DRIVERS OF THE GROWTH IN MEDICINES EXPENDITURE

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FOREWORD

Increases in expenditure on medicines, above the level of increases in health care expenditure generally, are a feature of all Western health systems, including the UK's. This paper examines the causes of these increases in the UK. It reports on a study carried out by the Office of Health Economics, with technical assistance from the Department of Health, under the auspices of the Industry Strategy Group, a forum for joint discussion of matters of strategic interest to the pharmaceutical industry and the Government. The study shows that the position is complex: a number of different forces are at work. Analysis suggests that the largest effect is that of 'product mix', the prescribing of newer, more expensive medicines, followed by the 'volume effect', comprising growth in the number of prescription items and in the number of tablets per prescription. As the paper shows in examining growth in asthma prescribing, these effects are driven by innovation, morbidity, demography and changing treatment patterns. The detailed analysis presented in this paper provides important background for the current debate about NHS expenditure and the Government's own Comprehensive Spending Review. The paper concludes that expenditure on medicines can be expected to show continued real growth and take an increasing share of total NHS expenditure in the medium term. The challenge for the Government, pharmaceutical industry and medical profession is to ensure that we have and use medical advances offering genuine benefit to patients whilst seeking to ensure that all expenditure on medicines represents value for money for patients and the NHS as a whole.

MAURICE PESTON
House of Lords

SUMMARY AND CONCLUSIONS

National Health Service (NHS) expenditure on pharmaceutical products totalled £4.7 billion in 1995, 11.5 per cent of total NHS expenditure. Medicines expenditure continues to increase at a greater rate than total NHS expenditure. This paper discusses the key drivers of growth in expenditure and considers their implications for future rates of growth.

VARIANCE ANALYSIS

Variance analysis has been used in order to estimate the relative importance of volume growth (number of prescription items dispensed) and increases in the average cost per prescription item (net ingredient cost of medicines) on medicines expenditure growth.

Both the Intercontinental Medical Statistics (IMS) and the Department of Health (DoH) have developed their own techniques for such analysis. The DoH model, using a more disaggregated analysis than IMS, estimates that between 1989 and 1994 the movement from older products to newer, more expensive products (a product mix effect) contributed around 55 per cent, on average, of the total overall growth. Increases in the number of prescription items contributed around 30 per cent. Changes in the 'size' of a prescription item (tablets, bottles, or packs) contributed 13 per cent. These changes in the number and size of prescriptions constitute a 'volume effect'. IMS analysis does not allow these effects to be split and refers to the two together as 'volume increase', accounting for about 75-80 per cent, on average, of total overall growth each year (1989-95). The DoH approach is therefore of greater value to this paper. Price changes have, on average, had a small negative effect over the period.

DRIVERS OF GROWTH

This paper focuses on the key factors driving product mix effects and volume growth.

PHARMACEUTICAL INNOVATION AND THE PRODUCT MIX EFFECT

Pharmaceutical innovation impacts significantly on the size of the medicines bill. Its effect on expenditure will be influenced by the cost of developing new medicines, the rate at which new medicines are brought to market (the rate of innovation), the return allowed on medicines and the degree of market penetration which the new medicines achieve. The costs associated with bringing a product to market are likely, in the long run, to influence companies' pricing policies and hence the level of medicines expenditure. Evidence suggests that the cost of bringing a new product to market is increasing. As such, therapeutic advances may contribute to an increase in medicines expenditure, as GPs prescribe newer, more expensive medicines (the product mix effect). The degree of impact on the medicines bill will also be affected by the extent of price competition in the market, from other innovative products during the patent period and from generics after patent expiry. Generic competition has increased substantially since the 1970s producing a deflating effect on expenditure, but not sufficient to counterbalance the other components of the product mix effect.

DEMOGRAPHIC FACTORS, CHANGING TREATMENT PATTERNS, AND THE VOLUME EFFECT

Prescribing for the elderly population

The principal volume driver of medicines expenditure up to the beginning of the 1990s was the increase in the absolute number and proportion of prescription items dispensed to elderly people. This is a result of growth in the number of elderly people (65+) and of changing treatment patterns, due to either the introduction of new interventions or a realisation that the expected health gain available from existing interventions is sufficient to justify treatment. Changing treatment patterns have had most impact on the rate of volume growth. Between 1985 and 1995 the number of prescription items dispensed to elderly people increased by 54 per cent compared with an increase of 4 per cent in the total number of elderly people. The increase in the number of prescription items dispensed to elderly people has a particularly significant impact on the size of the medicines bill as they are the largest per capita consumers of medicines. Although the total number of elderly people has plateaued, the age structure has continued to alter during the decade, with the very elderly constituting an increasing proportion of the total elderly population. Persons 85 years of age and over have approximately treble the per capita consumption of medicines of those aged 65-74. Population forecasts indicate sustained growth in the number of elderly after 2001, and in the proportion of the population who are very elderly.

Other demographic factors

The impact on medicines expenditure of other demographic factors is less pronounced:

- Females currently have greater utilisation of medicines than males. However, the impact of this is likely to diminish over time as population predictions estimate a narrowing in the gap between the number of males and females resident in the United Kingdom, particularly for the sixty-five and above age group.

- The degree of influence that levels of unemployment and deprivation have on the medicines bill is unclear. Although regions with the highest unemployment rates generally report the highest rates of per capita use of prescriptions and per capita prescribing costs, and studies have shown a clear link between unemployment, deprivation and ill health, there is a lack of evidence as to the importance for prescribing of changes in unemployment and deprivation over time.

Increased notification of disease

Increasing consultation rates per 1000 population have consistently been recorded for the population as a whole since the first National Morbidity Survey was carried out in 1955-6. Consultation rates have increased most among the younger (0-14 years) and the more elderly (45+) age groups. If the number of people consulting their general practitioner (GP) is used as a proxy for ill health then the evidence from all four of the National Morbidity Surveys carried out to date indicates that people are, on average, experiencing a greater degree of morbidity, with consequential growth in prescribing. A significant proportion of the increased notification of disease is likely to be the result of greater awareness of certain conditions through media coverage or general education.

IMPACT OF GOVERNMENT POLICY ON PRESCRIBING AND MEDICINES EXPENDITURE

The government's policy aims are threefold. First, to ensure patients have access to the medicines they need and that doctors' retain clinical freedom to prescribe what best meets a patient's needs. Second, to ensure the NHS pays a fair and reasonable price for medicines that secures (a) value for money for the service and (b) properly reflects the R & D costs and investment to the Industry – thus encouraging innovation. This is secured through the Pharmaceutical Price Regulation Scheme (PPRS), which is a profit constraint impacting on company prices and revenues. The negligible overall contribution of price changes to the growth in medicines expenditure over the period 1989-1995 is due to the operation of the PPRS. Third, to ensure that doctors prescribe as efficiently, and as cost effectively, as possible (e.g. generic prescribing where appropriate).

Many government policy measures have been designed to impact on GP prescribing behaviour. The introduction of GP fundholding in the 1991 NHS reforms was expected to have an effect on the prescribing costs of fundholding GPs and help drive the search for more cost-effective prescribing as part of the incentive to produce better service for patients within allocated budgets. The impact of GP fundholding on the 'appropriateness of prescribing' is currently unclear as there has been limited research evaluating the outcomes of GP prescribing. Studies carried out suggest that fundholders' do have lower growth rates of prescribing expenditure and attain lower average costs per prescribing unit than non-fundholding GPs. However, it is unclear whether these lower growth rates can be sustained as recent studies have indicated that they were a result of increased generic prescribing by fundholders. By 1994 the variation in the growth rate of generic prescribing had ceased and the generic prescribing level of non-fundholding GPs ran parallel with that of fundholding GPs. The significance of fundholding on future medicines bill expenditure will depend on whether further savings can be realised and, if so, on how many GPs become fundholders in the future.

The different financial incentives that operate for dispensing and non-dispensing doctors is a likely explanation for the reported higher prescribing costs per patient for dispensing practices as opposed to non-dispensing practices. This is not a key driver of growth, however, as the total number of patients prescribed medicines by dispensing doctors has remained constant over the last ten years, a situation not expected to change.

The GP Contract implemented in 1990, and replaced by similarly functioning health promotion programmes in 1996, provided financial incentives for GPs to carry out certain health check programmes on a stipulated percentage of their patients, such as screening for high/low blood pressure and advice on smoking-related illness. GPs are also obliged to offer certain services to patients without receiving additional payment, such as health care programmes for the elderly. This additional throughput of patients is likely to have increased the identification of illness and raised levels of GP prescribing.

A DISEASE AREA APPROACH

Asthma medication was studied to gauge the benefit of analysing a specific therapeutic area to gain greater understanding of the factors impacting on total medicines expenditure. The analysis showed that isolating price and volume factors and weighting the importance of these factors is difficult, although it is possible to identify the main drivers of growth. For

asthma these include population growth, rising asthma prevalence, increased professional awareness of asthma, therapeutic innovation, and the higher price of new therapies.

The results of the analysis undertaken for the asthma medication market, and potential explanations for the analysis findings, are discussed in detail in Annex B.

IMPLICATIONS FOR FUTURE RATES OF GROWTH

The main components of growth in the medicines bill are product mix effects and volume growth effects. Department of Health variance analysis indicates that product mix effects have a greater impact on medicines expenditure growth than volume effects. Product mix effects are driven primarily by the cost of developing new medicines and their rate of adoption by GPs leading to the replacement of older products over time. Volume growth is driven predominantly by demographic change, quantity of treatment administered and levels of morbidity. Government policy measures produce dampening effects on levels of expenditure and rates of growth but their prime intended role is to improve the quality and cost-effectiveness of prescribing, not simply to act as a constraint on expenditure.

Available evidence suggests that these trends will continue. Medicines bill expenditure can therefore be expected to show continued real growth and take an increasing share of total NHS expenditure during the medium term period. Further analysis is still needed, however, to gain a greater understanding of future trends. Such analysis could focus, for example, on the impact of ageing on prescribing, the rate at which new products diffuse through the NHS market and subsequently lose market share to generics, trends in particular therapeutic areas, and on trends in morbidity. Any proposal for further research would, however, have to be carefully assessed to see if the findings were likely to be of value. Analysis of medicines bill growth, and discussion of policies designed to impact upon medicines expenditure, should be considered alongside work assessing the appropriateness and cost-effectiveness of prescribing. Prescribing should be evaluated within the context of the objectives of the NHS as well as in terms of expenditure levels.

1 GROWTH IN THE MEDICINES BILL

1.1 BACKGROUND

Concern is often expressed over the growing level of National Health Service (NHS) expenditure on pharmaceutical products. Such concern is not new. As far back as 1957 a Select Committee was appointed 'to investigate the factors contributing to the cost of prescriptions and to make recommendations'. The purposes of this paper are firstly to report upon the extent of growth, secondly to offer potential explanations for this growth, and thirdly to discuss how costs might develop in the future.

1.2 AGGREGATE TRENDS

In 1995 the number of annual prescriptions for NHS medicines had reached 544.8 million in the United Kingdom (UK), costing £4.7 billion (see Figure 1). The monetary growth in the size of the medicines bill was mirrored by growth in the percentage of total NHS expenditure attributable to pharmaceutical services, which reached 11.5 per cent in 1995 (see Figure 1). This rise in expenditure is a result of growth in both the total number of prescription items dispensed and the average cost per prescription item – the two components which comprise the total net ingredient cost (NIC) of all prescription items. The number of prescription items dispensed in England account for approximately 87 per cent of the total UK figure and as such significantly influence trends in the NHS as a whole. The main trends between 1985 and 1995 for prescription items dispensed in England were as follows (see Table 1):

- The number of prescriptions dispensed increased from 342 million to 473 million, an increase of 38 per cent.
- Prescription items per head increased from 7.2 to 9.7, an increase of 35 per cent.
- The average net ingredient cost of a prescription item increased from £3.90 to £7.78, an increase of 25 per cent at constant prices, as adjusted by the GDP deflator.
- The net ingredient cost of prescription items dispensed increased from £1,334 million to £3,681 million, an increase of 74 per cent at constant prices, as adjusted by the GDP deflator.

The prescribing trends outlined above show the significant impact that both the volume and cost of prescriptions make on the size of the medicines bill. Such data is, however, unable to explain the reasons for growth. Accordingly, variance analysis techniques have been employed to gain a greater understanding of the factors responsible.

