issue.

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The situation from the perspective of an individual manufacturer, however, is different. Manufacturers reported extremely high variations in sales by month, with some months having orders that may be several hundred per cent above the annual average. This is consistent with the view that generics are traded in a commodity market, where we would expect a manufacturer with a price just below its competitors to secure additional sales very quickly. It is also consistent with the stockpiling of products in the distribution chain, between manufacturers and patients.

1.4.2. Supply

Increasing the supply of generic medicines can be difficult, with manufacturers facing a number of potential bottlenecks, including:

- sourcing active pharmaceutical ingredients ("APIs") or other raw materials;
- manufacturing capacity; and
- packaging capacity.

Respondents generally told us that they operated near capacity, and hence that it would be difficult to increase total output quickly, although there may be scope to increase production of a single product line significantly by reallocating capacity. At the level of a single line, the need to source additional APIs was seen as the most significant difficulty. There can be a lead time of 2-4 months in sourcing APIs. Sourcing other materials (e.g. packaging materials) is usually quicker. Various respondents suggested that production of a single product might be increased by 20 per cent over a month, but could perhaps be doubled over a six month period. Such estimates are subject to considerable uncertainty.

Increases in overall production must overcome the above difficulties, and also depend on the overall manufacturing capacity of the plant. If that plant (or individual components) are near capacity expanding output is difficult, although there could be scope for subcontracting some processes (e.g. packaging). Even if there is scope to increase production (e.g. operate a third shift) this requires investment such as hiring and training staff, so manufacturers must be confident that increased demand will persist before they make such commitments.

1.4.3. Ex-factory prices

Pricing and marketing strategies by generic manufacturers vary, for example, in the pricing discretion permitted to sales forces and the use of strategies such as retrospective rebates. A number of points seem common to most manufacturers, however:

- prices are frequently reviewed, probably on at least a monthly basis, as well as whenever significant events affect the market;

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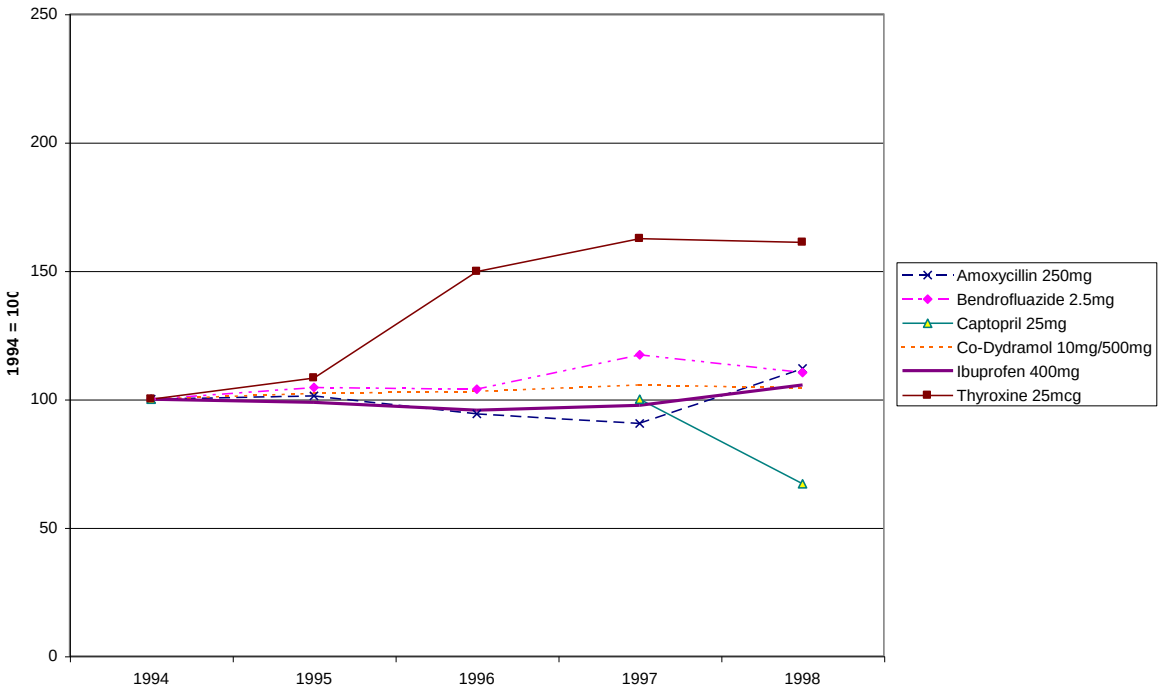
- prices are subject to significant volatility, as described in the charts below. High levels of volatility in pricing are a feature of many commodity markets, as also shown in the charts in Chapters 3 and 8; and
- the events of 1999 saw substantial changes in prices of some products. The market situation in 1999 is discussed more fully in Chapter 8. However, we note at this stage that large price movements are not unprecedented. The distinguishing characteristic of the market in 1999 was rather the number of products affected.

Figure 1.1
Changes in Price of Six Selected Generic Product Prices 1994-98 (NIC Per Item)



Source: Department of Health, Statistics Division 1E, Prescription Cost Analysis system

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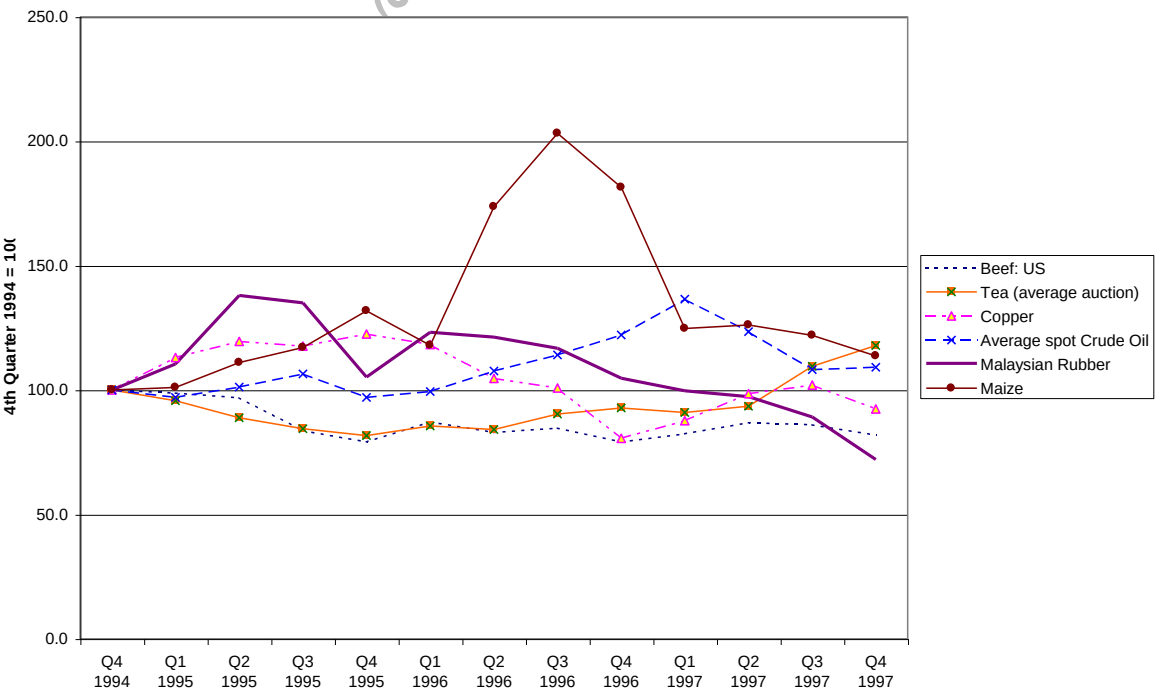
Figure 1.2
Quarterly Changes in Six Commodity Prices 1994-97



Source: The World Bank Pink Sheet <http://www.worldbank.org/html/ieccp/pink.html>

1.5. Conclusions

Between products with the same active ingredient substitutability between generics is very high, possibly perfect. Between those with different active ingredients, substitutability is zero at least at pharmacy level. Within the first group generics display many of the features of commodity markets. However, because the total generics market consists of 1,500 presentations it would be wrong to describe it in general as a single commodity market.

Patient demand for most generics is quite stable, but demand at individual manufacturer level is volatile. It is difficult for supply to be significantly expanded in the very short term, as it can be hard to source materials. In the medium term it may be possible to expand production of a single product significantly, but it is more difficult to increase overall output.

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2. MARKET ENTRY

In this chapter, we provide an overview of the costs and barriers associated with bringing a generic medicine to market in the UK. Barriers can manifest themselves in a number of ways, including the costs of obtaining a marketing authorisation ("MA"), fighting patent litigation, capital costs and accessing raw materials. We discuss these and others below.

2.1. Product Licensing

Before a manufacturer can market a generic medicine in the UK, it must obtain a marketing authorisation from the Medicines Control Agency ("MCA"). The purpose of this is to demonstrate that a generic medicine is "essentially similar" to its branded equivalent and to satisfy the MCA that the product will be manufactured to the necessary quality and safety standards.

Many manufacturers hold MAs for products that they do not manufacture themselves (i.e. products that they buy in from other suppliers). The MA names the manufacturer(s) of the finished product and any intermediates involved in the manufacturing process.[2] The MA identifies the role of each agent in the manufacturing process (e.g. manufacturer(s) are X and Y, sterilisation is completed at site Z). Responsibility for ensuring the end quality of a product rests with the MA holder.

Obtaining an MA can entail a significant financial cost but the direct costs of the MCA's fees are relatively small compared with the other costs. For example, the MCA's fees for considering an abridged product licence application currently range from £1,795 (for an abridged simple application) to £17,955 (for an abridged complex application). In addition to obtaining an initial MA, it has to be renewed every five years.

The bulk of the costs in obtaining an MA are incurred in acquiring the information and data to support an application. The costs of conducting bio-equivalence studies vary considerably depending on the nature of the product. Estimates from our interviews suggest that a minimum cost is around £40,000, but that costs in excess of £0.5 million can occur for medicines with complicated release profiles.

It takes, on average, around 12 months to obtain an MA from the MCA (ranging from 6 to 18 months, depending on the product). This is more than the time reported by the MCA which relates only to the time to consider an application and excludes time spent queuing before an application is assessed. The time between obtaining an MA and selling a generic medicine in commercial quantities varies from immediately to around three months. If manufacture takes place in a country where patent protection is weak, manufacturers are able to begin manufacturing a product for sale in the UK before patent expiry and before obtaining the MA.

[2] To manufacture a product, a manufacturer's licence is required but this is separate from the MA.

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Generally, the time and costs of obtaining an MA are not seen as a major impediment to supplying generic medicines to the UK market. More significant barriers to entry can be the costs associated with patent litigation and data exclusivity requirements, which we discuss below.

2.2. Importance of R&D and Know-How

A widely held view is that very little R&D is associated with manufacturing generic medicines. In practice, the amount of R&D and know-how required to manufacture a generic medicine is product specific.

It is common for manufacturers of branded medicines to have a number of patents that relate to one chemical entity – this process is sometimes termed "rafting". Thus, there can be a patent relating to the actual molecule, patents covering the manufacturing process and so forth. When the patent relating specifically to the molecule expires, generic equivalents can then be manufactured without infringing the original patent. However, if the original patent is surrounded by supplementary patents then generic manufacturers have to develop manufacturing processes that do not infringe these supplementary patents. The research and development costs involved in this can be significant and our interviews suggested that expenditures on R&D are around five per cent of turnover on generic medicines.

2.3. Litigation Costs and Data Exclusivity

The majority of generic manufacturers avoid litigation surrounding patent protection issues. However, the larger generic manufacturers have been involved in patent litigation whilst trying to bring generic medicines to market once the branded equivalent has come off patent. The cost of patent litigation is high (we heard estimates of £1m) and may be a significant deterrent in some instances to bringing a generic to market. Even where the generic manufacturer is successful, we understand that only around 70 per cent of its litigation costs are recovered. Examples of medicines that have been subject to litigation include zopiclone, co-amoxiclav and cimetidine.

Currently, there are no instances of generic manufacturers pooling resources to fight patent litigation. Hence the costs are borne by one manufacturer (inevitably one of the larger manufacturers) even though the litigation may make it possible for other generic manufacturers to enter the market freely.

Data exclusivity rules can also act as a barrier to bringing generic medicines to market. When a branded medicine applies for an MA, the data used to support the application receive an exclusivity period during which they cannot be accessed by third parties to support subsequent MA applications by generic copies. In most of the EU, this period of data exclusivity is six years and in the UK it is 10 years. In the UK, there have been instances where the manufacturer of a branded medicine has withdrawn a product from market prior to the expiry of this exclusivity period, replacing it with a variation of the original product.

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This prevents generic manufacturers from accessing and using information from the original MA to support MA applications for a generic equivalent and provides another 10 years of data exclusivity for the re-launched product.

Applying for an MA for a generic copy during the period of data exclusivity, or without access to the original data, would require the applicant to undertake all the clinical trials and other testing required to support the MA of the original branded medicine. The costs of doing this would be an insuperable barrier to market entry.

2.4. Capital Costs of Producing a New Product

The capital costs associated with manufacturing a new generic product within an existing facility vary. If the product can be manufactured using existing production lines (i.e. there is capacity to vary production mix to accommodate new products) then the costs are moderate because most parts of the manufacturing process are not product specific. Within an existing facility, additional capital costs are those associated with tooling (for pressing the tablets and giving them identification) and packaging them into blisters. Orders of magnitude for these costs are £5,000 for compression tooling and £20,000-35,000 for blister tooling. These tools are product specific and so represent a minimum cost associated with manufacturing a new product.

Capital costs are inevitably higher if the production of a new product cannot be undertaken within existing facilities. For example, new tablet coating machinery can cost around £0.5million and a blister packing line costs in excess of £1million. If investment in a whole new production line is required, the costs can be over £4million. We discuss this in more detail in Chapter 3.

2.5. Suppliers of Active Pharmaceutical Ingredients

Data concerning the supply of APIs are limited. Within the EU, the main producers of APIs are based in Italy and in Spain (API manufacture has historically been sited where patent protection is weakest). Other west European countries with significant producers of APIs include France. Outside the EU, India, Hungary and Israel are the main sources of APIs. For medicines marketed in the UK, the APIs must come from a source approved by the MCA and whilst we understand that these are generally more expensive than non-approved sources, this does not seem to create supply difficulties.