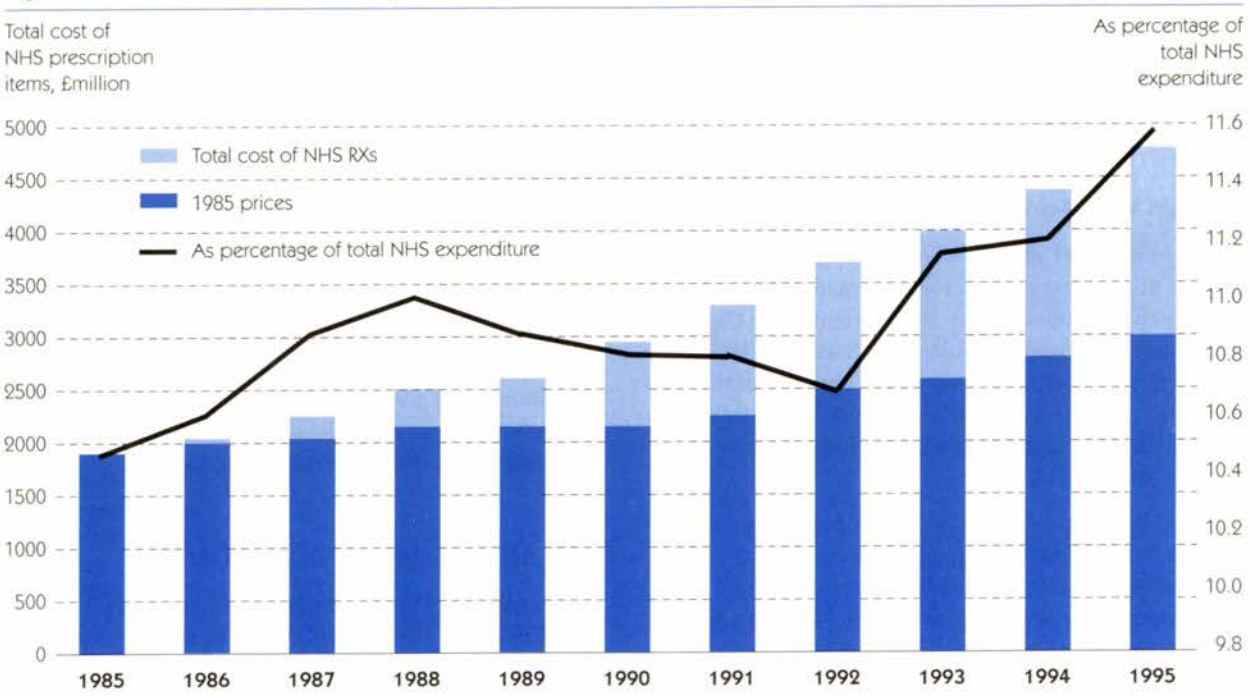
Table 1 **Number and cost of prescription items dispensed in FHSAs in England, 1985-1995**

	Number of items (millions)	*Prescription items per head*	*Total net ingredient cost (£m)*		*Average net ingredient cost per prescription (£)*	
			Actual prices	*1985 prices*	*Actual prices*	*1985 prices*
1985	341.8	7.2	1333.5	1333.5	3.90	3.90
1986	346.7	7.3	1458.5	1415.8	4.21	4.08
1987	361.6	7.6	1643.9	1515.1	4.55	4.19
1988	375.5	7.9	1864.6	1610.7	4.97	4.29
1989	383.5	8.0	2027.0	1636.7	5.29	4.27
1990	394.8	8.2	2242.7	1677.0	5.68	4.25
1991a	413.9	8.6	2519.8	1770.7	6.08	4.28
1991b	406.5	8.4	2519.8	1770.7	6.20	4.36
1992	425.1	8.8	2858.0	1927.3	6.72	4.53
1993	445.4	9.2	3158.5	2070.5	7.09	4.65
1994	456.0	9.4	3403.8	2192.1	7.47	4.81
1995	473.3	9.7	3680.6	2314.4	7.78	4.89

Notes:
1. 1985 to 1991a data are from the PD1 series of forms and based on fees. They cover prescriptions dispensed by community pharmacists and appliance contractors, dispensing doctors, and personal administration.
2. 1991b to 1995 data are from the new PCA system based on items and have the same coverage as Note 1 above
3. Figures at 1985 prices are calculated using the Treasury GDP deflator.
4. Net ingredient cost refers to the cost of the medicine before discounts and does not include any dispensing costs or fees.

Source: Department of Health statistical bulletin 1996/17.

Figure 1 **The Medicines Bill, Family Health Service Authorities, 1985-1995, UK**



Notes:

1. Total cost includes net ingredient cost, dispensing fees paid to pharmacists, container and on-cost allowances, oxygen payments and value added tax for appliances. Total cost shown also includes charges paid by patients, as well as prescriptions written by GP fundholders but dispensed by chemists.
2. Figures at 1985 prices are calculated using the Treasury GDP deflator.
3. Total NHS cost excludes charges to patients.
4. Figures are based on Family Health Services Authority dispensed prescription items and do not include Hospital and Community Health Services dispensed prescriptions.

Source: Office of Health Economics Compendium of Health Statistics, 1997.

2 SUB-ANALYSIS OF THE ELEMENTS OF GROWTH

2.1 VARIANCE ANALYSIS

Variance analyses provide data on the drivers of growth at an aggregated level. Contrasting techniques have been developed by the Department of Health (DoH) and Intercontinental Medical Statistics (IMS). Although both techniques involve analysis of past trends in medicines expenditure the DoH and IMS have different approaches for the collection and analysis of the data.

IMS and DoH produce similar, but not identical, total annual growth figures. There is, however, a discrepancy between the values attributed to the component parts of total growth. The estimated total annual growth rates and the varying components analysed by the two approaches are shown in Table 2. Both analyses indicate that the main driver of total cost /sales value is a combination of the shift from prescribing older medicines to newer, more expensive items (the product mix effect) and the increase in the number of and size of prescription items (the volume effect). The DoH approach separates these effects and shows that the shift to more expensive items has a bigger effect than the increase in the number of prescription items. IMS combine these two effects as a 'volume increase', which contributes approximately 75-80 per cent of the total annual overall growth. 'Pure' price increases for those medicines which were on the market a year ago and changes in the 'size' of a prescription item (tablets, bottles, packs, etc.) account for the remainder of the growth.

2.2 RECONCILIATION OF APPROACHES

Reconciliation of DoH and IMS indices was first carried out in 1994, using 1992-3 data. The overall growth in cost/sales value for the 25 selected products analysed was 13.5 per cent for IMS approach and 12.5 per cent for the DoH approach. The exercise was repeated using data for 1993-4. The main findings of the reconciliation are shown in Table 3.

The reconciliation of the DoH and IMS indices shows that overall annual growth estimations are very

Table 2 **Analysis of the percentage changes in NHS spending, 1989-1995**

	IMS							*DoH*						
	Overall growth	*New products*	*Line extensions*	*Price*	*Volume*	*Interaction*	*Residual*	*Total NIC increase*	*Items/head + pure demogr'y*	*NIC/Rx (existing)*			*Entry effect*	*Exit effect*
										Price/ Rx	*Quantity/ Rx*	*Product mix residual*		
	(sum 1-6)	*(1)*	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*	*(sum 1-6)*	*(1)*	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*
1989	10.0	0.9	1.1	1.8	4.8	0	1.5	9.0	1.7	2.2	–1.1	5.1	2.3	–1.3
1990	10.6	1.0	0.3	1.7	7.0	0	0.6	10.1	2.5	–0.3	1.9	5.3	0.7	–0.2
1991	11.9	0.9	0.8	1.3	8.4	–0.2	0.7	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1992	14.0	1.0	1.0	0	11.0	0	1.0	13.4	4.7	0.6	0.6	9.1	1.7	–3.5
1993	11.0	0.8	0.6	–0.9	10.1	–0.3	0.8	10.5	4.8	–3.2	2.3	5.2	1.3	0
1994	8.3	0.7	0.6	–1.6	8.3	–0.2	0.5	7.8	2.4	–2.0	0.7	4.3	2.7	–0.4
1995	8.7	0.8	0.7	–0.2	6.6	–0.1	0.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Notes:
N/A=figures not available.
IMS data:
1. All new products introduced during the year.
2. New packs, either new formulations or new strengths.
3. Changes in prices of existing products, excluding new products and line extensions.
4. Changes in sales of existing products in packs, excluding new products and line extensions.
5. Interactions between simultaneous price and quantity changes.
6. Discontinued products and packs, and new packs of existing form strengths.
DoH data:
1. The data are from the PCA data based on items dispensed in England.
2. The data cover prescriptions dispensed by community pharmacists and appliance contractors, dispensing doctors and personal administration.
3. Figures based on cash terms.
4. Figures are not available for the increase of 1991 over 1990 as prior to 1991 data are based on fees, from 1991 data are based on items.
5. Price/Rx is a Paasche price index measuring how much of overall change in average NIC per prescription item of existing preparations can be attributed to the change in the price of individual preparations.

Sources: Intercontinental Medical Statistics, Department of Health SD1E.

Table 3 **Comparison of variance analyses of expenditure growth, 1993/4**

DoH approach	*% increase*	*DoH approximation to IMS approach*	*% increase*	*IMS approach*	*% increase*
Increase in total NIC	12.5	Increase in total NIC	12.5	Increase in total sales	14.4
Increase in average NIC (all)	7				
Entry effect	0.0	Growth due to new preparations	0.1	Growth due to new products	0.0
				Growth due to line extensions	0.2
Paasche price index	–2.5	Laspeyres price index	–2.4	Growth due to price changes	–1.9
Increase in number of prescription items	5.1	Price-weighted quantity index	15.2	Growth due to volume changes	15.1
Quantity per prescription index	0.4				
Product mix effect	9.3	Growth due to interaction	–0.4	Growth due to interaction	–0.4
Exit effect	0.0	'Residual growth'	0.0	Residual growth	1.4

Table 4 **Number and cost of prescriptions dispensed by selected British National Formulary (BNF) therapeutic groups, England, 1985-1995**

	Number of prescriptions (million)			*NIC of prescriptions (£ million)*			*Average NIC per prescription (£)*		
BNF Chapter	*1985*	*1995*	*% change*	*1985*	*1995*	*Real % change**	*1985*	*1995*	*Real % change**
All groups	341.8	473.3	38	1333.5	3,680.6	74	3.90	7.78	25
Gastro-intestinal system	21.1	38.2	81	118.5	532.0	182	5.60	13.95	57
Cardiovascular system	53.9	85.3	58	283.1	658.4	46	5.26	7.72	–8
Respiratory system	34.9	46.8	34	130.1	457.6	121	3.73	9.78	65
Central nervous system	64.1	86.0	34	151.6	447.8	86	2.36	5.20	38
Infections	40.5	53.7	33	118.6	239.7	27	2.93	4.47	–4
Endocrine system	11.7	27.7	137	60.2	295.1	208	5.13	10.67	31
Musculoskeletal & joint diseases	20.2	25.5	26	164.1	193.5	–26	8.11	7.59	–41

Notes:

1. *In real terms, as adjusted by the GDP Treasury deflator.
2. Figures for 1985 are based on fees and on a sample of 1 in 200 prescriptions dispensed by community pharmacists and appliance contractors only. Figures for 1995 are based on items and cover all prescriptions dispensed by community pharmacists, appliance contractors, dispensing doctors and prescriptions submitted by prescribing doctors for items personally administered. The total for 1985 includes some items which cannot be assigned to a therapeutic group in BNF terms.
3. Therapeutic classes are based on the British National Formulary (September 1994).
4. The net ingredient cost (NIC) refers to the cost of the medicine before discounts and does not include any dispensing costs or fees.

Sources: Office of Health Economics, Department of Health statistical bulletin 1996/17.

similar given the variations in the data sets and the methodology used. For the purposes of this paper, however, the more disaggregated DoH analysis provides a greater insight in to the factors driving expenditure growth. Detailed analysis and discussion of the variations in data sets, methodology used, and results obtained in this reconciliation exercise are contained in Annex A.

2.3 THERAPEUTIC TRENDS

Analysis can also be undertaken at the level of individual therapeutic areas. The significant variations in prescribing trends between therapeutic groups are shown in Table 4.

- Medicines for the cardiovascular system comprise the largest grouping in terms of total NIC, at a cost totalling £658m in 1995. The 46 per cent increase in the total NIC of prescriptions relating to the cardiovascular system reflected the large increase in the total number of prescriptions dispensed from 53.9m in 1985 to 85.3m in 1995; in real terms the average NIC per item decreased by 8 per cent over the period. Greater dispensing of nitrates, calcium-channel blockers, potassium-channel activators, medicines affecting the reninangiotensin system, anti-hypertensives, and anti-platelet medicines have had a particularly significant effect on the growth in the number of cardiovascular system medicines dispensed.

- Much of the 121 per cent real growth in the NIC of prescriptions for the respiratory system is a result of the increased dispensing of inhaled corticosteroids in asthma management. Inhaled corticosteroids have a higher average NIC than other forms of asthma treatment.

- The development of ulcer-healing drugs, most notably cimetidine and ranitidine, and more recently omeprazole, has been responsible for much of the increase in both the number of prescriptions dispensed and the NIC of prescriptions for the gastro-intestinal system.

- For the musculoskeletal and joint diseases therapeutic group there has been a decrease in both the total NIC of prescriptions and the average NIC per prescription (measured in real terms) despite the number of prescriptions rising by 26 per cent over the period. Medicines coming off patent since 1985 and now being available in a generic format, notably ibuprofen, naproxen, diclofenac sodium and indomethacin, have been mainly responsible for the decline in 'real' average cost per prescription between 1985 and 1995.

In an attempt to gain a clearer understanding of the expenditure growth this paper focuses primarily on the factors driving volume growth and product mix effects, shown by variance analyses as being the key components of growth. We then look at one particular disease category, asthma, to see how the drivers impact on an individual therapeutic area. The analysis carried out of the asthma market is presented in detail in Annex B.

3 DRIVERS OF GROWTH OF THE MEDICINES BILL

3.1 PHARMACEUTICAL INNOVATION AND THE PRODUCT MIX EFFECT

Pharmaceutical innovation is a significant supply side factor impacting upon the size of the medicines bill. Its impact on expenditure is influenced by the cost of developing new medicines, the rate at which new medicines are brought to market (the rate of innnovation) and the degree of market penetration which the new medicines achieve. The costs of bringing a product to market are likely, in the long run, to influence companies' pricing policies and hence the level of medicines expenditure.

Current evidence indicates that the cost of bringing a new product to market is increasing. The two most authoritative studies estimating the cost of bringing new medicines to market were based on samples of new chemical entities (NCEs) first entering human testing in specified time periods (Hansen, 1979; DiMasi et al, 1991). The earlier study examined 67 NCEs, discovered and developed by 14 US pharmaceutical companies, that first entered human trials between 1963 and 1975. The later study examined 93 NCEs, from 12 US companies, that first entered human trials between 1970 and 1982. Hansen and DiMasi et al employed different assumptions to generate their estimates, such as varying cost of capital rates, and the results are, therefore, not wholly consistent. However, the similar methodology and data sources used means that comparison of results is justifiable (Office of Technology Assessment, 1993). The authors of the studies constructed a time profile of expenditure made throughout the development period. Combining the time profiles with data on the survival experience of the NCEs being studied enabled estimations of the average cash outlay for clinical research to be made. The total cash outlays per successful NCE were estimated at $65.5 million and $127.2 million (all in 1990 dollars) by Hansen and DiMasi et al, respectively. This represents an increase of 94 per cent in the estimated real outlay per successful NCE over the period of the two studies. Using the midpoint of the study years to calculate the rate of increase in cash outlays these studies indicate that real R & D cash outlays per successful NCE increased at 9.5 per cent per annum in the study years[1]. Based on the same calculation principle total R & D costs capitalised to the date of approval for marketing rose from $108 million to $259 million (all in 1990 dollars). This is a real increase of 139 per cent, or 12.4 per cent per annum.

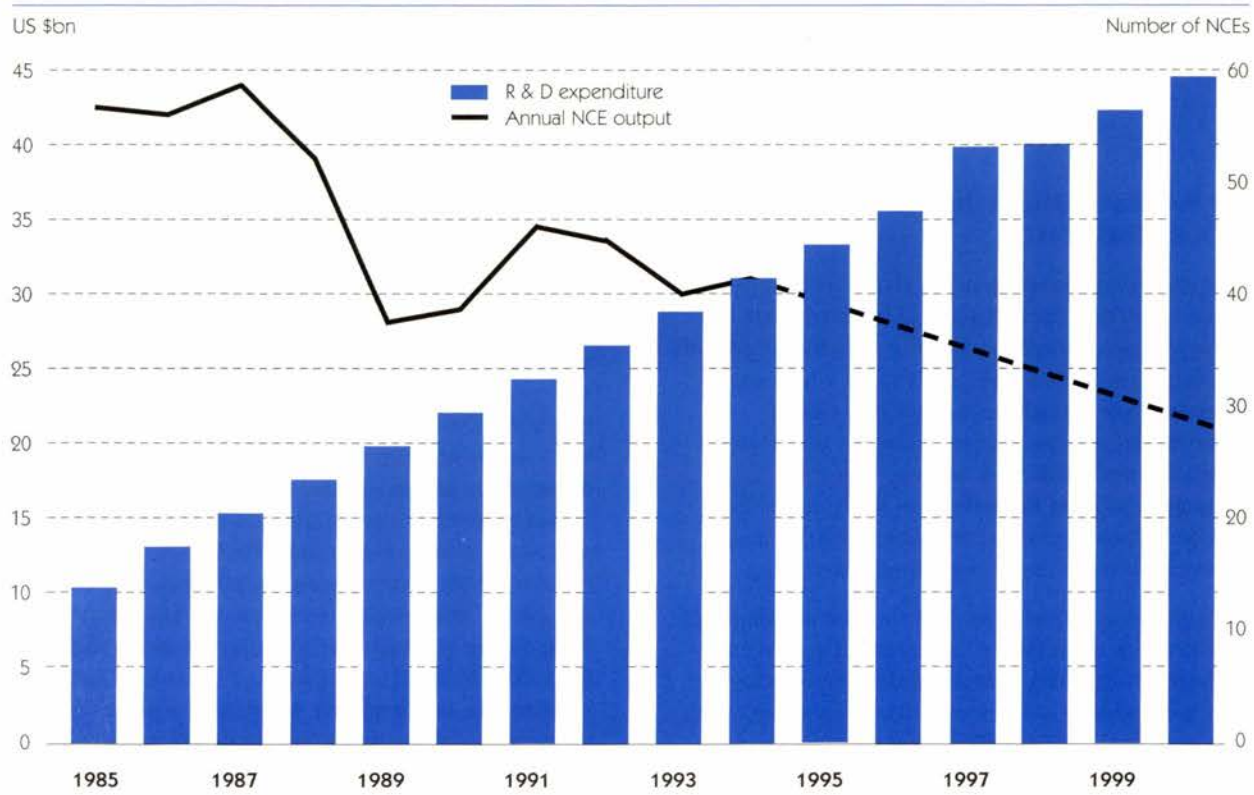
Although estimations have not been made on the cost of bringing an NCE to market in the 1990s there is evidence to suggest that the reported upwards trend in costs is continuing. The pharmaceutical industry in the UK spent £1.64 billion in 1993 on the research and development of new medicines, an increase of 15.1 per cent over 1992 (Centre for Medicines Research, 1995a). Pharmaceutical R & D expenditure in 13 major pharmaceutical producing nations increased in nominal terms from approximately $8 billion in 1985 to over $22 billion in 1991 [an approximate 60 per cent increase in real terms (Centre for Medicines Research, 1995b)], whilst the number of NCEs reaching the market has decreased from 58 in 1985 to 40 in 1993 (Centre for Medicines Research, 1995a) (see Figure 2). Pharmaceutical companies are attempting, however, to constrain the rising cost of bringing an NCE to market, using measures aimed at reducing the lead times to market and at better project selection so increasing the probability of a medicine reaching the marketplace.

In general, the quicker the rate of diffusion the greater will be the upwards pressure on NHS medicines expenditure, as new products will achieve increasing sales at the expense of older, cheaper products. The rate of movement in market share from old to new pharmaceutical products can be seen in Figure 3. This charts the market share of products by age, at 3-year intervals, from 1978 to 1993. In 1984, for example, 75 per cent of the UK medicines bill was spent on products which were launched in or before 1978. This figure had dropped to 32 per cent by 1993, a reflection of the shift towards newer products, particularly those first marketed from 1981.

A deflationary product mix effect will occur as products experience market erosion due to price competition from other innovative products during the patent period and from generics after patent expiry. The market share life-cycle stages of a

1. Comparison of the midpoints of the study years may understate the true difference in time between the two studies and may therefore overstate the rate of change over the time period. Although the database from which the sample of NCEs in each study was drawn shows the median years for self-originated NCEs receiving investigational new drugs in the two studies were 7 years apart, the cost estimates in the early study were based more heavily on the older NCEs in the sample than were the cost estimates in the second study. If a steady upward trend in the real cost of R & D was occurring throughout the decades of the two studies, the cost estimates of the early study would be biased downward (Office of Technology Assessment, 1993).

Figure 2 **Pharmaceutical R & D: expenditure and output of NCEs**



Notes:
1. R & D expenditure based on 13 major pharmaceutical producing nations.
2. Regression analysis of annual NCE output on to a 20 country market.

Source: Adapted from Centre for Medicines Research News, 1995

pharmaceutical product, principally growth and decay, are illustrated in Figure 4. Analysis is based on product cohorts launched during a 5-year period from pre 1954 through to 1993. Figure 4 demonstrates that pharmaceutical products are subject to successive waves of replacements. During the period analysed a product typically matured in about 5 years, and dominated the market for a further 5 years before encountering market share erosion. In recent years products have experienced a reduced period of peak sales.

The replacement of older products with newer, more expensive products is clearly a key driver of medicines bill expenditure. The deflating effect of increasing generic competition (see Table 9) has not been sufficient to offset this. Trends in R & D expenditure, NCE output, rates of diffusion and period of peak market sales all suggest that the significant impact on the medicines bill of product mix effects will continue over time.

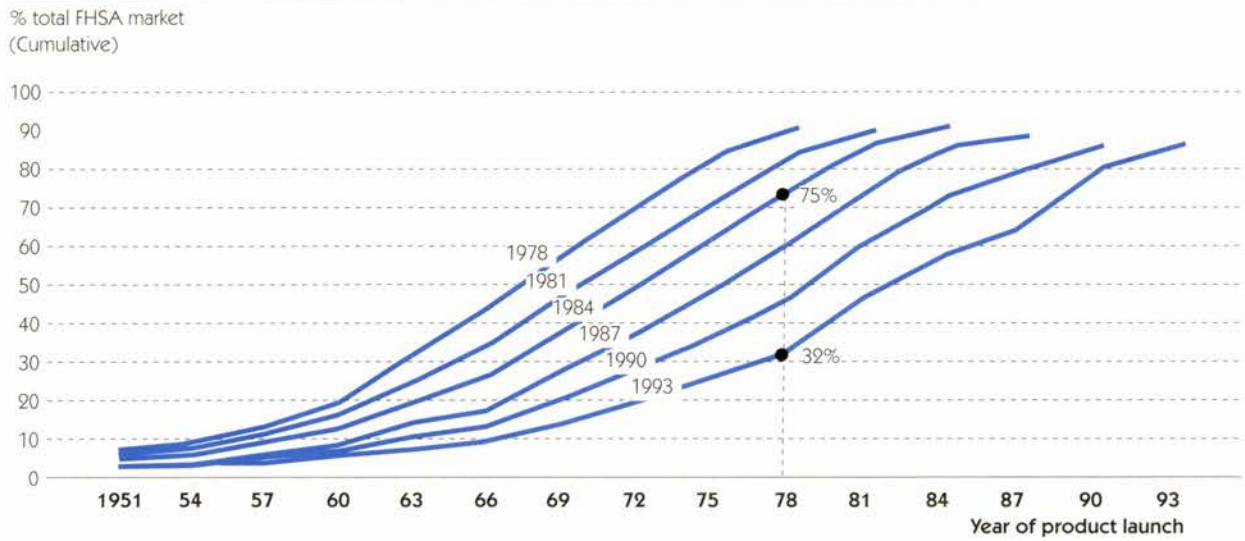
3.2 IMPACT OF GOVERNMENT SUPPLY SIDE POLICIES

The main policy tools available to the government for controlling rising pharmaceutical expenditure, whilst seeking to encourage innovation and retain clinical freedom, are outlined below:

- Pharmaceutical Price Regulatory Scheme (PPRS): The principal method used to ensure that the NHS pays a fair price for its pharmaceuticals that rewards the R & D investment of the Industry and thus, in turn, promotes the continued presence in the UK of a strong pharmaceutical industry. It is a voluntary agreement negotiated between the Department of Health and the suppliers of branded medicines. The PPRS places constraints on the maximum level of profits that pharmaceutical companies can make on the capital that they have invested in plant for research, development and manufacturing for sales made to the NHS. As such, the PPRS has the effect of constraining pharmaceutical price increases and, therefore, medicines bill expenditure growth. The variance analysis in Table 2 on page 12 suggests price increases made a negative contribution overall to expenditure growth during the period 1989-95. The effectiveness of the PPRS in restricting product price increases after launch was demonstrated in a study comparing UK and USA pharmaceutical prices (General Accounting Office, 1994). The study found that prices were slightly lower at launch in the UK than in the USA, but the gap grew as the product aged due to post-launch price increases in the USA.

- Selected List: This consists of a variety of named medicines from various therapeutic areas which cannot be prescribed on prescription under the NHS.

Figure 3 **Market share of prescription items dispensed by year of launch, UK (Family Health Service Authority sector)**



Notes:
1. All figures are based on year of launch
2. Market share includes generics but they are not included in the graph as their years of launch are unknown. Market share does not, therefore, total 100 per cent.
3. Data covers prescription items dispensed by chemist and appliance contractors of the FHS Pharmaceutical Services.

Source: Office of Health Economics.

Figure 4 **Market share of prescription items dispensed by period of launch, UK (Family Health Service Authority sector)**

Notes:
1. Data covers prescription items dispensed by chemist and appliance contractors of the FHS Pharmaceutical Services.
2. Market share includes generics but they are not included in the graph as their years of launch are unknown. Market share does not, therefore, total 100 per cent.

Source: Office of Health Economics.

The List, introduced in 1985 and extended in 1993, mainly consists of branded products and therefore encourages the use of generic medicines. Any future extension of the Selected List would produce a one-off deflating effect on the medicines bill; although restricting patient access to particular medicines may result in increasing total health care costs.

3.3 GROWTH IN THE SIZE OF THE TREATED POPULATION

- **Patient demography**

AGE: The increase in the number of prescriptions dispensed to elderly people has been the principal volume driver of medicines expenditure in England since the inception of the NHS in 1948. Prescriptions to the elderly have increased in absolute terms, per capita, and as a percentage of the total number of prescription items dispensed. This growth is a result of an increase in the number of elderly people (65+), both in absolute terms and as a percentage of the total population (see Figure 5), and of changing treatment patterns. These may reflect the introduction of new interventions or from a realisation that the expected health gain available from existing treatments is sufficient to justify treatment. Elderly patients may also have greater expectations of receiving treatment. Between 1985 and 1995 the number of prescription items per person dispensed to the elderly increased by 49 per cent compared with an increase of 4 per cent in the total number of elderly.

The elderly are the largest per capita consumers of medicines (see Figure 6A). Amongst the elderly there is significant variation in prescription per head usage, with persons 75 years of age and over having approximately double the per capita consumption of medicines compared with persons aged 65-74 (Griffin, 1990). There has been a larger growth in the number of prescriptions per head for the elderly than for any other age group. As Figure 6A shows, prescriptions per head dispensed to the elderly have increased by 49 per cent between 1985 and 1995 whereas the increase in the number of prescriptions per head for all age groups over that time period was 29 per cent[2]. The average NIC per prescription item for the elderly, £7.55 in 1995, is, however, slightly lower than the combined average NIC for all age groups, which totalled £7.81 in 1995 (see Figure 6B).

The NIC per person is therefore greater for the elderly than for any other age group (see Figure 6C). In 1995 the average NIC per person for all ages was £68.70, compared with £164.40 for elderly people.

The growth in the number of elderly people resident in England has plateaued during the 1990s. However, the proportion of the elderly population aged 85 and over (the largest users of medicine) has continued to increase during this decade. Demographic factors will continue to exert an upwards pressure on the medicines bill well in to the next century. Population projections predict the number of elderly people will again increase after 2001. Elderly people (65+) constituted 15.8 per cent of the total England population in 1991. It is predicted that this figure will rise to 23 per cent by 2031, with the increase being most pronounced from 2001 onwards (see Figure 5).

The largest percentage growth will occur in the 85 and over age group. It is anticipated that the number in this age group expressed as a percentage of the total England population will double from 1.6 per cent in 1991 to 3.2 per cent in 2031.

In response to the significant disparity in medicine utilisation between individuals, particularly with respect to age, Roberts and Harris (1993) derived demographic weightings for use in analysing general practitioners' prescribing[3]. The authors constructed the weightings to reflect the relative cost of prescribing to different sections of society[4]. The weightings they calculated were based on prescribing data obtained from the VAMP research data bank for 90 practices, in 80 family health service authority areas, with list sizes in excess of 1500 registered patients, for the year ending 31 March 1991. The relative frequency with which items were prescribed was calculated, for each sex, in nine age bands and for temporary residents. As the prescribing unit weightings are age, sex and temporary resident originated, they have been given the acronym ASTRO-PUs.