During our research we have not identified any instances where generic manufacturers have had problems obtaining APIs. Sourcing APIs does have a significant lead time (one to four months) and there can be seasonal fluctuations depending on the specific source of the APIs. Lead times can be longer for controlled products. Prices of APIs have been reasonably stable over time and do not vary much between suppliers (except for differences between MCA approved and non-approved sources).

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By way of an illustration, Table 2.1 summarises the sources of APIs for six big selling products. The data are drawn from an informed industry source and provide an indication of the number and location of manufacturers of APIs.

Table 2.1
Number of Sources of APIs for Six Products

	Number of Sources			
Active ingredient	**UK**	**Europe**	**Other**	**MCA Approved (where known)**
Amoxycillin		11	54 (Far East), 9 (RoW)	10–12
Bendrofluazide		1		
Captopril			12 (Far East), 12 (RoW)	5
Co-dydramol	1	3	2	
Ibuprofen			23 (Far East)	10
Thyroxine		4	1	

Source: an interviewee

2.6. Average Number of Competitors for Each Medicine

It is rare for there to be only one manufacturer (or MA holder) of a generic medicine in the UK. Interviews with manufacturers suggested that there are usually four or more manufacturers of a specific product and it is not uncommon for this figure to be much higher (in excess of 10 manufacturers).

For some products, however, there are recognised market leaders. For these products, the lead manufacturer has a significant market share (perhaps in excess of 40 per cent) and its price acts as a benchmark for other manufacturers. Examples of products with a recognised market leader include atenolol (CP Pharma), bendrofluazide (Cox), trimethoprim (APS), inhalers (Norton), lofepramine (Generics UK) and amiodarone (Sterwin).

For the six products in Table 2.1, we have obtained data from five manufacturers about their sales volumes, based on monthly data between May and December of 1999. There may be other sources of supply to the market for the products listed so the data should not be taken as representative of the whole market.[3] However, the data provide an indication of the volatility of market share and the number of suppliers. The data in Table 2.2 show the maximum market share of any one manufacturer in a given month (measured by volume). The number of manufacturers in our sample supplying the market in a month is shown in parenthesis.

[3] We know that at least two significant manufacturers who are not in our sample.

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The data are problematic because some manufacturers were transferring production from bulk packs to patient packs at this time. Hence, we have excluded data for May and June for amoxycillin and bendrofluazide because most manufacturers were transferring from bulk to patient packs.

Table 2.2
Maximum Market Share and Number of Suppliers for Selected Products, May-Dec 1998

Product	May	June	July	Aug	Sept	Oct	Nov	Dec
Amoxycillin 250mg	-	-	44% (4)	50% (4)	53% (4)	41% (4)	32% (4)	46% (4)
Bendrofluazide 2.5mg	-	-	53% (2)	65% (3)	49% (3)	59% (3)	65% (3)	73% (3)
Captopril 25mg	44% (4)	42% (4)	44% (4)	34% (4)	36% (4)	48% (4)	64% (4)	40% (4)
Ibuprofen 400mg	38% (5)	39% (5)	48% (5)	43% (5)	30% (5)	41% (5)	41% (4)	58% (4)

Source: NERA

On the basis of the products listed above, typically four out of our sample of five manufacturers were supplying each product, although for some products there may be fewer sources of supply. For products with four or more suppliers, one manufacturer typically had a relatively high market share (around 40 to 50 per cent) with other suppliers making up the rest of the market.

Bearing in mind that these data do not necessarily cover all suppliers (we have data only for five suppliers), generally there looks to be a significant number of suppliers for the products listed. Market shares in the Table can look high, but as significant suppliers are missing from our sample these market shares represent an upper bound.[4]

2.7. Conclusions

For existing manufacturers, generally the barriers to obtaining an MA and bringing a product to market are not large and would not act as a significant barrier to entry. Barriers are more significant if, for example, a manufacturer is the first supplier of a particular generic and encounters patent difficulties, or if there are data exclusivity problems. But beyond the initial period of patent expiration and being the first generic entrant, market entry does not seem problematic.

Within existing facilities, provided there is spare capacity or flexibility to adjust the mix of production, the capital costs of manufacturing a new product are relatively modest. Under these circumstances, entry barriers are not high. However, if plant and facilities are working at full capacity and substantial capital investment is required then barriers to increasing production are more significant.

[4] This is true unless one of the suppliers missing from our sample is by far the dominant supplier of a particular product. As far as we are aware this is not the case.

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3. PRODUCTION

This chapter relates solely to the operations of generic suppliers who manufacture some finished products themselves. As noted previously, manufacturers also buy in many lines ready-made, sometimes already in their own livery. These, formally, are purchasing decisions and are not considered below.

3.1. Factors Influencing Production Decisions

Data on production and prices were provided by some members of BGMA and are reproduced graphically in Chapter 8 where we describe the events of 1999 and how that year compared with 1998. In the present chapter we draw on the more qualitative information that was obtained from generic manufacturers at interview.

In general (and unsurprisingly) manufacturers decide the products to make, the quantities and the timing that maximise profits. However, they freely admit that rapidly changing prices even at normal times and the ability of competitors to switch production of particular lines quickly mean that planning production beyond a horizon of three months is barely practicable. While overall demand for particular product lines is predictable, in most cases with only moderate seasonal variations such as for antibiotics in winter, supply variations and competitors' price changes mean that sales by volume and value may diverge by 25 per cent from company forecasts made three months earlier.

One constraint on what a generics plant can make is that a plant that makes antibiotics cannot be used for any other form of medicine. However, other plants have considerable flexibility in what they can produce, as discussed below.

The cost of APIs is significant and accounts for 30 - 70 per cent of production costs, so there is an incentive to minimise the stock of APIs held. However, as noted in the previous chapter, the lead-time for obtaining them is in the range of one to four months. This can be a primary constraint in production planning.

The commercial justification for accepting short planning horizons is that production volumes of individual products can be increased quite quickly if needed. One respondent gave us the following estimates as to by how much the volume of an existing line can be increased within given time spans.

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Table 3.1
Possible Production Increases of an Existing Line

Time period, months	Possible increase in volume compared with production in the previous period, per cent
1	25
3	50
6	100
12	200

Source: a major generic manufacturer

Although production volumes can be increased quite quickly orders must be delivered much more quickly than production can be increased, typically within a week. This means that stock holding must lie in a range of one to three months.

The costs of adding new capacity are variable. For example, equipment for granulation/drying and with solvent recovery costs about £1.5m; a blister packing line £1m; compression £500,000; coating equipment £500,000 and so on. Installing such equipment therefore represents long-term planning rather than meeting the short-term needs of the market.

3.2. Switching Between Product Lines

When a manufacturer has the know-how to make a particular line, switching production takes hours or days rather than weeks. Two respondents told us that changing packaging requires about 5-15 hours and changing the APIs about 14-16 hours. The length of production run needed to justify switching lines is less than a week, typically 3-4 days. In cash terms, the cost of outage from switching may be around £80,000 for changing a product and £12,000 for changing packaging.

3.3. Stocks

Stockholding levels in the industry depend on a number of factors. The most important of these is likely to be the strength of customer demand. In an industry where orders are volatile and difficult to predict, levels of stockholding are driven predominantly by customer orders. In particular, manufacturers face the potential for sudden demands for large amounts of stock, and can easily be cleaned out. The volatility of some stocks is shown in Figure 3.1.

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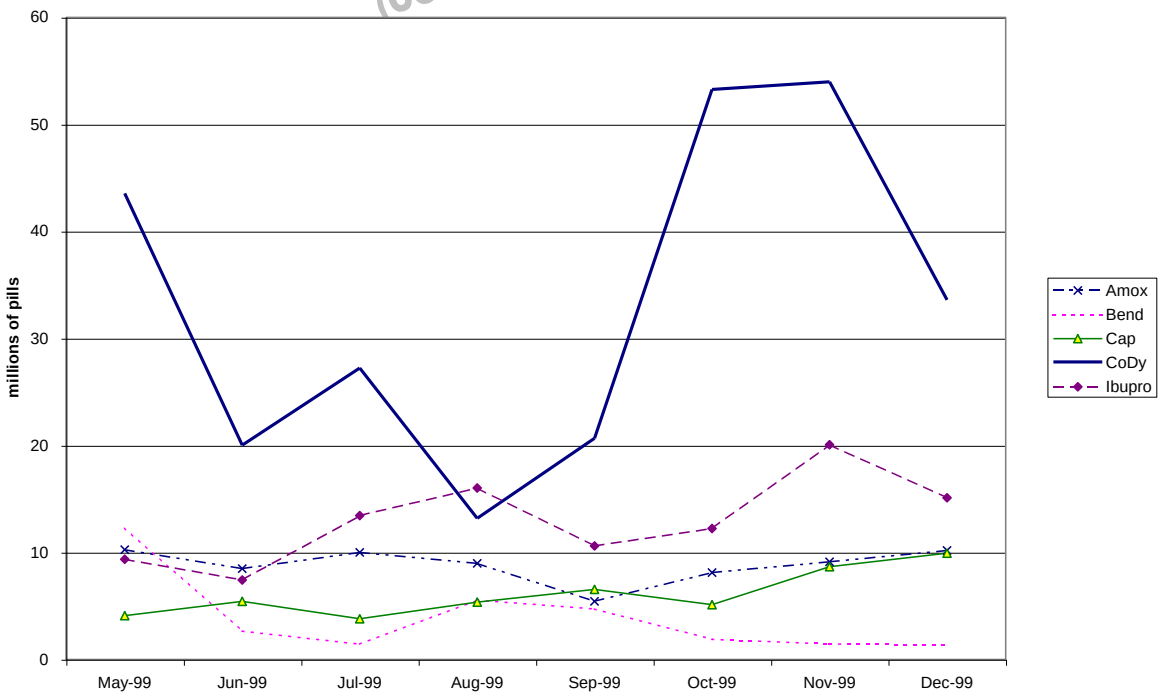
Figure 3.1
Absolute Stock Holdings of Six Generic Pharmaceuticals by Five BGMA Members in 1999



Source: BGMA members' data

Discussions with manufacturers suggested the following points:

- manufacturers often aim to keep about three months stock. Some of this may be stored as finished product and some as unpacked bulk;
- manufacturers may aim for lower stock levels for products that they manufacture themselves, compared with the stock levels they seek for products that they buy in;
- current and expected prices may play some role in stockholding decisions. For example, a company may be reluctant to sell bought-in stock at a loss if there is a price fall, especially if they believe prices may rise in the future. However, a more common approach is to sell current stocks and exit that market. Shelf times make it difficult for manufacturers to hold stock for long; and
- the move to patient packs requires significant extra space for storage.

3.3.1. Stock sharing between companies

The concept of stock sharing between generics companies has been raised in the recent debate. Such stock sharing may take place at different levels.

Generic "manufacturers" frequently buy in products rather than manufacturing them themselves. This usually (although not uniquely) happens when the firm holds a marketing

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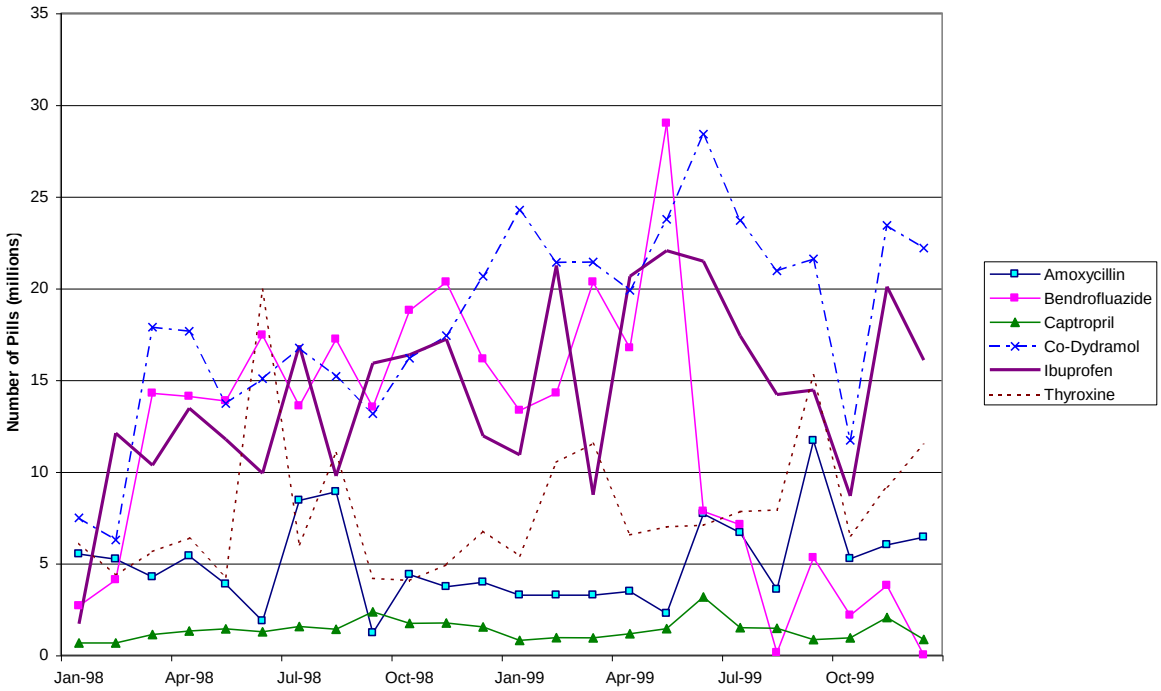
authorisation for the product concerned, which they then market under their own licence. This practice is common in the industry. Indeed, there are firms who hold product licences and market generic medicines that have no production capacity of their own.

Exceptionally, during the recent market shortages, there was stock sharing in the sense of one company acquiring stock in the livery of a competitor and dispensing it against its own orders. We understand that this happened rarely and was a response to the exceptionally tight supply situation. Usually, bought-in stocks are repackaged in a firm's own livery.

3.4. Volatility

As described in chapter 1.4, sales at manufacturer level are far more volatile than final customer demand, which is relatively stable for most products.

Figure 3.2
Total number of Pills Sold by Manufacturers Each Month



Source: BGMA members' data

3.5. Long-Term Supply Contracts

Contracts in the industry differ substantially, both between firms and according to the type of customer that a firm is dealing with.

Hospitals are usually supplied on the basis of long term contracts, which generally are competitively tendered. These may stipulate a price and may run for a period of years

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varying between contracts, although there may be provision for the contract to be ended by either party on a notice period of a few months. Hospital contracts usually contain penalty clauses, and if a manufacturer is unable to supply the hospital it will have to pay the difference between the contracted price and the price at which the hospital secures an alternative supply, which could be the full price of the branded equivalent.

Long-term supply contracts with non-hospital customers are rare, although they may account for some business with large customers. In general, since generic manufacturers face a small number of customers that offer access to large elements of the market, manufacturers are in a weak position in terms of enforcing contractual rights. In the event of a dispute, a manufacturer might back away from enforcement action for fear of losing future sales to an important customer.

Most generics business is transacted on the basis of individual orders, for which a price is negotiated at the time the order is placed. (Some but not all manufacturers utilise back order systems when they are out of stock of an item.) Sales are usually made on a firm basis, with the exception of some new products, but powerful customers may be able to pressurise manufacturers into accepting stock returns (e.g. if price movements have been unfavourable).

3.6. Conclusions

Generics plants have considerable flexibility in their production possibilities providing there is suitable equipment and know-how to produce the required lines. This enables manufacturers to respond to the market rapidly. The costs of switching in terms of outage at around £80,000 are not a major impediment, but it is clear that if the market becomes turbulent, as happened in 1999, the costs of frequent switching to chase short-term shortages in the market result in less efficient production. Rising prices may justify manufacturers in more frequent switching and shorter production runs, which in turn absorb some of the additional margin provided by the higher prices.

NERA concludes that if changes to the system for reimbursing generic medicines had the effect of reducing market instability and hence the frequency of switching production, there would be efficiency gains in manufacture that could be shared with distributors and the NHS.

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4. PRICING

4.1. Price Lists

Manufacturers and wholesalers publish printed price lists, typically monthly, but these do not reflect the prices at which transactions occur. The lists' real function appears to be to inform customers of new lines on offer and particular discounts. Wholesalers and the more technically advanced pharmacies keep their own electronic databases of suppliers' list prices together with the transaction prices that they are achieving. One respondent gave us a print - out from such a database. For the more common products 6 – 10 suppliers are listed, and with substantial price differences. For example, in April 2000 the price of the cheapest supplier of amoxycillin 250mg 21s was listed at one half the price of the most expensive supplier.

It was made clear to us that no transaction would take place at the highest price. The market clears by wholesalers ringing round the listed suppliers and playing them off against each other until bargains are made. In this context the possession of up to the minute information is the key to successful purchasing by wholesalers. Suppliers learn quickly through their tele-sales teams what prices are being offered by competitors. Though the prices in question are second-hand information quoted by parties who have an interest in driving prices down, the final proof to suppliers of whether their prices are competitive or not lies in whether they are making sales and the resultant level of their stocks. If a line is moving faster than normal and stock levels are correspondingly low, suppliers increase its price, and vice versa.

At pharmacy level the system is replicated but in a less sophisticated way. We were told that some small pharmacy chains with perhaps 5-10 branches keep databases in order to compare prices to the penny. More traditional pharmacies receive a stream of special offers by telephone, fax or post and make mental price comparisons for the better known lines.

4.2. Discounts

Since the active ingredients of generics are uniform and the quality of the source of supply is the responsibility of the MCA, discounts, availability and speed of delivery are the three forms of competition. Full-line wholesalers deliver to pharmacies twice daily and the larger short-liners do so also, at least for pharmacies within a certain radius of their warehouses. Short-line wholesalers who carry fewer lines — perhaps as few as 100 — deliver less frequently. Thus pharmacies make a trade-off between price and speed of delivery.

Since the final price of a generic product is the most important form of competition, discounts come in various ways. NERA identified three forms of discount.

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4.2.1. Transaction discounts

Some discounts are printed in suppliers' and wholesalers' sales lists but, as noted, even these are indicative only and negotiation is normal at the time of the transaction. Transaction discounts derive from purchasers' bargaining power and their knowledge of what is happening in the market. They do not appear to be formally volume related, but clearly customers with large buying power get better discounts than independent single pharmacies.

4.2.2. Loyalty rebates

Manufacturers and wholesalers give loyalty rebates to customers, typically at the end of six months or a year. These are based on the value of purchases during the period and are non-negotiable since in large measure they reflect the trading results of the suppliers.

4.2.3. Brand equalisation rebates

British doctors are trained and encouraged by the DH to write prescriptions generically. These are reimbursed by the PPA at Drug Tariff prices which are usually well below those of branded originals. In general, therefore, pharmacists fill generically written prescriptions with generic products.

To recapture lost market share some branded manufacturers have collaborated with the full-line wholesaler Unichem, trading as Pharmacy Alliance, to produce a "brand equalisation formulary". The April 2000 list contains about 300 lines of brand name products and indicates those that may be substituted for generic prescriptions and also for parallel imports. No prices are shown. Pharmacies place orders with Pharmacy Alliance and use the originals supplied as *reverse substitutes* for prescriptions written generically. They are reimbursed by the PPA at the Drug Tariff price and at the end of each month pharmacists receive a rebate from Pharmacy Alliance. The rebate is not negotiable.

The attraction to the branded manufacturers of the scheme is that they make some sales at Drug Tariff prices on prescriptions that otherwise would have been filled generically. The attraction to pharmacies is that they get rebates that, although outside their power of negotiation, are evidently attractive enough to compete with the discounts offered by wholesalers on generics. In addition, they gain goodwill from customers who do not wish to see changes in packaging, the information leaflet and appearance of the tablet depending on which particular generic the pharmacy has in stock at the time.

4.3. Comparison of the Prices of Selected Generic Medicines

As noted, the list and transaction prices of generic medicines vary considerably at different time periods even in normal years. In Table 4.1 we show examples of different list prices that were gathered in April 2000. A comparison between them and the Drug Tariff is

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illuminating. To enable comparison, prices are expressed as £s per pill, with the figures after the decimal point being pennies.

In the columns we see the Drug Tariff price, a full-line wholesaler's "promotional" list price, a specialist generic wholesaler's list price and a short-line wholesaler's "daily offer" price. The next column shows the ratio of the lowest of the prices divided by the Drug Tariff price, giving a range of 0.21 to 0.42. Using these ratios, the amount of money that must be clawed back by the DH's annual discount survey can be estimated.

Since we do not know the average transaction prices, for estimation purposes we take the specialist generic short-line wholesaler's list price as a proxy. For the eight lines concerned the amount to be clawed back is £27.2m out of an NIC of £48.5m, or 56 per cent.

4.4. Conclusions

Price is the overriding form of competition in the supply of generics. Printed price lists are still prominent in the market but more as promotional material than the basis of transactions. Indeed, the rapidly increasing sophistication of suppliers and wholesalers in maintaining electronic databases of transactional prices in a real-time market mean that the supplier-to-wholesaler sector is in effect a dispersed electronic exchange. It is possible that within a year or two printed price lists at this level will be redundant.

The fact that printed price lists are a poor indication of transaction prices means that Drug Tariff prices, being based on printed price lists, bear little relationship to transaction prices.

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Table 4.1
Comparison of Price per Tablet, Selected Generic Medicines, April 2000

						Price of						
				Specialist		cheapest						
			A full-liner's	generic		tablet divided	Total NIC	Estimated				
	Number	Drug tariff	"promotional	wholesaler's	A short-liner's	Drug Tariff	cost, England	surplus to be				
	per pack	price	list price"	list price	"daily offer"	price	1998	clawed back				
		£	£	£	£	Ratio	£m	£m	Notes			
Amoxycillin caps 250mg	500		45.71	24.5								
- price per tablet			**0.09**	**0.05**								
Amoxycillin caps 250mg	100				3.50							
- price per tablet					**0.04**	**0.35**						
Amoxycillin caps 250mg	21	2.13										
- price per tablet		**0.10**							Assume the average price per tablet			
							6.01	**3.05**	paid by pharmacists was £0.05			
Amoxycillin caps 500mg	21	2.75		1.95								
- price per tablet		**0.13**		**0.09**								
Amoxycillin caps 500mg	100	17.88	17.90	6.35	5.00							
- price per tablet		**0.18**	**0.18**	**0.06**	**0.05**	**0.28**			Assume the average price per tablet			
							2.74	**1.82**	paid by pharmacists is £0.06			
Cimetidine 400mg tab	60	16.12	17.15	5.9	3.40							
- price per tablet		**0.27**	**0.29**	**0.10**	**0.06**	**0.21**			Assume the average price per tablet			
							10.14	**6.37**	paid by pharmacists is £0.10			
Diclofenac sodium tabs 25mg	100	3.56	3.50	2.35	1.50							
- price per tablet		**0.04**	**0.04**	**0.02**	**0.02**	**0.42**			Assume the average price per tablet			
							1.35	**0.59**	paid by pharmacists is £0.02			
Diclofenac sodium tabs 50mg	100	6.58	6.40	3.21	1.69							
- price per tablet		**0.07**	**0.06**	**0.03**	**0.02**	**0.26**			Assume the average price per tablet			
							28.28	**15.39**	paid by pharmacists is £0.03			
TOTALS							**48.52**	**27.21**				

Source: NERA

5. DISTRIBUTION

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5.1. Overview

The functions of production, supply and distribution of generic medicines are somewhat blurred.

The manufacture of generic medicines begins with the production of the active pharmaceutical ingredients ("APIs"). This is a specialist process that is capital intensive, may entail anything from five to fifteeen technical steps. It is commonly undertaken by specialist producers located outside the UK who are independent of the makers of finished generic medicines. The latter buy APIs, add excipients, convert the APIs into dosage form, pack the units (which may be tablets, capsules or other presentations), add a patient information leaflet if the final presentation is in individual patient packs, and sell to wholesalers and others.

In the UK, there are three forms of wholesaler: full-line, short-line and Boots. The latter is sometimes described as a self-distributor. Full-line wholesalers stock virtually every medicinal product, both prescription and generic, that is to be found in the British National Formulary ("BNF"). By contrast, short-line wholesalers (who are not permitted in some EU member states), stock a much smaller selection, chosen for commercial reasons and focussing on those products with high demand and quick turnover.

At retail (or dispensing) level, there are independent pharmacies, chain pharmacies, hospitals and dispensing doctors. The latter are found mainly in rural areas.

Though this general structure is clear, blurring between functions occurs for the reasons discussed below.

British "manufacturers" of generic medicines frequently contract out the manufacture of particular lines. Two members of the British Generic Manufacturers' Association buy in all their product lines, making no medicines at all. To this extent, they are carrying out a marketing rather than a manufacturing function. Other manufacturers buy in a range of products ready made in their own livery to complement those that they make in-house.

Manufacturers who make and market finished products and suppliers who buy them do so by virtue of possessing a marketing authorisation for the products concerned. This is obtained by applying to the Medicines Control Agency, submitting documentation and samples, and having the MCA inspect the production facilities including those of the APIs supplier. In some cases generic manufacturers need to fight patent litigation against the manufacturers of the original brand. An MA, therefore, is a potentially valuable asset that determines the owner's right to market the product, whether by manufacturing it, buying it in or both. The distinction between the two functions therefore is blurred, as shown in Figure 5.1.

Suppliers sell to full-line and short-line wholesalers, to pharmacy chains, hospitals and also direct to independent pharmacies. Only dispensing doctors are not among their customers. From the figure it can be seen that the role of manufacture/supply is partly blurred with that of distribution direct to retailer.

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An additional function of "grey market" trading sometimes occurs at short-line wholesaler and at pharmacy level. We define "grey market trading" in this context as meaning the buying and selling of stocks of medicines specifically in anticipation of exceptional price changes with the intention of realising speculative profits. Grey market trading, thus defined, entails hoarding for profit rather than distributing or dispensing at a normal rhythm and as a normal service.

Figure 5.1
Production and Distribution of Generic Medicines

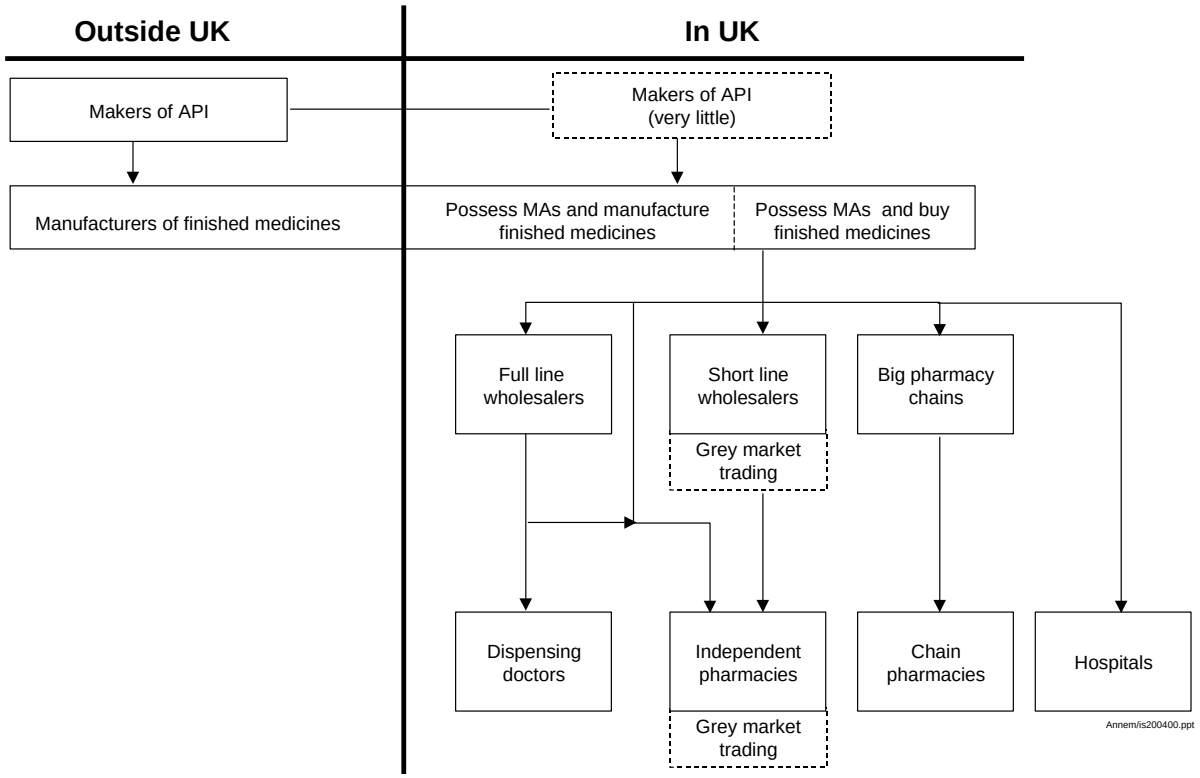

Figure 5.2
Distribution Routes for Five BGMA Members

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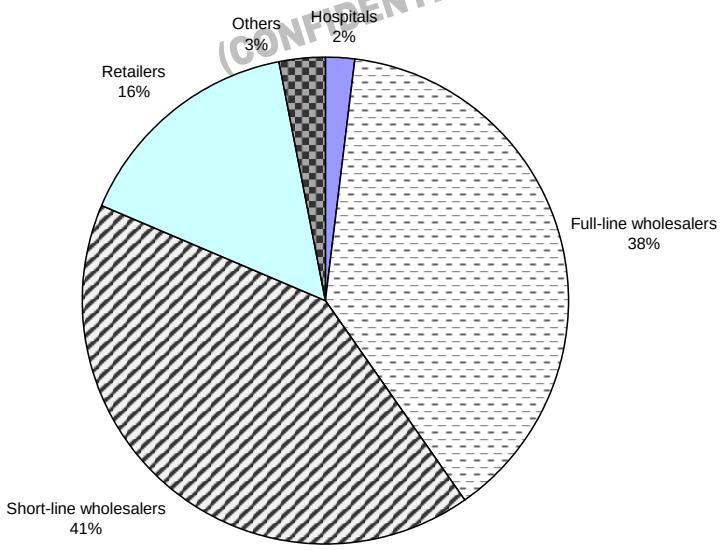

Source: BGMA members' questionnaire responses

Figure 5.2 shows the distribution routes for the products of some BGMA members. We see that wholesalers are the most important distribution route for these companies, with sales roughly evenly divided between short-line and full-line wholesalers. Sales direct to retailers (including major chain pharmacy and small independent pharmacy) account for a substantial minority of sales, and is a much more significant distribution route for some firms. Sales to hospitals are a small proportion of the business of each of the manufacturers.