The study showed that age was the most important factor when analysing per capita item utilisation. Male utilisation was fairly constant from childhood to the 35-44 age group, after which it rose considerably (see Table 5). In women the rate increased from the

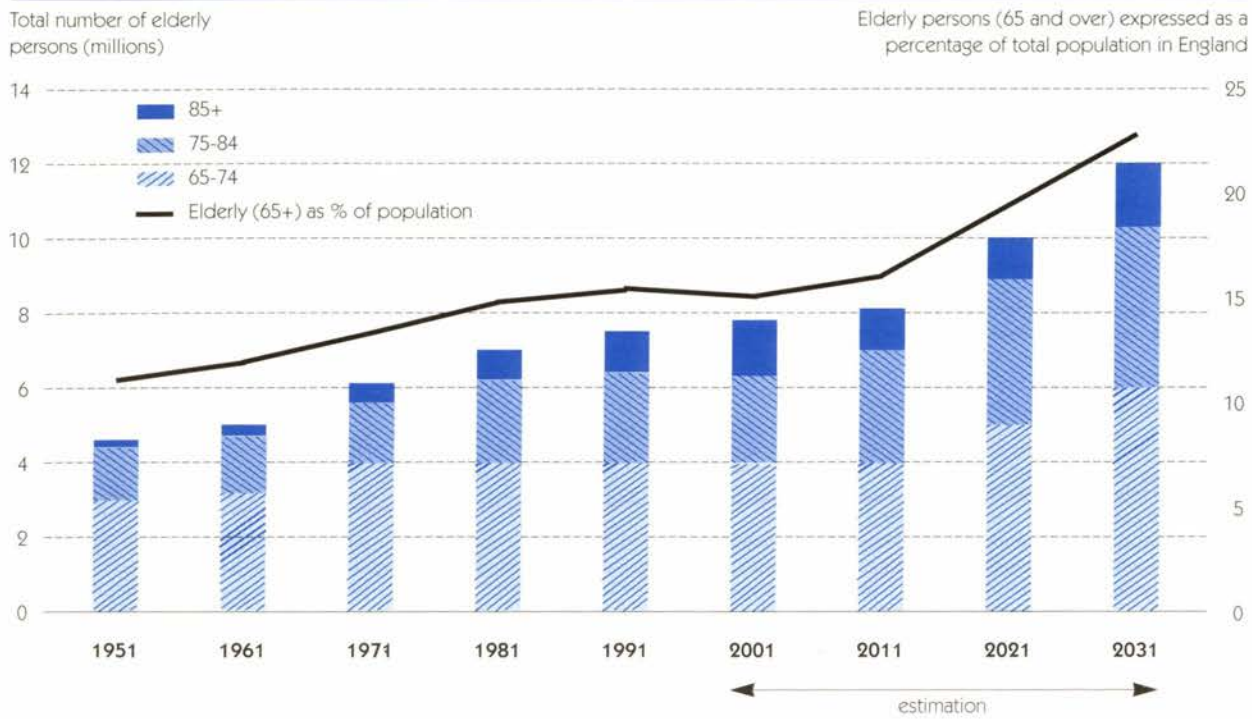
Table 5 **Estimates of item based and cost based relative prescribing rates for age-sex patient groups ('males 0-4' standardised to 1)**

Age (years)	*Male*		*Female*	
	Item	*Cost*	*Item*	*Cost*
0-4	1.00	1.00	0.91	1.00
5-14	0.58	1.75	0.57	1.75
15-24	0.45	2.85	0.84	2.15
25-34	0.44	3.00	0.95	2.15
35-44	0.59	3.25	1.03	2.70
45-54	0.91	3.25	1.55	2.75
55-64	1.82	3.15	2.43	2.50
65-74	3.18	2.05	3.70	2.50
75+	3.46	2.70	5.10	2.25

Source: Roberts and Harris (1993).

2. Does not include prescriptions dispensed by dispensing doctors.
3. A weighting factor for prescribing was first introduced in 1983 by the Department of Health. Each patient under 65 years of age counted as one prescribing unit and each patient aged 65 and over counted as three.
4. This study, along with others discussed later in this section, looked at the importance of age and other factors in explaining differences in prescribing patterns amongst GPs at one point in time. Care has to be taken drawing conclusions from this cross-sectional analysis about changes in prescribing over time. These studies have been used to help set prescribing targets for GPs and, as discussed below, the findings have been confirmed by later studies.

Figure 5 **England home population aged 65 years and over, 1951-2031**



Note:
1. Figures for 2001 to 2031 are estimates.

Source: Office for National Statistics, Census Marketing.

5-14 age group throughout life. As in other studies (see earlier) males were shown to have lower item utilisation rates than females for all age groups, except in the two youngest groups (0-4 yrs and 5-14 yrs). The generally higher item utilisation rates of females compared with males were not repeated when item cost was also considered (see Table 5). Although cost per item rates increased for both sexes from childhood until the 45-54 age group, the male cost-based prescribing rate was typically higher than the female equivalent. Taken as a whole the ASTRO-PU cost-based system suggests that there should be a large differential in weighting between young and old (see Table 6).

Table 6 **Integer scales for cost based prescribing rates. The ASTRO-PU**

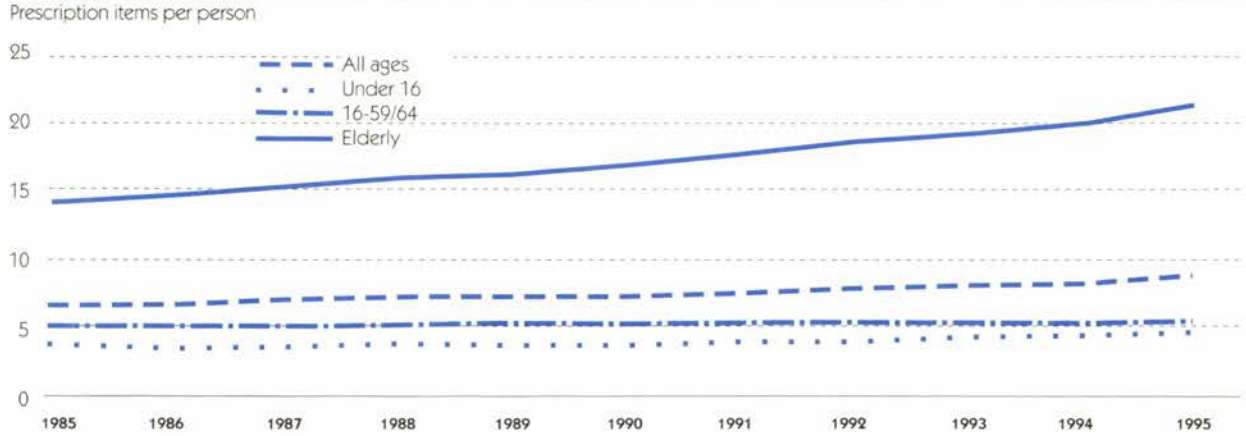
Age (years)	*Male*	*Female*
0-4	1	1
5-14	1	1
15-24	1	2
25-34	1	2
35-44	2	3
45-54	3	4
55-64	6	6
65-74	10	10
75+	10	12

Source: Roberts and Harris (1993).

A further study attempted to derive cost based weightings, using the demographic bands of the ASTRO-PU system, for GP prescribing for 8 eight specific therapeutic groups (Lloyd et al, 1995). The weightings (specific therapeutic group age-sex related prescribing units, STAR-PUs) were calculated from one year's prescribing data, covering 112 English practices with 739,672 patients, held on the MediPlus database. The weightings showed a large variation in prescription usage for different age-sex bands between the therapeutic groups (see Table 7). The gastrointestinal and cardiovascular medicine groups were the most demographically sensitive with age as the most important factor. Sex difference was of most importance in the endocrine group of medicines.

The new dataset allowed for comparison between cost based weightings (STAR-PUs) and ASTRO-PU values. There was encouraging similarity between the values despite being derived from the prescribing of different doctors, in a different year, and by a different method. The authors estimated that the ASTRO-PU weightings accounted for about 25 per cent of the variation in costs between practices at a national level. The authors have since found that the weightings account for up to 50 per cent of the variation in prescribing cost per head of population at FHSA level. Although the research indicates that demography is a key component of prescribing costs it is clear that factors other than the age and sex of a

Figure 6A **Prescription items per person by age group, England 1985-95**



Notes:
1. The age related analysis is based on a 1 in 20 sample of all prescriptions submitted to the PPA by community pharmacists and appliance contractors only.
2. The calculation of the number of prescriptions per head for children includes prescriptions from April 1988 of persons under 19 in full time education, although the population figure used is for children and young people aged 15 years and under only.
3. 'Elderly people' includes men aged 65 and over and women aged 60 and over. From 20 October 1995 'Elderly people' includes men aged 60 and over although the population figures used in 1995 are still for men aged 65 years and over and women aged 60 and over.
4. NIC refers to the cost of the drug before discounts and does not include any dispensing costs or fees.
5. ONS mid-year population estimates have been used.
6. 1985 to 1990 prescription data are based on fees; 1991 to 1995 prescription data are based on items.

Source: Adapted from Department of Health Statistical Bulletin 1996/17, Department of Health Statistical Division 1E.

practice population influence prescribing patterns to an even greater degree. The weightings for both ASTRO-PUs and STAR-PUs are likely to require occasional adjustment to reflect variations over time in the prescribing trends of general practitioners. The population projections discussed earlier could be used in conjunction with the ASTRO-PU and STAR-PU weighting systems as a tool in estimating future trends in the size of the medicines bill.

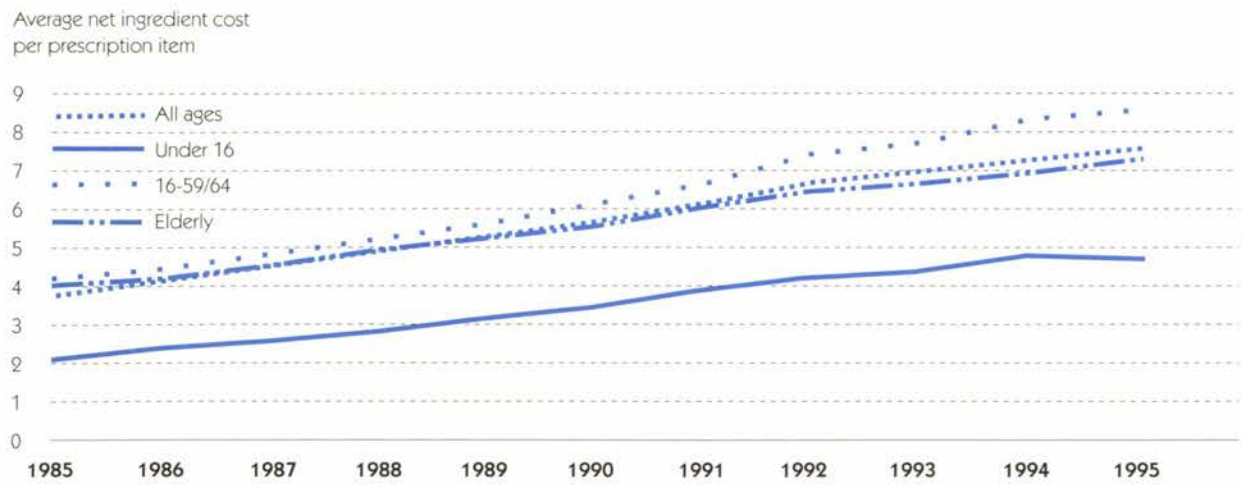
GENDER: As well as the elderly being bigger users of medicines than younger age groups in society, it is also consistently reported that women use a greater number of prescribed medicines than men do (Roberts and Harris, 1993; Ferguson, 1990; Svarstad, 1987; Wells, 1985; Verbrugge, 1985). Differences in gender utilisation rates are most apparent in medicine groups which have an obvious relationship with a woman's reproductive system. (Zadoroznyj and Svarstad, 1990). The multiple roles that many women fulfil (homemaker/parent/paid employee) and variations in employment levels between genders have also been offered as possible reasons for differences in utilisation rates (Gore et al, 1983; Arber et al, 1985). Since there are approximately 46 per cent more women than men of sixty-five years of age and over in the UK (based on figures for 1995) this has led many to presume that sex demography plays a key role in determining the total number of prescriptions used. However, the impact on the medicines bill of increased medicine utilisation by females is likely to diminish gradually over time as

Table 7 **Cost based weightings (STAR-PUs) for five specific therapeutic groups by age and sex of patients and temporary resident status**

	Gastrointestinal		*Cardiovascular*		*Respiratory*		*Central nervous system*		*Endocrine*	
	M	*F*	*M*	*F*	*M*	*F*	*M*	*F*	*M*	*F*
0-4	0	0	0	0	3	2	1	1	0	0
5-14	0	0	0	0	5	4	1	1	1	1
15-24	1	1	0	0	4	4	2	2	2	1
25-34	3	2	0	0	2	3	3	4	1	3
35-44	5	4	3	2	3	3	4	7	1	6
45-54	8	8	9	7	3	4	6	10	1	13
55-64	15	15	27	21	6	8	8	11	2	12
65-74	23	23	42	36	12	10	10	13	3	4
75+	30	33	41	38	13	6	16	20	3	2

Source: Lloyd et al, 1995.