5.2. Full-Line Wholesalers

Full-line wholesalers carry a comprehensive stock of prescription and non-prescription medicines. They deliver twice a day and supply community pharmacists, hospitals and dispensing doctors. There are 16 full-line wholesalers, all of whom are members of the British Association of Pharmaceutical Wholesalers ("BAPW"), and they provide 80 per cent of the medicines used in the UK. They appear to regard their function as one of social service rather than being purely commercial because three quarters of the lines held are non-profit making.[5]

5.3. Short-Line Wholesalers

As their name implies, short-line wholesalers hold only a selection of the faster moving stocks. They can enter and leave the market for a particular line quickly. Their wholesaler's

[5] Memorandum by the BAPW to the Commons' Health Committee, p19.

licence permits them to buy from any supplier that has an MA for the product concerned. Some, but not all, give delivery at least every working day, and probably a small minority give delivery twice a day, thus competing in this respect with full-liners.

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We do not know the number of short-line wholesalers and they do not have a trade association to provide such information. We believe that there may be 20-40 short-liners and according to the BAPW they account for eight per cent of the market.

Short-liners have a comparatively small number of lines on offer — typically 100-500. This compares with a total of 1,500 lines that BGMA members provide.[6] It is easy to see that the logistics of handling fewer, fast-selling lines allow for economies that can be shared with customers through discounts. In Table 4.1 we showed examples of two short-liners' list prices that lay well below those of a full-liner. While it must be remembered that list prices are indicative only, they support what we were consistently told, namely that short-liners undercut the prices of full-liners.

Because short-liners are specialists in a limited range of products, they can and do "take views" on future price movements. The point at which taking a view becomes "speculation and hoarding" is grey. However, we found hard evidence that in 1999 some short-liners bought speculatively on lines that were transferred to Category D status. We were shown faxes from such firms that in April 2000 were now offering such products at give-away prices, evidently to unwind the positions they had taken. Some of the firms stated the stock volumes they held, which were substantial.

5.4. "Parallel Importers"

Parallel imports ("PIs") are products, normally still in-patent, that are imported into the UK by firms who obtain special licences — PL(PI)s — to do so. In-patent products, and hence most PIs, lie outside the scope of this report, but we point out that leading short-line wholesalers offer PIs as well. While, as noted, there is no trade association for short-liners, for a decade or more there has been a trade association of parallel importers. Originally called the Association of Pharmaceutical Importers, the association has recently changed its name to the British Association of European Pharmaceutical Distributors ("BAEPD"). Over the years this association has generally had about 10-12 members of leading parallel importers.

BAEPD members deal mainly in PIs and generics, but in some circumstances they also offer direct-route (i.e. non-imported) branded originals under what are known as equalisation deals. These occur when branded manufacturers, wishing to reduce the volume of PIs of their product, sell direct to BAEPD members at the price that the latter would pay for PIs.

It is clear to NERA that the role of BAEPD members overlaps that of short-line wholesalers.

[6] Memorandum by the BGMA to the Commons' Health Committee, p15.

5.5. Boots and Other Down-Stream Integrated Wholesalers

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The Boots chain of retail chemists accounts for about 10 per cent of the UK market for ambulatory medicines. This enables the company to buy centrally for its retail outlets, performing the wholesale function. We believe that Boots supplies only its own pharmacies.

It is worth noting, however, that there are two other examples of significant down-stream integration. Two of the largest wholesalers, AAH and Alliance Unichem own the Lloyds and Moss chains respectively. We discuss the implications of this integration later in the context of the reimbursement system (Chapter 7).

5.6. Conclusions

Distribution is done partly by suppliers as well as by full-line and short-line wholesalers. Boots, as a self-distributor is a special case, and there is also some vertical integration between some major wholesalers and pharmacies. All suppliers and wholesalers give discounts in order to win business. Some also give loyalty rebates in addition. The discounts mainly reflect the power that individual wholesalers have when buying from suppliers. Higher stock turn combined with far fewer lines enable short-liners to offer bigger discounts.

The market has developed naturally in this way in the UK and constitutes a level playing field because there is no statutory obligation, as exists in some EU countries, for wholesalers to carry a full range of medicines.

Some short-liners are also grey-market traders who in 1999 exploited the opportunities offered by the Category D system.

6. DISPENSERS

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6.1. Overview

The final part of the supply chain is the dispensing of medicines to patients. This is typically done through three routes:

- Hospital pharmacists dispense medicines for inpatients and outpatients. Medicines are funded directly by a hospital's budget, and hospitals are responsible for procuring their own medicines. Pharmacists are employed directly by hospitals and do not receive a dispensing fee for dispensing services. It is possible for out- patients to have a prescription written by a hospital prescriber dispensed in the community.
- Community pharmacists are independent contractors and are responsible for dispensing the bulk of NHS prescriptions outside the hospital sector. Most of these are written by GPs, and the pharmacist receives a dispensing fee for each item dispensed. They are responsible for ensuring continuity of supply of medicines to patients and are required to dispense medicines with reasonable promptness. They are responsible for purchasing their medicines and usually do this through wholesalers, but some source direct from suppliers.
- Dispensing doctors are GPs who are licensed to dispense medicines. They are usually located in rural areas. Dispensing doctors procure and dispense medicines in much the same way as community pharmacists.

Measured by total NHS expenditures on medicines, community pharmacists account for the largest portion of the UK market for prescribed medicines. Table 6.1 shows the total cost of medicines to the NHS for 1998 and each purchaser's share of the market. (The data relate to both branded and generic medicines and are at ex-manufacturer prices).

Table 6.1
Total UK NHS Expenditure on Pharmaceuticals at Manufacturers' Prices, 1998

	Community Pharmacies	Dispensing Doctors	Hospital	Total
Value of expenditure (£m)	£4,423	386	1,247	6,056
Market share	73.0%	6.4%	20.6%	100%

Note: The majority of expenditures for community pharmacies relate to prescriptions written by GPs and dispensed by community pharmacies. However, prescriptions written by nurses, dentists and hospital doctors are also included, provided they were dispensed in the community.

Source: OHE Compendium of Health Statistics, 11th Edition, 1999.

The hospital sector typically procures medicines through a different route to community pharmacists and dispensing doctors. The pricing strategies of manufacturers for branded and generic medicines may also differ. We turn to each of these in the following sections.

6.2. Purchasers

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6.2.1. Hospitals

Responsibility for procuring medicines in secondary care is the responsibility of individual NHS Trusts. There is no national procurement programme or centralised purchasing for hospital medicines.

Typically, each hospital operates its own formulary, which lists the medicines that its doctors and nurses are able to prescribe. The medicines included on the formulary reflect the prescribing preferences of hospital consultants and their particular specialities. The use of a formulary places the hospital in a strong position when negotiating with medicine suppliers. Medicines that are deemed too expensive can be excluded from the formulary. New medicines have to demonstrate cost effectiveness or they may be included for a trial period during which hospital consultants assess their value.

Hospital formularies include both branded and generic medicines. Branded manufacturers often supply hospitals at a low price (perhaps even at a loss). This loss-leading ensures that the branded medicine is included on the formulary and places downward pressure on generic medicine prices in the hospital sector. It has been suggested to us that branded manufacturers follow this strategy in the belief that when a patient is discharged from hospital, GPs will continue to prescribe branded medicines in the community because that prescription has been initiated by a hospital consultant. They may be reluctant to switch a patient's medication.

The combination of loss-leading and the use of formularies to limit access to the hospital sector means that generic medicine prices are invariably lower in the hospital sector than in the primary care setting.

Hospitals typically procure generic medicines direct from manufacturers rather than buy generic medicines from wholesalers. Contracts between hospitals and generic manufacturers, specifying price and supply volumes, are common and they usually run for one to three years. However, we understand that these contracts in practice are a commitment on the part of manufacturers to supply but that enforcing a commitment on the part of hospitals to buy is not normally pursued.

Compared with the wider market for generic medicines, the hospital sector is typically a small part of a manufacturer's business. As noted in Figure 5.2 our research suggests that the hospital sector on average accounts for around two per cent of manufacturer sales.

6.2.2. Community pharmacists and dispensing doctors

Community pharmacists are responsible for dispensing the bulk of prescribed medicines in the NHS. They dispense most of the medicines prescribed by GPs and receive a fee for providing this service.

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Dispensing doctors are GPs who are licensed to dispense medicines and they operate, essentially, in the same way as community pharmacists. They benefit from discounts on medicines, which are also supposed to be clawed back when their remuneration is determined. In our study, we have not investigated the role of generics in prescribing by dispensing doctors.

Community pharmacists procure their own medicines. They have a responsibility to ensure that they dispense medicines within a reasonable time period and so have to ensure that they have sufficient stock to meet demand. Independent pharmacies and small chain pharmacies usually buy their medicines direct from wholesalers (both short and full-line wholesalers) and may deal with more than one supplier. Evidence from our interviews suggests that pharmacists usually buy branded medicines from full-line wholesalers and generic medicines from short-line wholesalers. Large chain pharmacies often buy their medicines direct from manufacturers (i.e. they act as wholesalers, supplying their own stores). Our interviews suggested that independent pharmacies (i.e. less than ten pharmacies in a chain) form the bulk of sales for short line wholesalers and that chains are a smaller but still significant part of the short-liner's market.

Community pharmacists are reimbursed for the medicines they dispense. For branded medicines, pharmacists are reimbursed at the manufacturer's list price. For generic medicines, a reimbursement price is set through the Drug Tariff, which we discuss below in Chapter 7. Pharmacists are able, and have an incentive, to negotiate discounts with wholesalers and shop around to try and procure medicines at the lowest prices. The reimbursement system is structured so that any discounts pharmacists receive below the reimbursement price are supposedly "clawed back" by the DH. The intention is to ensure that the discounts do not remain with pharmacists but are returned to the NHS. We discuss the clawback mechanism in section 7.2

The clawback is intended to ensure that the average discount negotiated by pharmacists is paid back to the DH. Hence, pharmacists that negotiate better than average discounts retain some of the financial benefits of the discounts, whilst those negotiating smaller discounts lose on average. The combination of encouraging pharmacists to negotiate discounts with wholesalers and recouping these discounts is an effective way to place downward pressure on prices. This is evidenced by the value of discounts that are recouped by the DH which we understand will be around £575 million for 1999/00.[7]

Some pharmacists, particularly small chains, monitor prices of wholesalers systematically in order to obtain the best discounts. When a particularly attractive price is found there is scope for buying additional stock and selling it on to other pharmacists who have been less observant. This has given rise to a form of secondary distribution at pharmacy level, and in 1999 we found that some of the grey market traders who bought heavily into Category D products were pharmacists. One respondent for our benefit went through a pile of special

[7] This figure includes discounts on generic medicines, branded medicines and parallel imports.

offers identifying those that came from short-liners and those from grey-trading pharmacists.

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6.2.3. Primary care groups

Currently, Primary Care Groups ("PCGs") are not responsible for procuring the medicines that they prescribe (unless they contain dispensing doctors). We mention them here for completeness because in principle they could become a purchaser in the future, perhaps in a similar way to the hospital sector at the moment. They hold budgets to pay for the costs of the medicines that they prescribe and in the future could develop their own formularies to limit the prescribing of GPs within the PCG to products on the formulary.

6.3. Stocks Held

Manufacturers and wholesalers usually deliver stock to their purchasers within days of receiving an order (for in-stock items). It is common for wholesalers to provide a same-day or next day service to pharmacies, often with twice daily deliveries. Given the speed of supply through the supply chain, large stock holdings appear to be unnecessary.

We noted above that pharmacists acted as grey market traders in 1999 although evidence contained in the Health Select Committee report suggests that pharmacists do not have the capacity to do so.[8] Pharmacists do have an incentive, if they are able, to speculate on changes in prices or discounts. Although discounts are recouped, to some extent, by the Department of Health, pharmacists can benefit financially if they are able to anticipate changes in market and reimbursement prices and adjust their stock positions in response. Indeed, a pharmacist will lose financially if others are doing this and he does not because the recouping of discounts is based on average discounts, the incentive is always to do better than the average. Pharmacies are allowed to undertake some wholesaling activities within limits.

The incentives for the hospital sector to hoard stock and speculate are much less. For hospitals, the incentives are always to procure medicines at the lowest prices possible. The use of formularies and contracts are an effective way of ensuring this and the scope for speculating is removed because there is no difference between reimbursement prices and trading prices in the hospital sector (the hospital is not reimbursed by a third party). If at all, hospitals have an incentive to maintain small stockholdings to allow them to benefit fully from a switch quickly to a lower cost source of supply, if one becomes available.

[8] For example, Mr Dove of the PSNC states that "our pharmacies do not have elastic walls, the possibility of hoarding, certainly at the pharmacy level is very low" (page 24, para 59).

6.4. Conclusions

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Differences between reimbursement prices and market prices provide scope for community pharmacists to benefit financially from movements in these prices. Some entered the grey market in 1999 and are now having to sell surplus stock at low prices. In the hospital sector, medicines are generally procured and financed directly by NHS Trusts through contracts with manufacturers.

The pricing strategy of generics in this market depends on their desire to be included on hospital formularies and whether they wish to compete with the branded equivalents. The use of formularies and contracts places hospitals in a strong position to purchase at low prices. There is little scope for hospitals to speculate against changes in market prices and the incentive is for stockholdings to be small to allow stock to be used up if better prices become available.

7. REIMBURSEMENT: THE CURRENT SYSTEM

NERA REPORT (CONFIDENTIAL TO BGMA MEMBERS)

7.1. The Drug Tariff

The Department of Health has recently issued proposals for setting maximum reimbursement prices for generic medicines. These proposals are in response to the market instability and price rises that we discuss in Chapter 8. The generics suppliers are currently being consulted on these proposals which include a statutory price control scheme and the abolition of Category D (see below). The one month consultation period will end on 24th May 2000.[9]

The discussion in this section examines the incentives and operation of the reimbursement mechanisms for generic medicines as they currently stand.

7.1.1. Overview of the Drug Tariff

Community pharmacists are reimbursed for the medicines they dispense based on dispensing fees set by the DH. The system for fixing the reimbursement prices of generic medicines dispensed in primary care is known as the "Drug Tariff". Part VIII of the Drug Tariff lists the reimbursement price for all generic medicines. Reimbursement prices depend on the category in which a medicine is placed. The five categories are as follows:

- **Category A** contains generic medicines that are readily available. The reimbursement price is based on the list prices of a basket of suppliers. The basket consists of three manufacturers (Norton, APS and Cox) and two full-line wholesalers (AAH and Unichem). The basket suppliers used in the calculation do not change from product to product. The basket price is a weighted average of the suppliers' list prices, with manufacturers' prices each receiving a weight of one and wholesalers' prices each receiving a weight of two. For a medicine to be placed in Category A and the reimbursement level to be set in this way, the number of weights in the basket calculation must equal at least four. In other words, to be placed in Category A, a generic medicine must be available from either at least one of the wholesalers and two manufacturers, or both of the wholesalers. Reimbursement price are updated monthly.

- **Category B** contains generic medicines whose usage has declined over time and so no longer are readily available to qualify for Category A. The reimbursement price is based on the list price of one of four suppliers. There is a "batting order" for determining which supplier's price becomes the reimbursement price.

- **Category C** contains products that are not readily available as generics at the time, but whose usage is expected to increase. For example, it may list a branded product

[9] Department of Health (2000) *Consultation on a proposal to set maximum prices for sale of generic medicines to community pharmacies and dispensing doctors*.

that is coming off-patent, and as generics enter the market it ensures a rapid inclusion in the Drug Tariff. As supply picks up, the product would be expected to move to Category A. Products in this category are based on the prices of a particular manufacturer (e.g. of the branded product until the generic becomes available).

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- **Category D,** which the government is proposing to abolish, contained products that pharmacists could not readily source at the Drug Tariff price, which is usually the Category A price. When a product was placed in Category D, the pharmacist was able to endorse the prescription and dispense any equivalent version of the medicine, including the branded equivalent, and to be fully reimbursed for the price of that medicine. By allowing higher reimbursement levels, Category D was intended to ensure continuity of supply of generics to the market and encourage supply when there were shortages of a medicine at the Drug Tariff price. There were agreed definitions for determining whether a medicine was genuinely in short supply (see below).

- **Category E** contains extemporaneous products (i.e. those that are made up from other products). The Drug Tariff lists separate fees for these products.

The usual process for placing a medicine in Category D was that pharmacists reported to the Pharmaceutical Services Negotiating Committee ("PSNC") that they were experiencing difficulties obtaining a medicine at the tariff price. The PSNC then contacted the five suppliers that form the basket price calculations (for Category A medicines). If both the wholesalers or one wholesaler and two manufacturers declared that they had a stock shortage (defined as less than four weeks of stock – this was subsequently reduced to two weeks) then the PSNC contacted the PPA. The Prescription Pricing Authority ("PPA") then contacted the basket suppliers to confirm that there were shortages of stock at the tariff price and, if this was confirmed, the product was placed in Category D. Once placed in Category D, the pharmacist was reimbursed the actual price of the medicine dispensed rather than the generic (Drug Tariff) price.

Category D status was reviewed periodically (usually once a month) by the DH/PPA and when shortages eased, a product was moved out of Category D.

7.1.2. Weaknesses of the Drug Tariff and Category D

Although the Drug Tariff appears to have worked adequately for a number of years and has been seen as an effective mechanism for securing generic medicines for the NHS at a reasonable cost, there were a number of inherent weakness.

- The basket (reimbursement) price for a medicine was determined by the combined prices of three manufacturers and two full-line wholesalers. The suppliers used in the basket calculation did not vary from product to product. Hence they may have been only minor suppliers for a particular product but dominated the market in terms of setting the reimbursement price. Similarly, where the suppliers dominated

the market, there was considerable scope for influencing reimbursement prices with little reason for price moderation.

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- The weightings used to calculate the basket price (one for each manufacturer and two for each wholesaler) had no particular basis. Further, there was no clear rationale for combining wholesale and ex-manufacturer prices in this way.

- The Drug Tariff sets reimbursement prices on the basis of list prices of suppliers. But, as discussed in earlier chapters, the generic medicine market does not operate on list prices and large discounts are common. List prices could be described as indicators only. Trade rarely takes place at them and discounts are routinely expected. As shown in Table 4.1 this leaves scope for large differences between list and actual prices. Given that list prices are the basis for reimbursement prices there is clearly scope for significant cash to be held in the supply chain in the form of discounts which may or may not be recouped effectively.

- At a more macro level, a significant divergence between list prices and the costs finally incurred by the NHS may be a barrier to the cost-effective use of resources. GPs are encouraged to prescribe cost effectively basing prescribing decisions on reimbursement prices, but because these diverge from the true costs to the NHS the information may be misleading and give rise to a sub-optimal use of resources.

Although Category D was intended to be a solution to market shortages at the Drug Tariff price, its workings were problematic. For example:

- Category D status, in principle, could be triggered or influenced by manufacturers and wholesalers. This gave suppliers scope to manipulate the market.

- The mechanism for determining Category D status involved confirming stock levels with the basket suppliers. However, these suppliers may have been minor players in the market for the product in question so a review of their stock levels may not accurately have reflected supply in the market. Where the basket suppliers are minor suppliers, it left scope for other suppliers (who were excluded from stock checking) to manipulate the market, for example by hoarding to engineer a shortage.

- Once in Category D, suppliers were free to raise their prices at will. Pharmacists are keen to secure the highest discounts available so they had an incentive to buy from the supplier offering the largest discount (who was likely to be a supplier with high prices and so had considerable scope for discounting). Even if a portion of discounts were recouped (see Section 7.2), this was not an effective way to ensure good value for the NHS.

7.2. The Discount Inquiry and Clawback

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7.2.1. Overview

As discussed above, the Drug Tariff is used to determine reimbursement levels for generic medicines dispensed by community pharmacists and dispensing doctors, based on manufacturer and wholesaler list prices. However, these prices do not reflect the prices at which generic medicines are traded in the market. Manufacturers and wholesalers deviate significantly from list prices and offer discounts both point of sale and retrospective discounts to downstream buyers. Hence there can be large differences between Drug Tariff reimbursement levels and the final price paid by the pharmacist for a medicine.

In an effort to recoup the discounts obtained through the supply chain, the Department of Health conducts a Discount Inquiry once a year (although a year was omitted in 1999). An implied level of discounts on generics is imputed by comparing the price lists of generic suppliers with Drug Tariff prices. Pharmacists are also asked about retrospective discounts.

The Discount Inquiry is based on a survey of 350 pharmacies. The survey sample is selected at random, although it is stratified to be representative of pharmacy size and ownership. The information is collected through a standard form and ten per cent of responses are audited against copy invoices. Data are collected for one month, usually April, which is believed to be representative of the year. Pharmacies are informed towards to the end of that month that they have been selected for the survey. Out of the 350 pharmacies surveyed, around 200 useable responses are received. This is reported by the PSNC to be enough for the sample to be statistically robust. Non-useable responses are usually from small pharmacies (due to the workload involved) and from one major chain that invoices its branches at full retail prices (i.e. offers them zero discount).

The Discount Inquiry is based only on a sample of products. We understand that if one of the products is in Category D at the time of the survey, it is dropped from the sample and replaced with another.[10]

Combining the information received from the Discount Inquiry, the DH estimates the average level of discounts on reimbursement prices received by pharmacists. This discount is a weighted average discount across all medicines, not just generics. To recoup these discounts, the DH reduces the reimbursement price published in the Drug Tariff by a percentage that is fixed for a year for each pharmacy. This fixed percentage is termed the "clawback". The clawback is based on the most recent Discount Inquiry and hence is always a year out of date. When a pharmacist dispenses a generic medicine, the actual payment received from the PPA excluding dispensing fees is the reimbursement price less the clawback. The size of the clawback depends on prescription turnover in pharmacies measured as the monthly value of medicines dispensed. Smaller pharmacies with low

[10] However, in principle it would be possible to have a specific Discount Inquiry if it was felt that the main inquiry had not picked up all significant discounts.

turnovers have a smaller clawback than larger ones. Pharmacies that are part of a chain are treated as individual pharmacies for the purposes of these calculations.

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The sums of money recouped through the clawback are considerable. In 1999/00 we understand that the total value of the clawback will be around £575 million. This relates to all medicines, not just generics. Information in the April edition of the Drug Tariff indicates that the average clawback in a medium to large pharmacy is around 12 or 13 per cent of the value of prescriptions.

Whether clawbacks of this order of magnitude reflect the true level of discounts received by pharmacists is less clear. There are indications that a significant portion of discounts are not being recouped by the NHS (i.e. a portion remains in the supply chain). For example, comparing the total reimbursement cost of generics to the NHS (around £700 million) to the estimated turnover of the UK generics industry (approximately £350 million), around £350 million in discounts remain in the supply chain. Approximately £170 million are clawed back through the Discount Inquiry in relatin to generics. On this basis, around £180 million are left in the distribution/pharmacy network.[11]

NERA's own calculations are consistent with these and suggest discounts in the distribution and pharmacy network can account for around 50 per cent of the reimbursement price. (See Table 4.1).

7.2.2. Weaknesses

A number of difficulties are apparent with the workings of the current clawback. For example:

- for generic medicines, the estimates of the average discount are based on a comparison of the list prices of generic suppliers with Drug Tariff reimbursement prices. However, discounts on list prices, both at the manufacturer and wholesaler level are the norm. These types of discounts are not picked up by the Discount Inquiry and remain in the supply chain.
- products that enter Category D were usually excluded from the Discount Inquiry. Hence some of the highest discounts received by pharmacists may have been excluded from the sample. In a typical year when the number of products in Category D is small (and usually low volume), this may not have been significant, but in the context of the events of last year the discounts missed in the clawback may have been significant.
- the Discount Inquiry appears to work in the favour of chain and vertically integrated pharmacies. For the purposes of calculating the clawback, pharmacies are treated as individual units, even if part of a chain. However, chain pharmacies are likely to be able to use their buying power to secure larger discounts than independent

[11] The data for this calculation are drawn from an informed industry source and NERA's estimates.

pharmacies. Because the clawback is fixed at the average discount (for a particular pharmacy size), independents who lack buying power lose relative to the average clawback whilst chain pharmacies gain.

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- the Discount Inquiry may not adequately reflect discounting within vertically integrated pharmacies. Some chain pharmacies undertake their own wholesaling and two major full-line wholesalers own chain pharmacies. In principle, the vertically integrated chain as a whole benefits financially if their pharmacies are supplied at reimbursement prices (i.e. zero discount) because it would reduce the total size of the clawback. Effectively, discounts are being kept at the wholesaler level.

7.3. Conclusions

The current system for defining reimbursement prices for generic medicines and reimbursing pharmacists has worked uncontroversially for a number of years but there are a number of fundamental weaknesses, described above. In particular there is scope for tightening the reimbursement mechanism to reduce disparities between list prices and the prices at which medicines are actually traded. This tightening would have reduce the need for recouping discounts through the clawback mechanism.

The current system also allows a small number of suppliers to have considerable influence over the determination of reimbursement prices. This influence is present, even if the suppliers are only minor players in the supply of an individual product. These were also the suppliers that were examined when Category D was triggered, and they may not have provided an accurate snapshot of supply in the market.

The Discount Inquiry has recouped significant sums of money for the NHS. This illustrates that the discounts given to pharmacies are large. However, because list prices rather than traded prices are used in the clawback mechanism, the sums of money that are left within the distribution system appear to be large in the case of generics.

8. IMPACT OF THE 1999 MARKET SITUATION

NERA REPORT
(CONFIDENTIAL TO BGMA MEMBERS)

8.1. Introduction

NERA's interest in the events of 1999 concerns understanding what happened. Ideally ways may be found to prevent a recurrence of what was an unstable period with apparent shortages, some significant price increases and resulting overspending by some health authorities on their medicines' budgets. We emphasise that we have no intention of proving, disproving or quantifying the Commons Health Committee's statement that "the stratospheric price rises of the past eighteen months...must have enriched many individuals at the expense of the NHS".[12]

8.2. Causes of Market Turbulence

At interviews with manufacturers, wholesalers and other authoritative sources in the industry we asked for respondents' opinions on why there had been supply shortages and price increases in the second part of 1999. Responses from all levels of the sector were remarkably consistent.