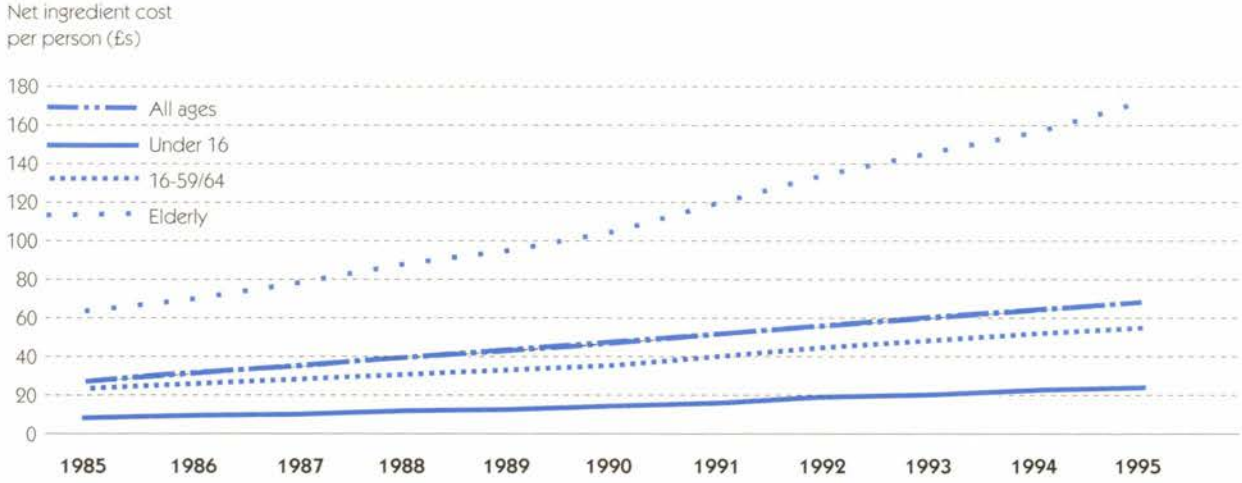
Figure 6B **Average net ingredient cost per prescription by age group, England 1985-95**



Notes:
See Figure 6A.

Source: Adapted from Department of Health Statistical Bulletin 1996/17, Department of Health Statistical Division 1E.

Figure 6C **Net ingredient cost per person by age group, England 1985-95**



Notes:
See Figure 6A.

Source: Adapted from Department of Health Statistical Bulletin 1996/17, Department of Health Statistical Division 1E.

population predictions estimate a narrowing in the divide between the number of males and females aged sixty-five and over resident in the UK. The differential will be reduced to 30 per cent by 2011 (Annual Abstract of Statistics, 1995). The increase in the ratio of elderly males-to-females during the next century will occur for two main reasons. Firstly, there will be a significant one-off rise in the numbers of men reaching pensionable age as the effects of the two World Wars disappear. Secondly, male life expectancy is increasing at a faster rate than that for females. UK male life expectancy is forecast to increase by 5.7 per cent between 1995 and 2025, as opposed to 2.6 per cent for women (United Nations, 1992).

UNEMPLOYMENT AND DEPRIVATION: There is a well documented association between deprivation in a community and morbidity and mortality (Carstairs and Morris, 1989; Marsh et al, 1986; Black, 1980). Using time series data provided from the OPCS Longitudinal Study Moser et al. (1984, 1986, 1987) reported that the mortality rate of unemployed men aged 15-64 in the period 1971-81 and 1981-83 was higher than would be expected for all men in the same age group. Taking allowance of socioeconomic distribution resulted in an excess of 20 to 30 per cent. It was also the case that the mortality rates of wives whose husbands were unemployed were higher than that of all married women.

Table 8 **Number of prescriptions dispensed and number of patients consulting by selected British National Formulary therapeutic groups, England, 1982-1992**

	Number of prescriptions dispensed (millions)			*Number of patient consulting their GP (thousands)*		
Therapeutic group	*1982*	*1992*	*% change 1982-1992*	*1982*	*1992*	*% change 1982-1992*
All groups	311.3	425.1	37	33,308	37,749	13
Gastro-intestinal system	20.2	34.2	70	2,406	3,628	51
Cardiovascular system	48.0	73.1	52	3,375	3,556	5
Respiratory system	33.4	42.9	28	12,619	14,852	18
Central nervous system	66.4	77.1	16	875	1,200	37

Notes:
1. Prescription numbers for 1982 are based on fees and on a sample of 1 in 200 prescriptions dispensed by community pharmacists and appliance contractors only. Figures for 1992 are based on items and cover all prescriptions dispensed by community pharmacists, appliance contractors, dispensing doctors and prescriptions submitted by prescribing doctors for items personally administered. The total for 1982 includes some items which cannot be assigned to a therapeutic group in BNF terms.
2. Therapeutic classes are based on the British National Formulary (September 1993).

Source: Adapted from Morbidity Statistics from General Practice, 1981-2/1991-2, Department of Health.

Studies also support the link between material deprivation, often in association with unemployment, and prescribing levels (Forster and Frost, 1991; Townsend et al, 1988; Townsend et al, 1985). Regions (FHSAs) with the highest unemployment rates generally have the highest rates of per capita use of prescriptions (OHE Compendium, 1995). There is also, however, a strong inverse relationship between per capita use of prescriptions and net ingredient cost per prescription item within regions (OHE Compendium, 1997). Based on the evidence provided from the 90 family health service authorities in England for the year to April 1990 Pringle and Morton-Jones (1994) noted that the northern, urban areas of England were characterised by a high number of low cost items per patient, whilst the southern semi-rural areas had a low number of high cost items per patient. The urban areas had a higher overall net ingredient cost per patient. Possible explanations for this inverse relationship include (1) GPs in areas of social deprivation are prescribing products which patients in semi-rural areas would buy over the counter e.g. cough medicine (2) illness that is related to deprivation may require treatment which has below average ingredient costs (3) different demographic composition, such as varying concentrations of elderly people, results in the dispensing of more, but less expensive, items per capita.

It is clear from the evidence provided by cross-sectional studies that a correlation exists between unemployment levels and morbidity rates. As such it seems logical to expect increases in unemployment levels to result in increased utilisation of medicines. However, measuring the level of this correlation over time is extremely difficult due to the presence of confounding variables.

- **Increased notification of disease**

Increasing notification of certain illnesses has also contributed to growth in the volume of total prescriptions dispensed. The increased number of notifications may be a result of increased incidence of disease. If the number of GP consultations is used as a proxy for ill health then the evidence provided by all of the National Morbidity Surveys carried out to date suggests that there is an increasing level of aggregate morbidity in the UK. Consultation rates for the population as a whole increased from 3156.8 per 1000 population in 1971/2, to 3396.1 per 1000 persons at risk in 1981/2, to 3478.5 per 1000 person years at risk in 1991/2 (Morbidity Statistics from General Practice, 1971/2, 1981/2, 1991/2). There was not, however, a uniform rise in consultation rates across all age groups. Consultation rates for persons aged 16-44 actually declined slightly between 1971/2 and 1991/2.

Increasing incidence may, however, reflect factors other than morbidity levels. Much of the increased notification of disease is likely to be the result of greater patient awareness and reporting of particular illnesses, and increased clinician awareness and diagnosis. Media coverage has made consumers increasingly aware of, and interested in, health issues. As a result they are more likely to take the initiative in seeking treatment from their GP's. Women seeking treatment with HRT to reduce the symptoms of the menopause and to prevent osteoporosis is one such example. The introduction by the Government of the Patient's Charter initiative has continued the trend of raising a patient's awareness of their rights and what services they can expect from their GP, with the likely consequence of greater demands being placed upon the GP.

The relationship between the number of patients consulting their GP and the growth in volume of prescriptions used is detailed in Table 8. The general trend has been for the number of prescriptions dispensed by therapeutic group to increase at a greater rate than the number of patients consulting their GP. This is particularly marked with respect to

the cardiovascular system, where the number of prescriptions dispensed increased by 52 per cent whereas the number of patients consulting their GP rose by only 5 per cent. This reflects the increased dispensing of nitrates, calcium channel blockers and hypertensives. The general trend of prescriptions dispensed rising at a greater rate than the number of patients consulting is not uniform across therapeutic groups. The number of patients consulting their GP with conditions related to the central nervous system increased by 37 per cent between 1982 and 1992 whereas the number of prescriptions dispensed rose by 16 per cent. In aggregate, however, there is no evidence to suggest that the trend of increasing numbers of patients consulting their GP, and the knock-on effect of growth in number of prescriptions dispensed, will not continue in the foreseeable future.

- **Over-the-counter medicines**

Greater consumer awareness may also present itself in the purchase of over-the-counter medicines (OTCs) which can be purchased without a prescription. Increasing self-medication may reduce the rate of growth of NHS pharmaceutical costs. The OTC market was estimated to be £1,269 million in the UK in 1994 (Proprietary Association of Great Britain, 1995). In 'real' terms, growth in the OTC market was low during the 1980s, but reported growth has increased. 1992-3 sales increased by 11.3 per cent when adjusted by the RPI. OTC sales comprise 14 per cent of total medicine sales in the UK.

Although the OTC market is increasing there is little evidence to suggest that it is at the expense of the prescription only medicine (POM) market. Painkillers and cough remedies are the two largest OTC product groups sold (Proprietary Association of Great Britain, 1995). The recent increase in the number of products switched from POM to OTC (15 in 1993) has not restricted growth in the medicines bill. Available evidence indicates that patient behaviour and doctor prescribing behaviour would have to alter markedly to affect NHS medicines expenditure, even if OTC sales do continue to increase (Maynard and Richardson, 1996). Avoiding direct payment or incorrect self-diagnosis currently seem sufficient incentives for many consumers to avoid OTCs and continue visiting their GP, even with apparently trivial complaints. With approximately 84 per cent of all prescriptions being dispensed free of charge it would seem unlikely that consumer behaviour will alter radically in the short-to-medium term. As such the increase in OTC sales, although reflecting greater patient choice, is not forecast to have a significant dampening effect on the growth in medicines bill expenditure.

3.4 IMPACT OF GOVERNMENT POLICY ON PRESCRIBING

Responsibility for the level of FHS' prescribing lies ultimately with GPs. As such many government policy measures have been designed to impact on GP prescribing behaviour. The main aim of such policies has been to improve the appropriateness of prescribing within allocated budgets, not merely to act as a constraint on levels of expenditure.

- **Prescribing budgets of fundholders and non-fundholders**

The 1991 NHS reforms introduced the Practice Budget Scheme and GP fundholding. Fundholders were given a prescribing budget and the opportunity to invest any surplus made back into the practice. Non-fundholders were set an indicative prescribing budget, now called a target budget, in an attempt to contain their expenditure. It was expected that the introduction of prescribing budgets would help to contain prescribing costs, with GPs becoming more aware of medicine prices, and drive the search for more cost-effective prescribing.

Initial evidence indicated that fundholders had a lower medicines expenditure rate per patient than non-fundholders, although both fundholders and non-fundholders had increasing prescribing costs. Increased generic prescribing was cited as the main reason for fundholders attaining lower growth rates in expenditure. The ability of fundholders to sustain these lower growth rates has been examined by several studies. Their findings indicate that the reduction in costs initially achieved by fundholders declined, to the extent that after the third year the increase in annual prescribing costs of fundholders and non-fundholders were similar, although the decrease achieved in the first three years was maintained. The main studies assessing the impact of fundholding on prescribing costs are discussed in Annex C.

- **Variation in prescribing between dispensing and non-dispensing practices**

A different group of incentives operate for dispensing[5] and non-dispensing practices. Some of the profits from discounts on medicine purchases are retained by dispensing practices, in addition to them receiving a fee of 10.5 per cent on the cost of all dispensed drugs. It is therefore possible for income to be made by increasing the number of prescriptions and prescribing more expensive medicines.

The possible existence of a variation in prescribing costs between dispensing and non-dispensing

5. A dispensing doctor is a principal (unrestricted or restricted) who provides medicines to patients who either have serious difficulty in obtaining medicines from a chemist or who live at a distance of more than a mile from a chemist.

practices was examined in a study which analysed the prescribing data for 1990-1 of 108 practices in the Lincolnshire Family Health Services Authority (Morton-Jones and Pringle, 1993). Data from PD2 reports from the Prescription Pricing Authority indicated that dispensing practices had 13 per cent higher prescribing costs per patient than non-dispensing practices. The lower use of generic medicines in dispensing practices explained 84 per cent of the difference in prescribing costs. 13 per cent of the difference was due to higher numbers of patients over 65 in the dispensing practices. The authors calculated that if all dispensing practices in Lincolnshire were to reduce their average prescribing costs to that of the non-dispensing practices then a saving of £1.97m per year for Lincolnshire could have been made (1993 prices).

The number of dispensing doctors in England increased from 3,115 in 1985 to 4,122 in 1995, an increase of 33 per cent (Department of Health: GMS, 1996). However, on average each doctor dispensed to a fewer number of patients with the net effect being that the total number of patients to whom drugs were dispensed rose by less than one per cent over this period (3.12m in 1985 to 3.16m in 1995) (Department of Health: GMS, 1996). This suggests that the higher prescribing costs per patient, on average, of dispensing doctors in comparison to non-dispensing doctors should not cause significant upwards pressure on the medicines bill in the long-term.

- **Screening and health check programmes**

Health check programmes for conditions such as high/low blood pressure, smoking-related illness, and childhood immunisation have been promoted under the GP Contract, and more recently through health promotion programmes, with GPs receiving financial reward for reaching set patient take-up targets. GPs are also obliged to offer certain services without additional financial gain, such as health care programmes for the elderly. This increased throughput of patients is likely to lead to more cases being identified and increased prescribing.

- **Generic prescribing**

Doctors are increasingly being encouraged to prescribe only the generic form of a product. Encouragement may come in the form of incentive schemes or from a policy of re-education. For example many medical schools now teach a generic prescribing policy. The recent growth in the dispensing of generic prescription items (see Table 9) suggests that government encouragement of the use of generics has proved effective. The market share of prescriptions dispensed generically in England increased from 26 per cent in 1985, when the Selected List was introduced, to 45 per cent in 1995. The importance of generic prescribing in keeping down costs can be seen when comparing the average cost of a generic prescription with a branded one (see Table 9). In 1995 the average cost of a dispensed branded prescription was 4 times that of a generic.