In essence, four causes were cited repeatedly.

a) The closure of Regent, which accounted for about 10 per cent of supply, resulted in acute shortages for particular products. To try to fill these, other manufacturers switched production, which in turn generated other shortages.

b) Two big manufacturers, Norton and APS-Berk, were in the process of transferring substantial production capacity to Ireland and Hungary respectively. This in turn meant that they could not respond to market shortages as readily as would normally have been possible.

c) The introduction of patient packs in place of bulk containers produced artificial shortages of certain products; and

d) When the products concerned were placed in Category D, larger orders were placed than normal causing further shortages and, hence, price rises. Some of these orders resulted from legitimate concerns among wholesalers and pharmacists that they would run out of stock. Others were pure speculation by grey-market traders wishing to make profits from a market in which certain prices were rising sharply.

The destabilising effect of the Category D system was made clear to us by one respondent. As soon as a new product was placed in Category D on the DH's website, within hours he would be out of stock. Grey market traders saw possession of stocks of Category D products as betting on a certainty.

[12] First report:. "The cost and availability of generic drugs to the NHS", 9 December 1999, p xox.

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Data provided by some BGMA members illustrate what happened in terms of movements of prices and volumes. These data are shown in the eight figures following. The following conclusions can be drawn from the charts.

- Even in a normal year such as 1998, there were huge fluctuations of volumes in and out at supplier level. For example, in Figure 8.1 we see that for amoxycillin 250mg, 500 per pack, in July 1998 the volume of pills sold was around nine million compared with around two million in June 1998. Other examples of huge month-on-month fluctuations can be seen in the Figures.

- In normal year 1998, there were significant fluctuations in ex-supplier prices. For example, the price of a tablet of amoxycillin 250mg, 500 per pack, rose from 2p a pill in January 1998 to nearly 4p a pill in January 1999. Within that trend between July and August, the price fell from about 3.5p to under 2p per pill (Figure 8.1). The price of captopril 25mg fell from 5p per pill in January 1998 to 2.5p per pill in January 1999 (Figure 8.5).

These examples support our analysis in Chapter 1 where we reasoned that sub-markets for generics with the same active ingredient would be expected to have the attributes of a commodity market: namely one in which supply and demand are matched by price movements which can be sudden and sharp. This being so, it should come as no surprise that when shortages of stock occurred overnight because of the closure of Regent, they should be reflected in sudden price changes of the sort, but much larger, than occurred in 1998 when no such shocks to the system occurred.

The impact of the uncoordinated and seemingly haphazard introduction of patient packs is also shown in the charts. For example, the ex-supplier price of a tablet of bendrofluazide, 500 per pack, in 1998 was steady about 1p. As the 500 bulk packs were phased out in place of packs of 28 the price rose to 3p (Figures 8.3 and 8.4).

A similar story is seen for co-dydramol 10/ 500 mg. In 1998 its ex-supplier price per tablet, 500 per pack, was steady at under a penny and, apart from a temporary rise to 2p in April 1999, it remained around 1p until March 2000. By contrast, when packs of 30 were introduced and were in short supply the price of a pill in these packs rose to 4p between May and October 1999 (Figures 8.7 and 8.8).

In essence, it is clear that shortages lay in patient packs rather than the pills themselves. The existence of Category D meant that real shortages resulting from the closure of Regent were exaggerated into artificial shortages because of inaccurate price signals that gave rise to panic buying and some intentional speculation.

Figure 8.1
Amoxycillin 250mg – 500 packs

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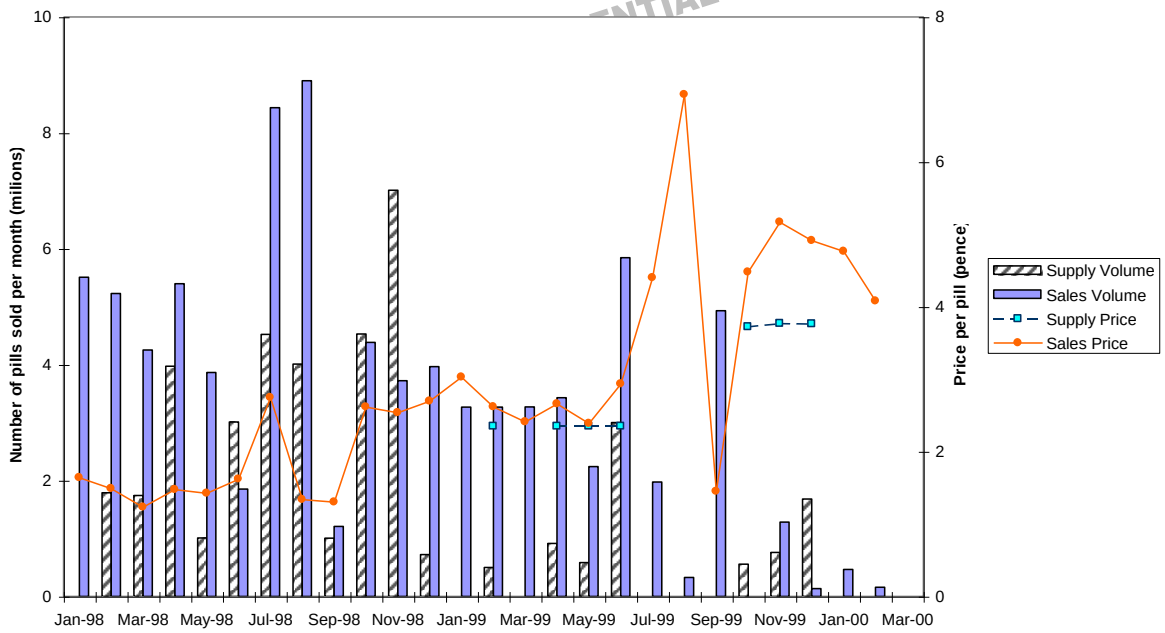

Figure 8.2
Amoxycillin 250 mg – 21 packs

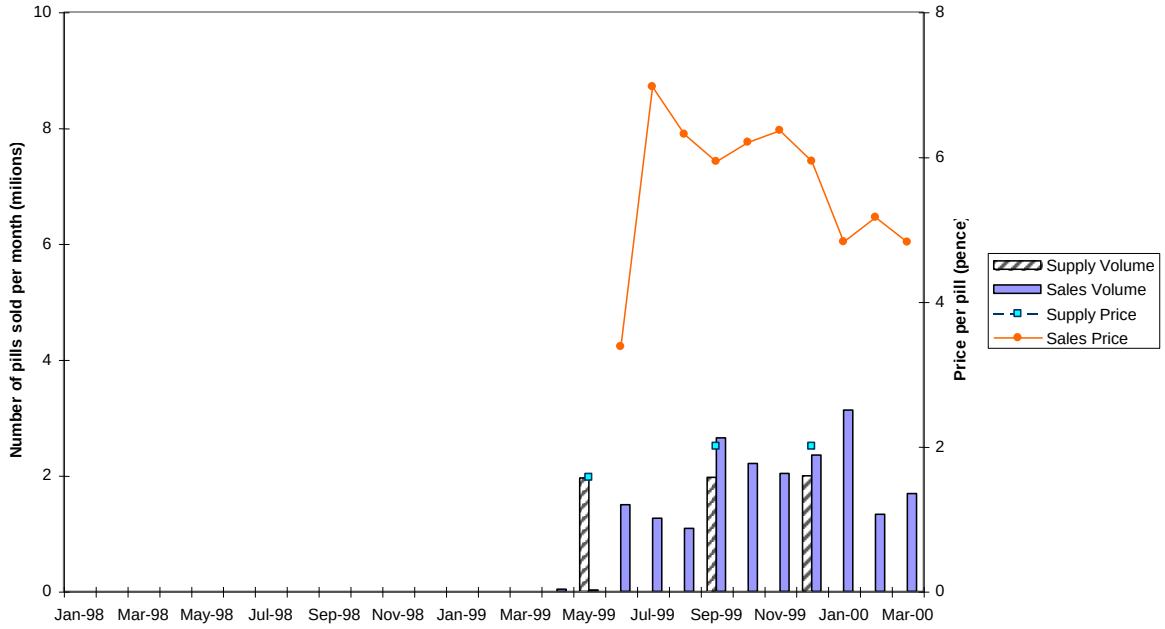

Figure 8.3
Bendrofluazide 3.5 mg – 500 packs

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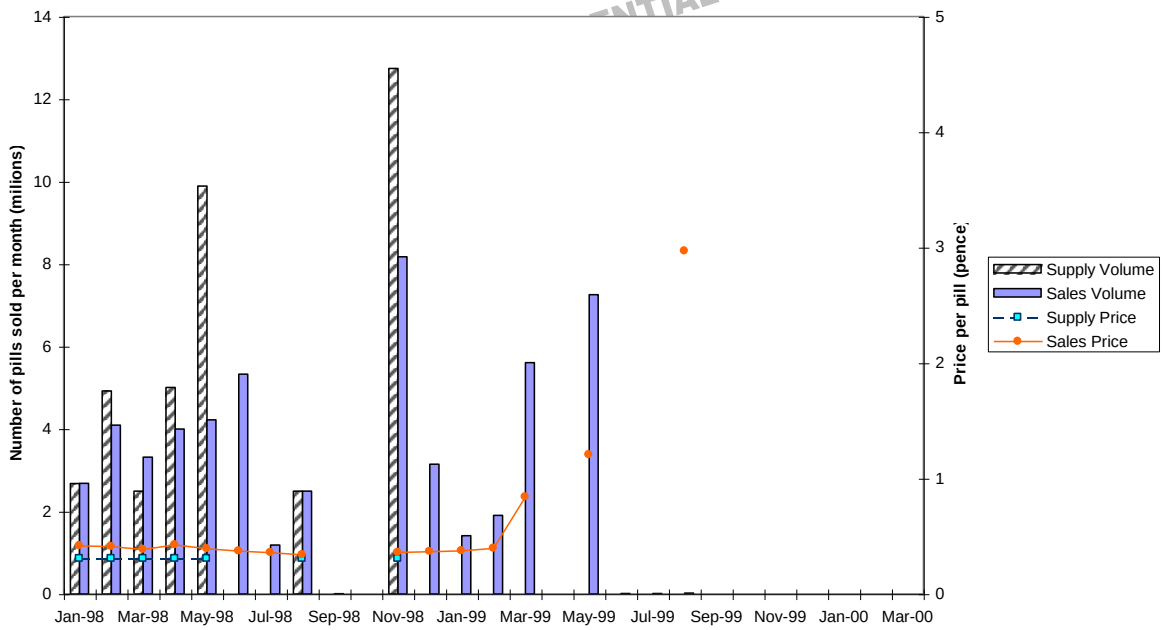

Figure 8.4
Bendrofluazide 2.5 mg – 28 packs

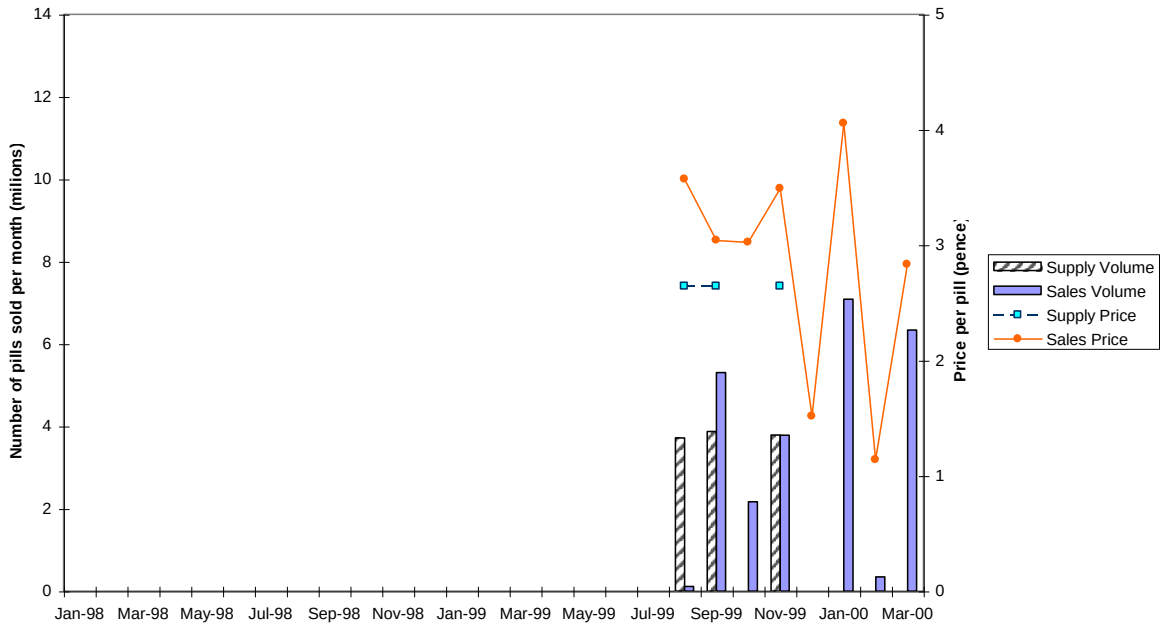

Figure 8.5
Captopril 25 mg – 56 packs

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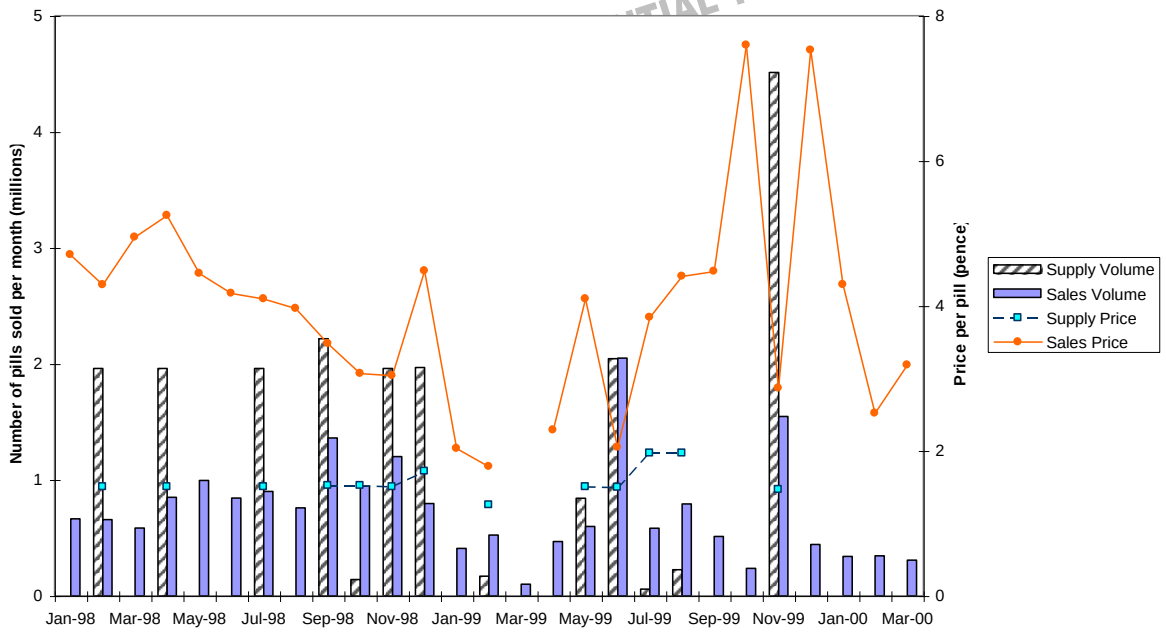

Figure 8.6
Ibuprofen 400 mg – 250 packs

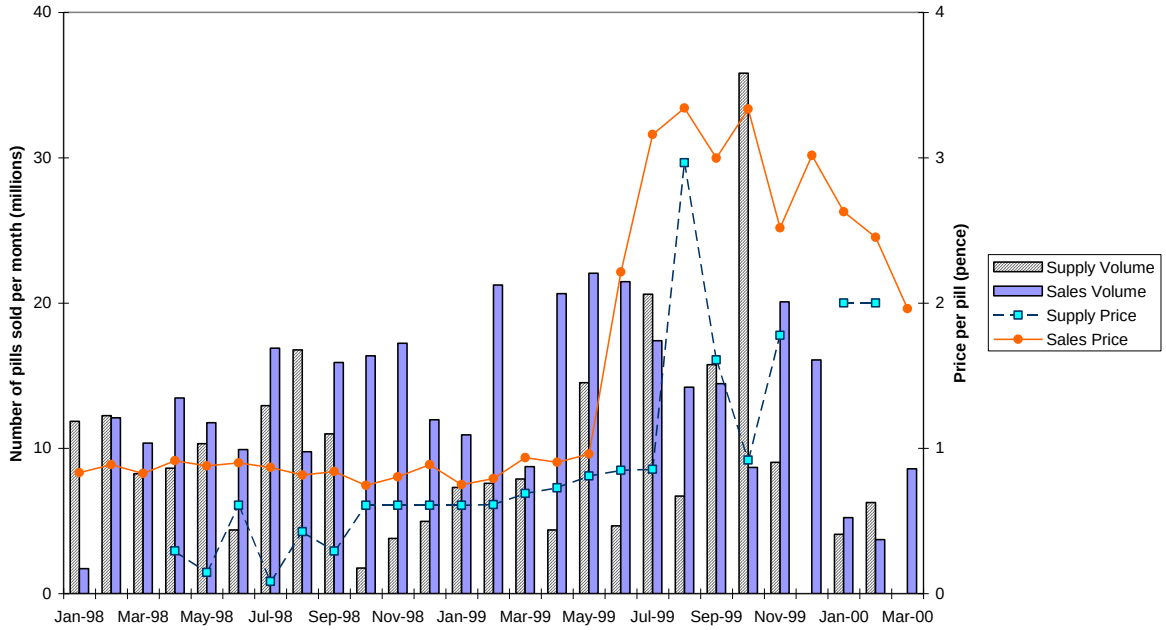

Figure 8.7
Co-Dydramol 10/500 mg – 500 packs

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ENTIAL TO BGMA MEMBERS)

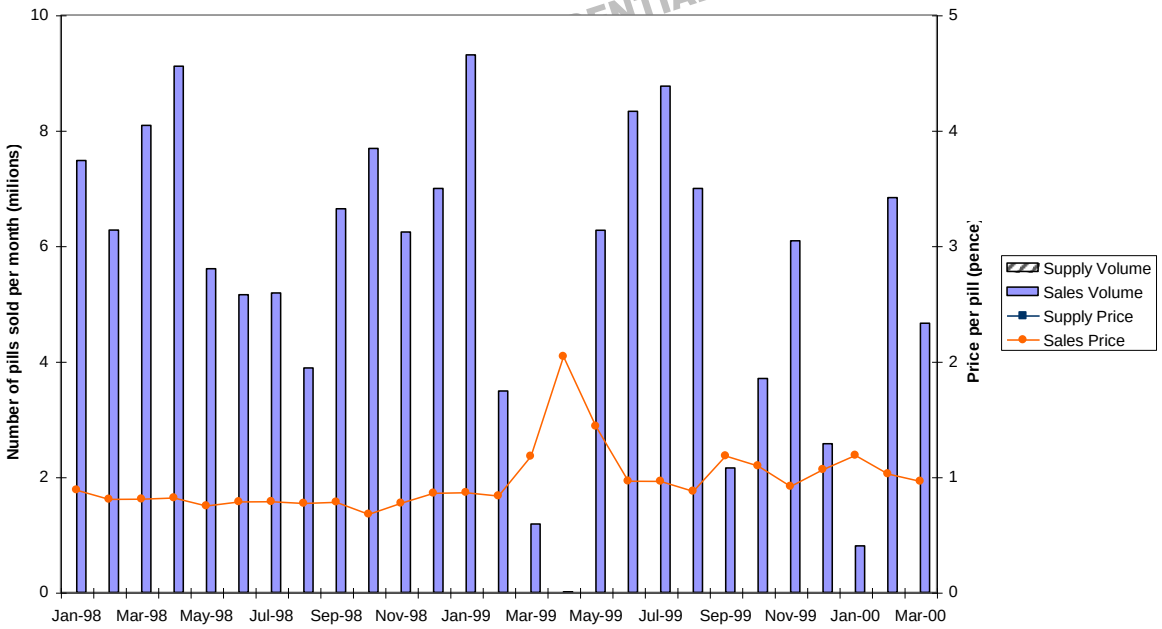

Figure 8.8
Co-Dydramol 10/500 mg – 30 packs

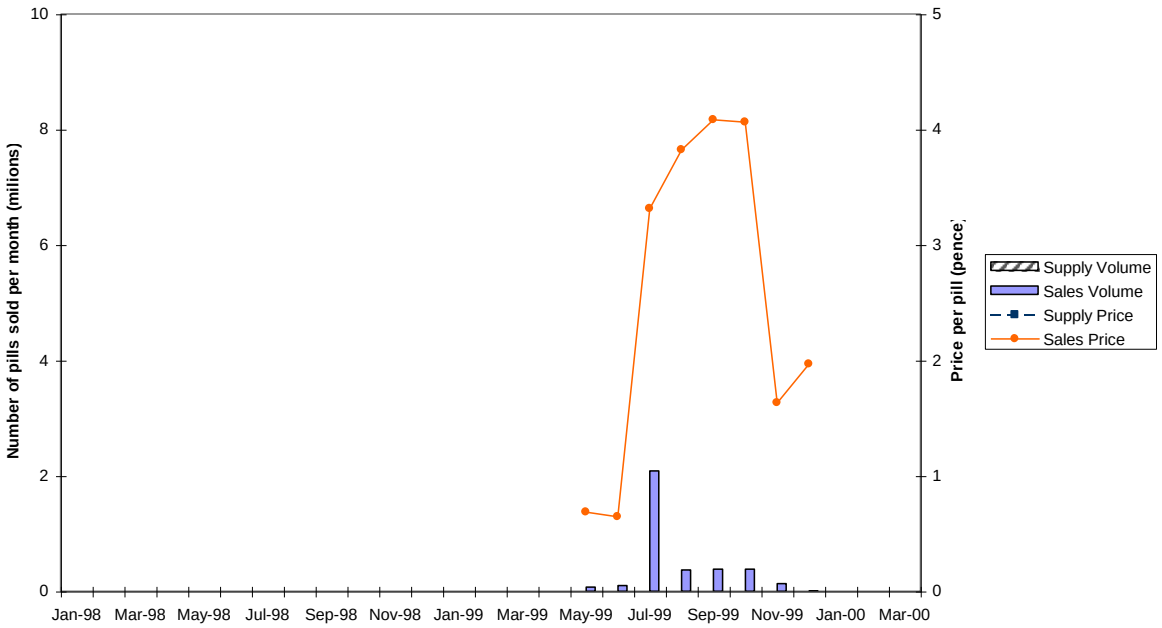

Figure 8.9
Thyroxine 25 mg – 500 packs

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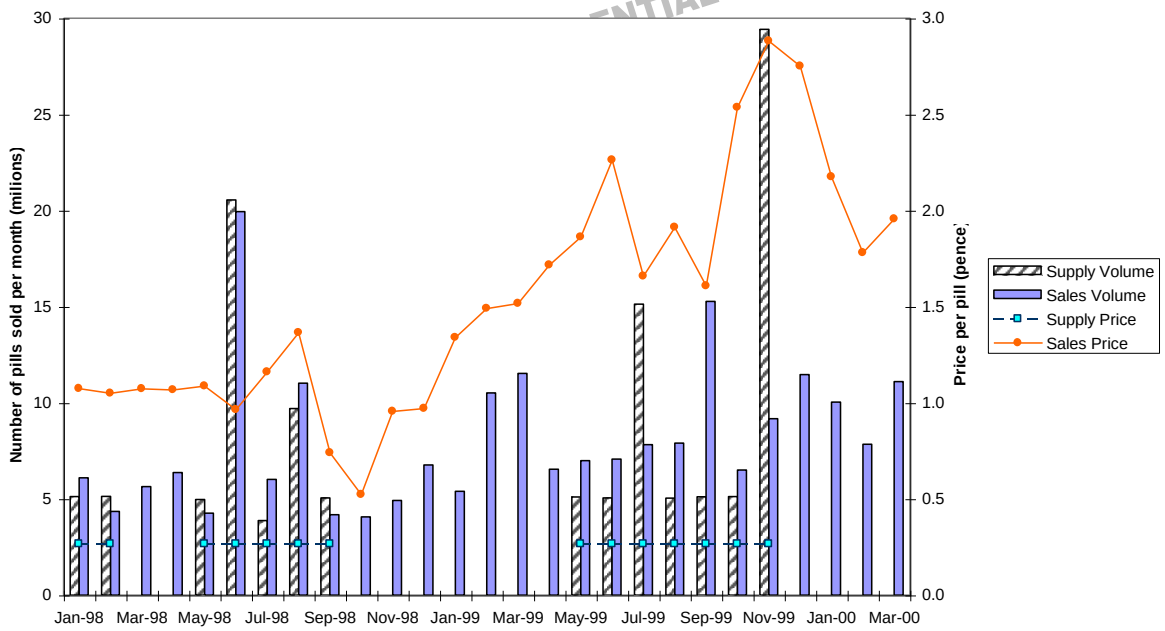

8.3. Did the Events of 1999 Represent Market Breakdown?

The significant and sometimes dramatic price and supply fluctuations in generic medicines in 1998, a normal year, suggest keen competition in a market in which products with commodity characteristics compete fiercely on price. Up to the second half of 1999 there appear to have been no concerns about the way the generic market worked. Indeed, the Health Committee demonstrated that the price of generics fell in real terms from 1994 to the end of 1998 by about 25 per cent.[13] Thus, apparently, the system was acceptable to ministers and the DH so long as it produced falling prices, but it became immediately unacceptable when, because of an atypical concatenation of independent events, prices rose sharply for about six months. But rising prices do *not* necessarily represent market breakdown. Indeed, they can represent the market working correctly.

The first and most clear-cut evidence of market breakdown is when supply fails to meet demand. In 1999, according to our research, this hardly occurred. Patients received medicines and *most of the time these were generics*. Only a few short-term shortages were made up by branded originals.

Markets for generics generally continued to clear despite the exaggerated prices that resulted from the impact of Category D and grey-market hoarding. This being so, it is hard to argue that there was market breakdown. Moreover, in NERA's judgement, the fact that markets cleared was despite the Category D reimbursement system, not because of it.

[13] First report:. "The cost and availability of generic drugs to the NHS, 9 December 1999, p44.

8.4. Who Benefited from the Events?

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Companies exist to make profits. This applies with equal force to generic suppliers, wholesalers, pharmacists and grey market traders. That the products concerned are medicines is immaterial. If prices rise for whatever reason, some parts of the supply chain from manufacturers to pharmacists may make additional profits but is uncertain that all parts of the chain do so equally.

In the generics market, we found that there are few fixed price long-term contracts (say over three) between manufacturers, distributors and pharmacists, so the opportunities for speculation do not exist in normal circumstances. In exceptional circumstances, however, as occurred in 1999, the opportunities for taking delivery of extra stock and hoarding it in the expectation of further price rises was a possibility and occurred. This is what we term the "grey market".

The grey market operators included some short-line wholesalers and some pharmacies. We could not obtain interviews with full-line wholesalers so we do not know whether speculative buying occurred at that level also. The firms that operated in the grey market simply increased stock levels of Category D products far above what they would normally have sold and waited for prices to rise further.

We saw evidence to illustrate the nature of the positions they had taken. One respondent showed us a pile of recent faxes received from grey-market operators listing the large quantities of stock they were holding and trying to sell it at almost any price. Such firms had taken a view, bought stock, perhaps a year ago, sold some of it, and now saw prices falling while the use-by dates on the medicines' packs were getting nearer.

In politicians' statements, such actions have been described as a "rip-off", but in commodity markets the activities of traders who take a view on future prices and the availability of supply is accepted as inherent in the way such markets work. If patients had been without medicines and therefore at risk because of such speculative stock-piling, public condemnation might be justified. But this did not occur. Further, the system itself, not least the operation of Category D, created the opportunities for speculation. As noted by the Health Committee, "products not in short supply are not only entering Category D but also staying in Category D too long".[14]

We asked manufacturers and short-line wholesalers whether they had benefited financially by the events of 1999. A number admitted that they had done so. One such answer was: "With rising prices and my staff costs unchanged, my margins improved". Another respondent said that 1999 had been a particularly good year for the company because of the views he had taken on price movements resulting from the functioning of Category D.

[14] Ibid, para 40, p xvi.

8.5. Conclusions

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We are satisfied that in the submarkets for generic medicines with the same active ingredient the characteristics of a commodity market obtain. Price changes are a market clearing mechanism and not a "rip-off". The large quantities of public money that lie in the distribution system make it unstable. If the present system remains unchanged, significant price fluctuations will continue to occur even in normal circumstances.