Future trends in the mix of generic/branded products will depend upon the success of new products entering the market and the market share of products coming off patent. Zantac and Prozac, for example, are both due to be off patent by the end of 2000, thus reducing the aggregate market share of branded products. Based on the number and market share of products coming off patent it has been estimated that 60 per cent of prescriptions will be dispensed generically by the year 2000 (Griffin, 1996).

Table 9 **Percentage of items dispensed generically and average cost of generic and branded items, England, 1985-1995**

	Dispensed generically (%)	*Average cost of generic item (£)*	*Average cost of branded item (£)*	*Cost ratio of branded to generic**
1985	26	1.27	4.80	3.8
1986	32	1.40	5.50	3.9
1987	34	1.66	5.98	3.6
1988	35	1.92	6.54	3.4
1989	37	2.26	7.07	3.1
1990	38	2.49	7.62	3.1
1991a	37	2.40	8.24	3.4
1991b	35	2.37	7.99	3.4
1992	36	2.20	8.92	4.1
1993	38	2.06	9.90	4.8
1994	42	2.58	10.61	4.1
1995	45	2.85	11.35	4.0

Notes:
1. 1985-1991a data are based on fees and cover prescriptions dispensed by community pharmacists and appliance contractors only.
2. 1991b-1995 data are based on items and cover all prescriptions dispensed by community pharmacists and appliance contractors, dispensing doctors, and personal administration.
3. All data based on Prescription Cost Analysis system Class 1-3 ie: dressings and appliances are excluded.
*Cost ratio is influenced by the fact that certain branded medicines do not have a generic equivalent.

Source: Adapted from DoH Statistical bulletin 1996/17.

4 FUTURE PROJECTIONS

4.1 FORECASTING

The benefits for policy analysis of being able to predict future levels of expenditure are obvious. As such, several methods for forecasting the future size of the medicines bill have been attempted.

DoH use a model based on regression analysis incorporating forecast demographic and socio-economic changes, and past trends in prescribing patterns. Data on volume and prescription cost are projected forward using regression techniques, and adjusted as necessary for the other components of drugs bill cost. The model was developed for forecasting. It lacks explanatory power but has historically provided a reasonable fit to outturn data over the intended forecasting period (up to three years ahead). The data generated by the model are not in the public domain.

IMS have constructed a model based on regression analysis which produces forecasts for a five year period. The forecasts are for calendar years, in money terms, of sales by manufacturers to wholesalers. The model includes macroeconomic forecasts for variables such as GDP, Government consumption, and Private consumption. A forecast of sales, at manufacturers' prices, is made for the total market. Sales are split between Retail (including generics and OTCs but excluding dressings and appliances) and Hospital sales. The total retail market consists of 15 therapeutic classes. This forecast is then broken down into medicine classification groups ATC1, ATC2 and ATC3. The forecast is modified by expert opinion at all stages. As such, the analysis 'models' the data as well as 'trending' it. When the 'top-down' analysis has been carried out, a 'bottom-up' forecast is built up from sub-market forecasts. This different forecast is allowed to influence the total forecast. The final forecasts for therapeutic classes are constrained to the agreed total market forecast.

The difficulty of predicting future growth in medicines expenditure was concluded by a study commissioned by the DoH to assess the feasibility of developing an explanatory model of the medicines bill, which would provide a tool for modelling policy options and assessing their likely impact on the medicines bill. The study concluded that it would not be possible to construct a model sufficiently robust for policy analysis, due to limitations in available data and the complexity of the relationships between factors.

4.2 WHERE WILL THE MEDICINES BILL GO IN THE FUTURE?

Despite the problems associated with accurately forecasting the level of growth in medicines expenditure it is still possible to predict likely trends. The variance analyses carried out by the DoH and IMS indicate that product mix effects and volume growth are the major components of increases in the size of the medicines bill, accounting for approximately 80 per cent of total overall growth. The more disaggregated analysis carried out by the DoH indicates that the shift to more expensive items has a greater impact on medicines expenditure growth then the increase in the number of prescription items dispensed.

The product mix effect is driven predominantly by pharmaceutical innovation and the replacement by doctors of older medicines with newer, clinically superior medicines. Volume growth has been fuelled primarily by increases in the number of prescription items dispensed to elderly people – the largest per capita consumers of medicines. This mainly reflects changing treatment patterns and increases in the total number of elderly. Increased notification of particular diseases has also stimulated volume growth. Recent trends in the cost of developing new medicines, rates of diffusion and period of peak market sales indicate that product mix effects will continue exerting upward pressure on medicines expenditure. Volume growth will continue to be driven by changes in treatment patterns and an ageing population. The medicines bill can, therefore, be expected to show continued growth, at least for the medium term period. It is possible, though, that future government policies could impact significantly on levels of expenditure. However, the evidence provided from previous policy measures suggests that new measures are unlikely to affect future growth rates significantly. The aim of government policy is not simply to constrain expenditure but to encourage quality and cost-effective prescribing.

The evidence provided from the analysis of past trends in medicines expenditure indicates that future levels of expenditure will show continued real growth and comprise an increasing share of total NHS expenditure over the medium term period. Further analysis is needed, however, to reach a level of forecasting that goes beyond predicting 'likely trends'. More in-depth analysis of factors such as the impact of ageing on prescribing, the rate at which new products diffuse through the NHS market and

subsequently lose market share to generics, trends in particular therapeutic areas, and of trends in morbidity may help us achieve a greater understanding of where the medicines bill will go in the future. Any proposal would have to be carefully assessed to see if the findings were likely to be of value.

Future rates of growth of the medicines bill need to be considered within the context of the objectives of the NHS as a whole. Medicines improve patient quality of life and life expectancy and help keep down costs elsewhere within the NHS. The emphasis of analysis needs shifting more to the appropriateness and cost-effectiveness of prescribing. As such, debate over future levels of medicines expenditure should be considered alongside more economic evaluation and outcomes based research. It is important to evaluate prescribing in terms of value-for-money as well as expenditure levels.

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ANNEX A

RECONCILIATION OF DOH AND IMS VARIANCE ANALYSIS TECHNIQUES, 1993-1994

CONTENTS

SUMMARY

Introduction and background

The Department of Health (DoH) and Intercontinental Medical Statistics (IMS) use variance analysis to estimate the relative importance of the components which impact upon the rate of increase in medicines expenditure. Such analysis is useful for explaining the reasons for growth and is an aid to accurate forecasting of future expenditure levels. The DoH and IMS have contrasting approaches, and use different data sets, for carrying out analysis.

The variation in technique between the DoH and IMS has produced conflicting evidence as to what is the main factor impacting upon the rate of change in total medicines expenditure. Representatives of the DoH and IMS met in April 1994 to discuss the differences between the data and methods used to construct the two sets of indices, and agreed that reconciliation of IMS and DoH indices might aid understanding of each others analysis and of reasons for growth in the drugs bill.

The first reconciliation of DoH and IMS indices was completed in November 1994, using data for 1992 and 1993 for 25 selected products. The overall growth in cost/sales value for all selected products in the analysis was very similar; 13.5 per cent for IMS approach using their own data (UK coverage) and 12.5 per cent for the DoH approach using Prescription Cost Analysis (PCA) data (England only coverage). This paper presents the results of the second reconciliation exercise which looks at growth for 25 selected products, using data for 1993 and 1994. Results of analysis using PCA data and DoH methodology are compared with analysis using IMS data and methodology, and potential reasons for reported differences in results are discussed.

Conclusions

As with the first reconciliation exercise the DoH and IMS reported a similar overall growth in drug costs between 1993 and 1994. The analysis indicated that the main driver of total cost/sales value was a combination of the increase in the number of prescription items and the shift from prescribing older medicines to newer, clinically superior, more expensive items (the product mix effect). IMS approach does not split these two affects, describing the two together as 'volume increase'. The DoH approach does allow them to be split and shows that the shift to more expensive items has a bigger effect than the increase in the number of prescription items.

Although in aggregate the two data sets produced similar estimates of total overall growth there were comparatively large discrepancies for certain products. A detailed examination of these products was carried out. Possible explanations for the discrepancies include (1) the dispensing of branded products against generically written prescriptions (2) the pricing of generics (3) the availability of some products OTC (4) parallel imports (5) time lag between the sale by wholesalers and the dispensing of a product (6) the pricing of branded products and the discounts offered by wholesalers.

The reconciliation exercise is a methodological exercise which does not cover the total medicines bill. Its purpose is to see if consistent messages are being given for the selected products by the different data sources and methodologies used. It does not imply the same would be true for all medicines. It does however raise a number of issues which warrant possible further investigation.

I DoH approach

II DoH approximation to IMS approach

III IMS approach

6. Price-weighted quantity index includes increase in the number of prescription items, QPP index and product mix residual. It is weighted by cost per quantity unit.

DESCRIPTION OF THE VARYING APPROACHES

Indices were calculated using three approaches (1) DoH approach [using Prescription Cost Analysis (PCA) data]; (2) DoH approximation to IMS approach (using PCA data); and (3) IMS approach (using IMS data).

Variance calculations

The three approaches vary in the way net ingredient cost (NIC) or sales value is broken down. The varying approaches are shown below. The formulae used for calculating the individual components of growth are shown in Appendix 2.

Sources of data

As well as the variations in approach IMS and DoH also use different data sets (see Table 1). Any differences in the coverage or definitions used in the data sets will affect the analyses, in particular the reconciliation of the two methods. There are various fundamental differences in the two data sets used, which are set out below:

RECONCILIATION EXERCISE

Methodology

The methodology used for the analysis is outlined below.

- In order to ensure that both analyses have the same coverage we had to match the DoH preparations to IMS products,
- IMS supplied a list to DoH of the top 50 products (which included some duplication of chemical entities) in 1994 by sales value, for all products not just oral solids. DoH selected 25 oral solid preparations (which were all from different chemical entities) with a high NIC value from the PCA database for 1994, each of which belong to a product in IMS's top 50. The 25 products to which these preparations belong were the base for the reconciliation exercise. The list of 25 selected products was sent to IMS for the analysis to be done using IMS data. The products used and the chemical entities to which they belong are attached at Appendix 3.
- The generic product cimetidine is one of the products included in the analysis (while the branded product

Table 1

	IMS approach (IMS data)	DoH approach (PCA data)
a.	IMS data cover the UK.	PCA data cover England only.
b.	IMS data records all sales of the products to the dispenser.	PCA data records the prescriptions for which the dispenser has been paid. If an item is prescribed generically and there is a generic available then the dispenser is reimbursed for the generic. However, the dispenser may choose to dispense the proprietary product but still be reimbursed for the generic equivalent (e.g. if they can obtain the proprietary more cheaply then the generic). Thus the PCA data may underestimate the volume of branded products dispensed if there is a generic equivalent available.
c.	IMS data are collected from invoices from manufacturers and major wholesalers, covering sales to chemists and dispensing doctors in the UK. Thus drugs bought but not dispensed may be included in the analysis.	PPA process data of prescriptions dispensed, for England only, including dispensing by dispensing doctors and personal administration. PCA data are all prescriptions dispensed in the community.
d.	IMS data include OTC sales, some 15 per cent of the total. IMS generally could not tell from the transactions which products would be sold via prescriptions and the proportion which went to OTC or private prescriptions, apart from those which could be identified by dose level.	PPA include dispensed items only.
e.	IMS data generally assume that goods sold are consumed mainly via prescription, regardless of re-exports (not significant) and over-stocking.	PPA include dispensed items only.
f.	IMS data are based on trade prices (the official price at which the retail pharmacy purchases the product from the wholesaler), after any discounts have been taken off. While this may be quite close to the NHS Net Ingredient Cost (NIC), the rate of wholesalers discounts can be much higher than the DoH's discount rate, both in total and at product level.	PPA use net ingredient cost (NIC), the reimbursed price before discount for pharmacists and dispensing doctors.
g.	IMS price levels for generics are based on average wholesale prices, which can be lower than DoH prices.	DoH generic prices (NIC) are based on the Drug Tariff (ie before discount) and they can be very different from IMS.
h.	IMS data cover transactions of parallel imports, which are priced at UK trade prices. Products known to be parallel imports are also separately flagged and treated as a branded product.	The PPA identify the preparation in the database if it is a known parallel import, but not all parallel imports can be identified as such.

Table 2 **Comparison of variance analyses of expenditure growth, 1993/4 (including generic cimetidine)**

DoH approach	*% increase*	*DoH approximation to IMS approach*	*% increase*	*IMS approach*	*% increase*
Increase in total NIC	12.5	Increase in total NIC	12.5	Increase in total Sales	14.4
Increase in average NIC (all)	7.0				
Entry effect	0.0	Growth due to new preparations	0.1	Growth due to new products	0.0
				Growth due to line extensions	0.2
Paasche price index	–2.5	Laspeyres price index	–2.4	Growth due to price changes	–1.9
Increase in number of prescription items	5.1	Price-weighted quantity index	15.2	Growth due to volume changes	15.1
Quantity per prescription index	0.4				
Product mix effect	9.3				
		Growth due to interaction	–0.4	Growth due to interaction	–0.4
Exit effect	0.0	'Residual growth'	–0.0	Residual growth	1.4

Tagamet was not). IMS and PCA generic prices may vary because IMS use wholesale invoice prices, which include a discount factor and PCA use the drug tariff price (ie NIC before discount). It was decided the analysis should be done including and excluding the generic product cimetidine in case the inclusion of a generic product made a difference to the results.

- When IMS analysis had been completed a copy of the report, which gave a breakdown of growth in sales for each of the 25 selected products, was sent to DoH. The report showed each of the strengths and formulations included for each product. This allowed DoH to match preparations from the PCA data to the products from IMS data, which in most cases was 'many to one'. The definition of 'product' used by IMS is neither a 'preparation' nor a 'chemical entity' in the DoH's terms (see Appendix 1) and 72 preparations made up the 25 products (see Appendix 3).

- In order to reconcile the DoH's indices with IMS's as fully as possible, it was necessary to adapt the DoH approach to approximate to that of IMS; this is because IMS do not have any measure corresponding to the DoH's 'prescription item'. In this approximation, the increase in NIC was split into the increase due to quantity (in fact, quantity weighted by cost since there is no 'pure' measure of quantity) and NIC per quantity unit (i.e. price).