The events of 1999 — the closure or Regent, the transfer of production abroad by two major generic manufacturers and the transfer to patient packs — produced temporary shortages in a number of generic lines. The existence of Category D exacerbated the resultant price increases and offered attractive opportunities for grey market speculative trading. Despite this, patients seldom if at all were kept waiting for the prescribed molecules, which mainly were still generic products. Some grey market traders made additional profits in 1999, but they may see these offset in 2000 as they now try to get rid of their remaining stock at almost any price.

The events of 1999 did not represent a breakdown of the market, but rather the impact of unusual events coupled with a flawed reimbursement system.

9. REVIEW OF ALTERNATIVE REIMBURSEMENT SYSTEMS

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9.1. Flaws in the Current System

In the past chapters of this report we have described how generic medicines in the UK are supplied and distributed, and we have identified the following flaws in the current system:

- the Drugs Tariff's reimbursement prices are based on list prices of a small number of suppliers who may not be representative of the market;
- Drugs Tariff reimbursement prices do not reflect the lower prices at which generic medicines are traded. Significant discounts are the norm, which leaves potential for surplus public money to remain in the supply chain and distorts the role of prices;
- there are flaws in the Annual Discount survey and the resultant clawback.
- despite stable market demand for generic products, an inherent instability in the volumes supplied by individual manufacturers causes sharp oscillations in prices within the supply chain even in normal trading years; and
- there are avoidable inefficiencies in production resulting from individual suppliers switching production to chase apparent shortages.

These flaws were present before 1999 and came into focus because of the market turbulence that followed the closure of Regent in 1999.

We are clear that the Drug Tariff's Category D system increased the problems of 1999 by giving rise to significant purchasing and hoarding of product lines as soon as they entered Category D. Abolishing Category D, however, will not alone be enough to tackle the inherent flaws noted above. More fundamental changes are needed.

9.2. Desirable Criteria for a New System

The BGMA, who commissioned NERA's work, favour fundamental reform of the present system for reimbursing generic medicines and in the light of our findings, summarised above, we agree. The BGMA gave us a draft working paper setting out alternatives and criteria by which the alternatives should be judged.

In the BGMA's view the criteria for a new system should be:

- "Sustainable: if not, (supplying) companies will move out of the industry, and competition will be reduced.

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- Stable: to ensure certainty for the supply chain and, most importantly, for patients.
- Transparent: if anomalies and waste are to be avoided.
- Pro-generic: if the cost savings due to increased generic prescribing and dispensing are to be continued.
- Fair: if true competition is to be fostered."

As independent economists NERA can endorse these criteria but with a *caveat* on the criterion "pro-generic". Government policy for some years has been to encourage the use of generics when branded originals come off patent. One justification for doing so is to provide head-room so that the savings on generics can be applied to new, branded medicines which, by their nature, are substantially more expensive. However, we point out that any system that overtly sets out to be "pro-generic" by definition reflects political choice and may not reflect the working of the market.

To the BGMA criteria, NERA adds two more, namely that a new system should:

- require the least possible government intervention and hence low public administration costs and low compliance costs to the industry; and
- produce efficiency gains from a correctly working market.

We now discuss alternative systems, alluding to some that are found in other countries. The order in which the various systems are presented is random. Some aspects of certain schemes are drawn from suggestions made to us by BGMA members. The sub-heading "Discussion" in each case is intended to be descriptive and not judgemental.

9.3. Co-operation Between the Generics Supply Industry Based on Reference Pricing

9.3.1. Proposal

The industry and government would agree a single, industry-wide fixed reference price for the existing generic portfolio. The prices of new generic introductions would be negotiated for direct supply and via wholesalers. There would be a legally enforced limit on levels of discount below list prices. Wholesalers and pharmacists would provide service for a fixed fee and discount at an agreed level. A dispensing fee would be paid to pharmacists together with other fees for service-related activities. Stakeholders would share data with other stakeholders to ensure that supply and demand remained in balance. Brand equalisation deals and dispensing doctors would be included in the system.

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9.3.2. Discussion

This system would have the characteristics and the flaws of those found in planned economies. A complex process of negotiation, information sharing and price-setting would not ensure that supply and demand balanced; that efficient companies were rewarded; that prices were the instrument of efficient market clearing; that resources were efficiently allocated; and that efficiency gains were passed on to customers. Such a system would place ultimate power in the hands of government who would thus effectively control the entire generics sector.

9.4. Tendering

9.4.1. Proposal

Suppliers from the UK and elsewhere in the EU would make competitive bids to provide defined volumes of specific products to the NHS at defined prices for defined periods.

9.4.2. Discussion

In the UK and elsewhere in the EU it is common practice for public health sector buyers such as hospital groups to invite bids for specific volumes of multi-source products. However, considerable difficulties would arise if individual suppliers were required to tender to the NHS as a whole on the basis of "winner take all". If large volume lines were reduced to smaller lots, problems would still remain. Under either variation:

- suppliers would need to bid for a range of lines in the hope of winning some of them. Thus their internal cost structure would not be defined until the outcome of the bidding process. This process could result in prices that did not reflect efficient production costs even for winning bidders;
- unsuccessful bidders might find themselves with zero sales. They would then have to wait until successful bidders ran short of capacity during which time their plants would be idle and the companies' financial position would be precarious;
- individual suppliers, having won bids for certain large product lines, would be likely to cease production of others in order to meet the required volume of the winning bid. The market would then face shortages that would have to be met by unsuccessful bidders also switching their production. The result would be the instability that currently characterises generic supply;
- if the bidding took place, say, once a year, the market would be inflexible to developments during that year. If the cost of APIs rose, bidders would have to absorb the costs. If they fell, cost savings would not be passed on to the NHS;
- if the tendering process were to cover only, say, the 100 most commonly used molecules, it would still be complex and would impose a considerable burden on

both suppliers and the NHS. Price and supply instability would continue for the molecules not covered by the system;

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- if the tendering process were to cover *all* generic molecules and lines, the complexity and burdens would increase correspondingly; and
- litigation could be expected by the NHS if successful bidders failed to meet their commitments. If the NHS did not call off all the full volume of the bid, suppliers would also be entitled to litigate but might be inhibited from doing so because of the cost and the disparity of financial muscle between even a larger generic company and the DH.

9.5. Profit Control

9.5.1. Proposal

By analogy with the Pharmaceutical Price Regulation Scheme ("PPRS") a profit control system could be agreed between the DH and the generic suppliers.

9.5.2. Discussion

Comparison between the reimbursement of research-based products under the PPRS and of generics must take account of the role of intellectual property ("IP") protection in the former. It is axiomatic that without IP protection there would be no incentive to bring new chemical entities to the market. The estimated cost of a new entity is widely held to be at least £300m and many molecules fail to recover their costs. The cost of failures has to be recovered also from new entities that are commercially successful.

By contrast, generic manufacturers do not have a huge investment in IP to protect although some development work is required. In general, the prices of individual generic products fall in relation to the number of suppliers who enter the market.

Given the inherent flexibility of generics' prices, the concept that the DH should look at each generic manufacturer's profitability on its supplies to the NHS and determine an individual rate of return, as happens within the PPRS, would be unworkable. Even if a fixed rate of return were set for all generic manufacturers, an audit would still be necessary to verify each company's capital base and sales to the NHS. Companies' compliance costs would be high and the scope for creative accounting would be extensive.

Indeed, the rationale for fixing a target rate of return, as in the PPRS, is to prevent manufacturers from exploiting their monopoly position by raising prices and hence profits. By contrast, generic products have no monopolies. However, in general, competition in the generic market would tend to put downward pressure on prices, making the introduction/need for some of kind of artificial ceiling on prices look perverse.

9.6. Reimbursement Prices Based On Suppliers' Average Selling Prices

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9.6.1. Proposal

Generic suppliers would submit to the DH in standardised electronic format their monthly volume of sales to the domestic market for each product line and the average selling prices ("ASPs") for the month in question. Loyalty discounts would be made illegal.

The DH would combine the volumes and ASPs to produce a weighted average ASP. To this would be added a fixed mark-up needed for the wholesale function, and the resulting figures would become the pharmacy reimbursement prices for the following month. These prices would be published on the Internet, and hard copy publication in the Drug Tariff would be phased out.

9.6.2. Discussion

The system would eliminate the large and needless discounts that currently are normal within the distribution chain and give rise to public cash leaking out of it despite the annual Discount Survey and clawback. Efficient suppliers and wholesalers would be able to offer discounts to pharmacists but these would be tiny (perhaps one per cent) since the system would be based on actual ASPs at ex-supplier level. Discounts based on efficiency are economically desirable in a correctly working market.

If shortages of a line arose in one month, suppliers would increase their prices. In that month, assuming that wholesalers maintained their standard mark-up, pharmacists would be reimbursed *below* their expenditure. Correspondingly, if suppliers' ASPs fell in the month, pharmacists would be reimbursed *above* their expenditure. Over time these over- and under-reimbursements should balance out.

The annual Discount Survey would become redundant. It would be desirable for the DH, or some other body, to have the authority to check the accuracy of the ASPs if necessary (with penalties for those caught submitting false information). However, manufacturers are unlikely to benefit from artificially increasing ASPs because the benefit, as now, would accrue to the distribution chain. Thus, the incentive to falsify information would be weak.

It is possible that marginal pharmacists who currently benefit from public cash in the system that is not clawed back by the Discount Survey might cease to be viable. The correct economic solution would be for the DH to compensate them by increasing their dispensing and other fees for service.

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9.7. Reference Pricing

9.7.1. Proposal

Under reference pricing, the prices of a basket of multi-source products are used to establish a reference price for all the products in the basket. A reference price is set that is the subsidy at which the health fund reimburses all products within the group. Patients are required to pay the excess for any product that is priced above the reference price.

9.7.2. Discussion

The aim of reference pricing is to enable health funds to save on their medicines bill and not pay over the odds for medicines with an identical molecule and hence equivalent therapeutic effect. Different formulae are used in different countries to establish the reference price for each group, but typically the reference price is set low down the prices of the chosen basket.

Reference pricing for multi-source products was introduced in Germany in 1989 and has been adopted or adapted in other EU countries including the Netherlands, Sweden, Denmark and, currently, Italy and Spain.

Reference pricing for multi-source products has been shown to save money for the sickness funds in Germany but to have been much less effective in producing savings in other countries.[15] These systems may be more pertinent in countries such as Germany where branded generics are common, and hence less so in the UK where they are not found.

However, the main economic arguments against reference pricing are that it constitutes a major intervention by government into the working of the market, and it does not guarantee that health funds get the best value for money. Once a reference price has been set, the prices of competing products converge at or just below the reference price which, as noted, can be manipulated by governments on the basis of how the price comparison system is constructed.

9.8. Direct Price Controls

9.8.1. Proposal

Using some formula, the government could set the prices that it was prepared to pay for generic medicines. On a given day, it could either set a price for, say, amoxycillin 250mg and another price for amoxycillin 500mg; or it could impose price changes across the board on all generic products based on whatever criterion it felt appropriate. Such a step was

[15] See for example Zammit-Lucia J and Dasgupa R. "Reference Pricing: the European Experience". Imperial College of Science, Technology and Medicine; and St Mary's Hospital Medical School, University of London, Health Policy Review, Paper No. 10, 1995.

proposed on 20 April 2000 when Lord Hunt, the Health Minister, announced that "prices will be reduced to their average level over the period November 1998 to January 1999".[16]

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9.8.2. Discussion

Direct intervention by governments on the prices of medicines has occurred in various EU member states over many years, but has not been a feature of government actions in the UK. For some years the European Commission has opposed direct control of medicines' prices, favouring demand-side measures to increase competition among suppliers.

> "From an economic point of view, out-of-patent products are far closer than in-patent ones to products in normal markets, in which cost-containment can normally be achieved through price competition. Consideration could be given to the possibility of *removing price control* in this sector whilst stimulating competitive arrangements for the supply of generic products."[17] (Emphasis added).

Any form of direct intervention by government on generics' prices individually or collectively reduces the informational role of prices as market-clearing signals and hence leads to distortions in the market. In those countries where direct governmental intervention on pharmaceutical prices generally has been most pervasive — for example France, Italy and Spain — generic medicines have market shares that are still embryonic.

9.9. RPI – X

9.9.1. Proposal

The system of regulating the prices of certain utilities by linking their prices to the retail price index less some percentage ("RPI-X") would be applied to generic medicines. The prices of a basket of, say, the 100 medicines with the highest NHS expenditure could be collected and, using some formula, the average price of each would be calculated. This price would become the basis for a pharmacy reimbursement price, published in the Drug Tariff. The prices would be adjusted periodically, say every quarter, on the basis of the RPI-X.

[16] Department of Health press release 2000/0248.

[17] Commission Communication on the Single Market in Pharmaceuticals. COM(98)588 final, 25 November 1998, p12.

9.9.2. Discussion

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The concept of RPI-X was introduced first in the UK for telecommunication, electricity and other utilities whose output is a measurable homogenous product. It has been applied particularly in cases where the supplier has a natural geographical monopoly, specifically to curb monopoly power and to encourage efficiency among suppliers.

It is difficult to see any such scheme being practicable for generic medicines. The problems in devising and operating such a scheme would be formidable for the following reasons:

- generic medicines as a whole do not constitute a homogenous product;
- given the price fluctuations that occur even in a normal year such as 1998, the choice of the date for the pricing exercise could significantly affect the base 100 on which subsequent calculations would depend;
- the basket would become unreliable whenever a significant molecule came off patent and entered the market as a generic;
- there is no obvious reason to suppose that the generics manufacturing sector is uncompetitive or has localised monopolies that might justify price controls;
- there is no intuitive concept for how the figure X might be computed in the case of generic medicines. For example, the international prices of APIs fluctuate, and the proportion of APIs in the cost of different generics is variable;
- if an RPI-X was imposed on the industry, it would be for debate whether it should apply uniformly to all lines in the basket or whether the prices of individual companies could be flexed so that overall they conformed to the RPI-X figure;
- if companies flexed their prices as often as they do now, the problems of monitoring whether they had done so in a way that produced the desired overall price change indicated by RPI-X would be a major burden for the DH and would entail heavy compliance costs by the suppliers; and
- since products not covered by the basket would be exempt from the scheme, suppliers would be free to increase these prices to compensate for the effects of RPI-X on the basket products.

9.10. Conclusions

Some of the systems described above have clear merits and demerits compared with the existing scheme for reimbursing generics in the UK. The current system, in NERA's judgement, is seriously flawed and should be revised.