Results

The results of the analysis are presented for two product groups – including and excluding the generic product cimetidine. A summary of the growth in total NIC/sales value for each of the three approaches is shown in Tables 16 and 17 and outlined below. Detailed disaggregated breakdown of results for the 25 products are shown in Appendix 4.

(1) Results for the sample including the generic product cimetidine (see Table 2).

DoH Approach (using PCA data)

- The increase in total NIC for the selected preparations in 1994 was 12.5 per cent (including cimetidine). This can be attributed to growth in both the number of items (5.1 per cent) and NIC per item for all preparations (7.0 per cent).

- The increase in NIC per item for 'existing preparations' was the largest factor (7.0 per cent) in the growth of total NIC per item. The exit effect of 'discontinued' preparations was negligible (less than 0.05 per cent), as was the entry effect of 'new' preparations. The 'discontinued' preparation was Gaviscon 250mg tablet and the 'new' preparations were Gaviscon 500mg chewable tablet (lemon), Gaviscon 500mg extra strength (lemon), Imigran 50mg tablet and Losec 10mg e/c capsule.

- The 7.0 per cent increase in NIC per item for existing preparations can be attributed to increases in the product mix residual (9.3 per cent) and the quantity per prescription (QPP) index (0.4 per cent). This was offset by a Paasche index with a value of 97.5, indicating a 2.5 per cent decrease in NIC per item.

DoH approximation to IMS approach (using PCA data)

- The increase in total NIC for the given preparations was 12.5 per cent (including cimetidine). This can be attributed to increases in the entry effect and the price-weighted quantity index of 0.1 per cent and 15.2 per cent respectively, which are offset by decreases in the Laspeyres price index and growth due to interaction of 2.4 per cent and 0.4 per cent respectively. Residual growth had a negligible effect.

IMS Approach (using IMS data)

- The increase in total sales for the given products is 14.4 per cent (including cimetidine). This can be attributed to increases in growth due to line extensions (0.2 per cent), volume changes (15.1 per cent) and residual growth (1.4 per cent). The line extensions for IMS data were Gaviscon 500mg (lemon) tablets in two pack sizes, Gaviscon 250mg (peppermint tablet), Imigran 50mg tablet and Losec 10mg capsule. These were offset by decreases in growth due to price changes (1.9 per cent) and interaction (0.4 per cent).There is no growth due to new products.

(2) Results from the sample excluding the generic product cimetidine (see Table 3)

Table 3 **Comparison of variance analysis of expenditure growth, 1993/4 (excluding generic cimetidine)**

DoH approach	*% increase*	*DoH approximation to IMS approach*	*% increase*	*IMS approach*	*% increase*
Increase in total NIC	13.2	Increase in total NIC	13.2	Increase in total Sales	14.8
Increase in average NIC (all)	8.1				
Entry effect	0.0	Growth due to new preparations	0.1	Growth due to new products	0.0
				Growth due to line extensions	0.2
Paasche price index	–2.0	Laspeyres price index	–1.8	Growth due to price changes	–1.6
Increase in number of prescription items	4.8	Price-weighted quantity index	15.4	Growth due to volume changes	15.2
Quantity per prescription index	0.5				
Product mix effect	9.8				
		Growth due to interaction	–0.3	Growth due to interaction	–0.4
Exit effect	0.0	'Residual growth'	–0.2	Residual growth	1.4

DoH Approach (using PCA data)

- The increase in total NIC was 13.2 per cent which can be attributed to growth in both the increase in the number of prescription items (4.8 per cent) and average NIC per item for all preparations (8.1 per cent). There were negligible changes in the other components of growth except for the Paasche price index; the decrease was reduced from 2.5 per cent to 2.0 per cent by the exclusion of generic cimetidine.

DoH approximation to IMS approach (using PCA data)

- The increase in total NIC was 13.2 per cent when generic cimetidine was excluded from the calculations. There were negligible changes in the other components of growth except for the Laspeyres price index; the decrease was reduced from 2.4 per cent to 1.9 per cent by the exclusion of generic cimetidine.

IMS Approach (using IMS data)

- The increase in total sales excluding generic cimetidine was 14.8 per cent. The price index was affected by the removal of the generic cimetidine; the decrease was reduced from 1.9 per cent to 1.6 per cent.

Analysis of 'untypical products'

Although in aggregate IMS and the DoH approaches produced very similar growth rates there was significant discrepancy between approaches for some of the 25 products. Table 4 shows information for four such products. Possible explanations for the discrepancies are discussed below.

A detailed look at the data showed that volume for the 5mg Frumil tablet (excluding Forte and LS) decreased more in the DoH data than IMS data. The generic prescribing of the 5mg Frumil tablet increased from 22 per cent in 1993 to 39 per cent in 1994. The discrepancy in the volume could be due to the branded product being dispensed against some generically written prescriptions. In addition, IMS data showed a price decrease of 2.1 per cent for the 5mg Frumil tablet, whereas the DoH data showed a decrease of only 0.2 per cent.

IMS data show an increase in total sales for Gaviscon of 2.3 per cent, while DoH data show a fall of 8.7 per cent in total NIC. The PCA data show two 'new' preparations entering the market in 1994:

Gaviscon 500mg chewable tablet (lemon) and Gaviscon 500mg extra strength (lemon), while IMS data show three for 1994: 250mg (peppermint) and 500mg (lemon) in two pack sizes. This could account for the difference in the DoH's entry effect and IMS's growth due to line extensions. The Gaviscon 250mg tablet was blacklisted in November 1993, so there were no prescriptions dispensed for this particular preparation in 1994. However, the 250mg tablet is available 'over the counter' which could in part explain the discrepancy between the two data sets.

IMS data include parallel imports for Innovace. For the 5mg tablets, the Innovace branded products decreased in both total sales and 'volume' for both data sets, while the Innovace parallel imports (for IMS data only) had large increases in sales and 'volume'. The PCA data does show a generic for the 5mg tablet, which has not been included in this analysis of branded preparations. Total NIC and the number of prescription items for the generic 5mg tablet have increased between 1993 and 1994. It is possible that the generic in the PCA data is the parallel import in IMS data; if so, this would give rise to the discrepancies between the two data sets.

There was a discrepancy between the total sales and NIC value and the price indices for Prozac. There was a price cut of 35 per cent for Prozac in January 1993. Looking at detailed quarterly PCA data, the price per tablet fell from 93p in the first quarter of 1993 to 69p in the second quarter of 1993. IMS data show no price change for Prozac between 1993 and 1994. As the price decrease took place in January 1993, one possible explanation is that the price change for wholesalers took place before 1993. This would have given rise to these discrepancies. Alternatively the wholesalers discount may have changed when the list price changed, giving no price change in IMS data.

Table 4 **Products displaying large discrepancies between approaches: Frumil, Gaviscon, Innovace and Prozac**

Products	*Frumil*		*Gaviscon*		*Innovace*		*Prozac*	
	PCA	*IMS**	*PCA*	*IMS*	*PCA*	*IMS**	*PCA*	*IMS**
Increase in NIC/sales	–31.5	–20.5	–8.7	2.3	9.1	18.0	35.3	45.6
New preparations	0.0	0.0	0.6	3.9	0.0	0.0	0.0	0.0
Laspeyres index	–0.2	–2.1	0.0	1.0	0.0	0.0	–7.0	0.0
Price-weighted quantity index	–31.3	–18.9	–9.3	–2.8	9.1	18.0	45.6	45.6
Interaction	0.0	–0.4	0.7	0.2	0.0	0.0	–3.2	0.0
Residual	0.0	0.0	–0.7	0.0	0.0	0.0	–0.1	0.0

Notes:

1. IMS figures are taken from the results for IMS methodology and terminology, using IMS data.
2. PCA figures are taken from the results for the DoH approximation to IMS approach, using PCA data.
3. Products followed by* have parallel imports included for this analysis.

DISCUSSION OF STUDY RESULTS

- Excluding generic cimetidine from the analysis, gives a closer match for the increase in total sales and NIC and also the price indices. The results for growth due to volume changes, interaction, new products and line extensions are close both with the inclusion and the exclusion of generic cimetidine. Thus part of the discrepancies in the analysis which includes cimetidine is due to the pricing of this generic. However, even excluding cimetidine from the analyses leaves some discrepancies.

- For the purposes of this exercise it is assumed that IMS's growth due to new products and line extensions corresponds to DoH's entry effect. There may be some discrepancies as IMS's growth to new products and line extensions is a component of total sales, while the entry effect is a component of average NIC per item. Any preparation which appears in the review period and not in the base period is referred to as 'new'.

- In addition the residual growth in IMS approach and the corresponding DoH approximation to IMS approach do not match exactly. Residual growth in the DoH approximation is calculated by difference and includes the exit effect. For IMS approach, it includes both the effect of discontinued pack sizes and new packs of existing forms/strengths. If a new pack size has a higher or lower price per tablet than the existing packs of the same form/strength, then this price change will be reflected in the 'residual growth'; however, it would be reflected in the price index of the DoH approximation to IMS approach.

- The DoH approach does not include an interaction effect because the indices are regarded as multiplicative to the increase in total NIC. IMS approach regards the indices as being additive to the increase in sales, therefore requiring an interaction effect.

- The product mix residual is the largest underlying factor for increase in total NIC using the DoH approach, whereas growth due to volume changes is the biggest factor using IMS approach.

- In the DoH approach, the inclusion of prescription items as a measure allows the separate calculation of the product mix effect. In the DoH approximation to IMS approach the product mix effect, QPP and the increase in the number of prescription items are incorporated into the price-weighted quantity index. The increase in the price-weighted quantity index (15.2 per cent) using the DoH approximation to IMS approach and the growth due to volume changes (15.1 per cent) from IMS indices are very similar. This explains why DoH cite the product mix residual as the largest underlying factor for increase in total NIC and IMS refer to volume as the largest factor for increase in sales.

- The new 2.5 per cent PPRS price cuts were implemented in November 1993. The price indices appear to reflect this fall.

- Tables are attached showing the indices for the 25 products separately (see Appendix 4).

CONCLUSIONS

- The reconciliation of the DoH and IMS indices shows that overall increase in cost/sales value for the selected products is very similar as are the components of growth, bearing in mind the differences between the two data sets and the methodology.

- The analysis was done including and excluding cimetidine from the data sets. This was because of the different price levels for generics used by IMS and DoH. It was not known how much this discrepancy would affect the data. Excluding generic cimetidine from the analysis gives a closer match for the increase in total sales and NIC and also the price indices. The results for growth due to volume changes, interaction, new products and line extensions are close both with the inclusion and the exclusion of generic cimetidine. Thus part of the discrepancies in the analysis which includes cimetidine is due to the pricing of this generic. However, even excluding cimetidine from the analyses leaves some discrepancies.

- For this analysis the main driver of total cost/sales value is a combination of the increase in the number of prescription items and the shift from prescribing older, cheaper drugs to newer, more expensive items. IMS analysis does not allow these two effects to be split and describes the two together as 'volume increase'. The DoH approach does allow them to be split and shows that the shift to more expensive items has a bigger effect then the increase in the number of prescription items.

- The reconciliation is a methodological exercise which does not cover the total FHS drug bill. Its purpose is to see if consistent messages are being given for the selected products by the different data sources and methodologies used. It does not imply the same would be true for all drugs. It does however raise a number of issues which warrant possible further investigation.

- A 'chemical entity' contains all drugs which have the same active ingredient, e.g. Nifedipine. The 25 chemical entities used in this analysis are shown in Appendix 2.

- A 'product' is a term used by IMS for IMS data. A product contains all preparations of a chemical entity with the same brand name or product name. For example, all preparations of the brand name Augmentin (different sizes or types of tablet) are described as one product. However, where a chemical entity is available both under a brand name and as a generic they are considered as two products. For example, the chemical entity cimetidine is available as both the branded product Tagamet and as the generic cimetidine, that is, two products. In this analysis, the generic cimetidine was selected for inclusion, but not the branded Tagamet. The twenty five products included in this analysis are shown in Appendix 2.

- IMS data flag parallel imports separately where they can be identified but treat them as branded products and are therefore included in this analysis. Parallel imports are included in the PCA data, but are not always separately identified. If they are shown in the PCA data with a different brand name and known to be a parallel import (e.g. Adalate) then they have been included in this analysis to try to get the closest possible match with IMS data. If a parallel import is shown in the PCA data as a generic preparation then they have not been included in this analysis.

- A 'preparation' is a distinct formulation of a product. If, for example, a drug is available in different strengths or if it exists in both tablet and liquid form, then each of these variants is considered a preparation, e.g. Augmentin 375mg and 625mg tablets. The 76 preparations used in this analysis are shown in Appendix 2.

- For IMS analysis using IMS data a 'line extension' is a new pack, either a new formulation or a new strength. The DoH analysis using PCA data refers to a new preparation as any preparation which appears in the review period and not in the base period.

- For IMS analysis using IMS data a 'discontinued' *product* has been sold in the base period (i.e. 1993) and not in the review period (i.e. 1994). The DoH analysis using PCA data refers to a 'discontinued' *preparation* as one dispensed in the base period and not in the review period.

- For IMS analysis using IMS data a 'new' *product* is one introduced during the review year (i.e. 1994). The DoH analysis using PCA data refers to a 'new' *preparation* as one dispensed in the review period but not in the base period (i.e. 1993).

- Existing preparations are those which are dispensed in both the base and the review period.

For PCA data, the quantity (QTY) of a drug dispensed is measured in Standard Quantity Units (SQUs) depending on the formulation of the product. For this analysis the SQU is a unit (e.g. tablet/capsule/pack).

Appendix 2

FORMULAE USED FOR CALCULATION OF INDIVIDUAL COMPONENTS OF GROWTH

0 indicates the base period (i.e. 1993) and 1 the review period (i.e. 1994).

DoH approach

Increase in total NIC $= \frac{\text{Total NIC in review period}}{\text{Total NIC in base period}} * 100$

Increase in number of prescription items $= \frac{\text{Total number of items in review period}}{\text{Total number of items in base period}} * 100$

Increase in NIC per item (all) $= \frac{\text{NIC/item1 ALL preparations}}{\text{NIC/item0 ALL preparations}} * 100$

Entry Effect $= \frac{\text{NIC/item1 ALL preparations}}{\text{NIC/item1 COMMON preparations}} * 100$

Exit Effect $= \frac{\text{NIC/item0 COMMON preparations}}{\text{NIC/item0 ALL preparations}} * 100$

Increase in NIC per item (existing) $= \frac{\text{NIC/item1 COMMON preparations}}{\text{NIC/item0 COMMON preparations}} * 100$

Paasche Price Index $= \frac{\text{S [(NIC/SQU1)* QTY1]}}{\text{S [(NIC/SQU0)* QTY1]}} * 100$

Quantity per Prescription (QPP) Index $= \frac{\text{S [QPP1* (NIC/SQU0)* PXS0]}}{\text{S [QPP0* (NIC/SQU0)* PXS0]}} * 100$

Product Mix Residual $= \frac{\text{(NIC/item1)/(NIC/item0) COMMON preps}}{\text{Paasche Index* QPP index}} * 100$

DoH approximation to IMS approach

Increase in total NIC $= \frac{\text{Total NIC in review period}}{\text{Total NIC in base period}} * 100$

Growth due to new preparations $= \frac{\text{S NIC for new preparations in review}}{\text{S NIC in base}} * 100$

Laspeyres Price Index $= \frac{\text{S [(NIC/SQU1)* QTY0]}}{\text{S [(NIC/SQU0)* QTY0]}} *100$

Price-weighted Quantity Index $= \frac{\text{S [QTY1* (NIC/SQU0)]}}{\text{S [QTY0* (NIC/SQU0)]}} * 100$

Growth due to interaction $= \frac{\text{S [(QTY1-QTY0)* (NIC/SQU1-NIC/SQU0)]} - 1}{\text{S NIC in base}} * 100$

Residual Growth = Residual growth is calculated as the remaining growth

IMS approach

Increase in total sales = Changes in sales of all products

Growth due to new products = Changes in sales due to all new products introduced during the year

Growth due to line extensions = Growth in sales due to new packs, either new formulations or new strengths

Growth due to price changes = Growth due to changes in prices of existing products, excluding new products and line extensions

Growth due to volume changes = Growth due to interactions between simultaneous price and quantity changes

Residual growth = Remaining growth due to discontinued products and packs, and new packs of existing forms-strengths

Appendix 3
LIST OF PRODUCTS

The 25 products and the chemical entities to which they belong used in the 1994 reconciliation of the DoH and IMS indices (products followed by * have parallel imports included for this analysis).

Product name	Chemical entity
Adalat*	Nifedipine
Asacol	Mesalazine
Augmentin	Co-Amoxiclav (Amoxycillin/Clavul Acid)
Bricanyl	Terbutaline Sulphate
Capoten	Captopril
Cimetidine	Cimetidine
Frumil	Co-Amilofruse (Amiloride HCL/Frusemide)
Gaviscon	Aluminium & Magnesium & Alginates
Imdur	Isosorbide Mononitrate
Imigran	Sumatriptan Succinate
Innovace	Enalapril Maleate
Istin	Amlodipine Besylate
Lamisil	Terbinafine Hydrochloride
Livial	Tibolone
Losec	Omeprazole
Lustral	Sertraline Hydrochloride
Minocin	Minocycline Hydrochloride
Prempak	Oestrogens Conjugated with Progestogen
Prozac	Fluoxetine Hydrochloride
Sandimmun	Cyclosporin
Seroxat	Paroxetine Hydrochloride
Ventolin	Salbutamol Sulphate
Voltarol	Diclofenac Sodium
Zantac*	Ranitidine Hydrochloride
Zocor	Simvastatin

The 25 products and the 72 preparations within them used in the 1994 reconciliation are as follows:

Product name	Drug name (PCA data)
Adalat (inc parallel imports)	Adalat – Cap 10mg Adalat Ret – Tab 20mg Adalat 5 – Cap 5mg Adalat A.R. – Tab 20mg Adalat Ret 10 – Tab 10mg Adalat LP – Tab 20mg* Adalat LA – Tab 30mg Adalat LA – Tab 60mg
Asacol	Asacol – Tab E/C 400mg
Augmentin	Augmentin – Tab Disper 375mg Augmentin – Tab 375mg Augmentin – Tab 625mg
Bricanyl	Bricanyl – Tab 5mg Bricanyl SA – Tab 7.5mg
Capoten	Capoten – Tab 25mg Capoten – Tab 50mg Capoten – Tab 12.5mg
Cimetidine	Cimetidine – Tab 200mg Cimetidine – Tab 400mg Cimetidine – Tab 800mg
Frumil	Frumil FTE – Tab Frumil – Tab Frumil L.S. – Tab
Gaviscon	Gaviscon – Tab Chble 500mg (Peppermint) Gaviscon – Tab Chble 500mg (Lemon) Gaviscon 250 – Tab 250mg Gaviscon 500 – Tab Ex Strength 500mg (Lemon)
Imdur	Imdur – Durule 60mg
Imigran	Imigran – Tab 100mg Imigran 50 – Tab 50mg
Innovace	Innovace – Tab 10mg Innovace – Tab 5mg Innovace – Tab 20mg Innovace – Tab 2.5mg Innovace – Titration Pack (Tab 2.5mg/5mg)
Istin	Istin – Tab 5mg Istin – Tab 10mg
Lamisil	Lamisil – Tab 250mg
Livial	Livial – Tab 2.5mg
Losec	Losec – Cap E/C 20mg Losec – Cap E/C 40mg Losec – Cap E/C 10mg
Lustral	Lustral – Tab 50mg Lustral – Tab 100mg
Minocin	Minocin – Tab 100mg Minocin 50 – Tab 50mg Minocin MR – Cap 100mg

Product name	Drug name (PCA data)
Prempak	Prempak – Comb Pack Tab 1.25mg/500mcg Prempak-C – Comb Pack Tab 0.625mg/150mcg Prempak-C – Comb Pack Tab 1.25mg/150mcg
Prozac	Prozac – Cap 20mg
Sandimmun	Sandimmun – Cap 25mg Sandimmun – Cap 100mg Sandimmun – Cap 50mg
Seroxat	Seroxat – Tab 20mg Seroxat – Tab 30mg
Ventolin	Ventolin – Tab 2mg Ventolin – Tab 4mg Ventolin CR – Tab 4mg Ventolin CR – Tab 8mg
Voltarol	Voltarol – Tab E/C 25mg Voltarol – Tab E/C 50mg Voltarol – Tab Disper 50mg Voltarol Ret– Tab 100mg Voltarol SR– Tab 75mg
Zantac (inc parallel imports)	Zantac – Tab 150mg Zantac – Tab 300mg Zantac – DISPER Tab 150mg Zantac – EFF Tab 150mg Zantac – EFF Tab 300mg
Zocor	Zocor – Tab 10mg Zocor – Tab 20mg

Table 1 **Elements of growth of NIC, England 1994 (DoH methodology and terminology)**
Based on PCA data with the 25 products including generic cimetidine (but not Tagamet) and 24 products excluding cimetidine (products followed by * have parallel imports included for this analysis).

	Percentage change over previous year							
	Increase in total NIC	*Increase in the number of prescription items*	*Increase in average NIC per prescription item*	*Exit effect*	*Entry effect*	*Paasche price index*	*Quantity per prescription index*	*Product mix effect*
25 products in 1994	12.5	5.1	7.0	0.0	0.0	–2.5	0.4	9.3
24 products in 1994	13.2	4.8	8.1	0.0	0.0	–2.0	0.5	9.8
Adalat *	–1.5	–2.9	1.4	0.0	0.0	–1.2	0.4	2.1
Asacol	25.0	12.4	11.2	0.0	0.0	9.0	2.1	0.0
Augmentin	11.0	4.2	6.5	0.0	0.0	5.9	–0.5	1.1
Bricanyl	–16.1	–16.0	–0.1	0.0	0.0	–0.2	–0.2	0.3
Capoten	8.9	8.1	0.7	0.0	0.0	0.0	0.4	0.4
Cimetidine	–11.2	11.1	–20.1	0.0	0.0	–19.9	–0.3	0.1
Frumil	–31.5	–29.9	–2.3	0.0	0.0	–0.3	0.0	–2.1
Gaviscon	–8.7	–6.6	–2.3	0.0	–0.2	0.0	–2.1	0.0
Imdur	51.8	51.4	0.3	0.0	0.0	0.0	0.3	0.0
Imigran	39.3	46.2	–4.7	0.0	–0.3	0.0	–4.5	0.0
Innovace	9.1	4.6	4.3	0.0	0.0	0.0	0.5	3.8
Istin	54.7	53.2	1.0	0.0	0.0	0.0	0.4	0.6
Lamisil	46.9	48.7	–1.2	0.0	0.0	–2.0	0.9	0.0
Livial	26.8	21.5	4.4	0.0	0.0	0.0	4.4	0.0
Losec	49.0	48.6	0.3	0.0	–0.5	–0.7	0.8	0.6
Lustral	64.7	63.8	0.5	0.0	0.0	0.0	0.4	0.2
Minocin	6.9	7.4	–0.5	0.0	0.0	–2.1	0.2	1.4
Prempak	7.3	2.8	4.4	0.0	0.0	0.0	4.4	0.0
Prozac	35.3	44.2	–6.2	0.0	0.0	–7.0	1.0	0.0
Sandimmun	14.2	20.7	–5.4	0.0	0.0	–2.0	–1.9	–1.5
Seroxat	11.1	37.1	–19.0	0.0	0.0	–20.1	1.1	0.4
Ventolin	–80.2	–56.8	–54.2	0.0	0.0	2.2	2.5	–56.2
Voltarol	–4.4	–7.0	2.8	0.0	0.0	0.0	1.0	1.9
Zantac*	–5.3	–0.9	–4.4	0.0	0.0	–4.2	0.0	–0.4
Zocor	25.8	24.3	1.2	0.0	0.0	0.0	0.8	0.5

Table 2 **Elements of growth of NIC, England 1994 (DoH data approximated to IMS approach)**

Based on PCA data with the 25 products including generic cimetidine (but not Tagamet) and 24 products excluding cimetidine (products followed by * have parallel imports included for this analysis).

	Percentage change over previous year					
	Overall growth in NIC	*New preparations*	*Price*	*Price-weighted quantity*	*Interaction*	*Residual*
25 products in 1994	12.5	0.1	−2.4	15.2	−0.4	0.0
24 products in 1994	13.2	0.1	−1.8	15.4	−0.3	−0.2
Adalat*	−1.5	0.0	−0.7	−0.4	−0.4	0.0
Asacol	25.0	0.0	9.0	14.7	1.3	0.0
Augmentin	11.0	0.0	5.9	4.8	0.3	0.0
Bricanyl	−16.1	0.0	−0.2	−16.0	0.4	−0.3
Capoten	8.9	0.0	0.0	8.9	0.0	0.0
Cimetidine	−11.2	0.0	−19.9	10.9	−2.2	0.0
Frumil	−31.5	0.0	−0.2	−31.3	0.0	0.0
Gaviscon	−8.7	0.6	0.0	−9.3	0.7	−0.7
Imdur	51.8	0.0	0.0	51.8	0.0	0.0
Imigran	39.3	0.7	0.0	38.6	0.7	−0.7
Innovace	9.1	0.0	0.0	9.1	0.0	0.0
Istin	54.7	0.0	0.0	54.7	0.0	0.0
Lamisil	46.9	0.0	−2.0	50.0	−1.0	−0.1
Livial	26.8	0.0	0.0	26.8	0.0	0.0
Losec	49.0	0.9	−0.7	49.1	0.5	−0.8
Lustral	64.7	0.0	0.0	64.7	0.0	0.0
Minocin	6.9	0.0	−2.1	9.1	−0.2	0.1
Prempak	7.3	0.0	0.0	7.3	0.0	0.0
Prozac	35.3	0.0	−7.0	45.6	−3.2	−0.1
Sandimmun	14.2	0.0	−2.1	16.6	−0.3	0.0
Seroxat	11.1	0.0	−20.1	39.1	−7.8	−0.1
Ventolin	−80.2	0.0	4.1	−80.6	−3.6	−0.1
Voltarol	−4.4	0.0	0.0	−4.4	0.0	0.0
Zantac*	−5.3	0.0	−4.1	−1.2	−0.1	0.1
Zocor	25.8	0.0	0.0	25.9	0.0	−0.1

Table 3 **Elements of growth of sales, UK 1994 (IMS methodology and terminology)**

Based on IMS data with the 25 products including generic cimetidine (but not Tagamet) and 24 products excluding cimetidine (products followed by * have parallel imports included for this analysis).

	Percentage change over previous year						
	Overall growth in sales	*New products*	*Line extensions*	*Price*	*Volume*	*Interaction*	*Residual*
25 products in 1994	14.4	0.0	0.2	–1.9	15.1	–0.4	1.4
24 products in 1994	14.8	0.0	0.2	–1.6	15.2	–0.4	1.4
Adalat*	–5.2	0.0	0.0	–1.3	–16.1	–0.5	12.6
Asacol	23.6	0.0	0.0	9.0	13.4	1.2	0.0
Augmentin*	11.4	0.0	0.0	7.2	3.9	0.2	0.0
Bricanyl	–16.6	0.0	0.0	–0.8	–15.9	0.1	0.0
Capoten*	7.3	0.0	0.0	0.0	4.4	0.0	2.9
Cimetidine	–4.7	0.0	0.0	–11.7	7.7	–0.8	0.0
Frumil*	–20.5	0.0	0.0	–2.1	–18.9	0.4	0.0
Gaviscon	2.3	0.0	3.9	1.0	–2.8	0.2	0.0
Imdur*	50.8	0.0	0.0	0.0	48.5	0.0	2.3
Imigran	36.2	0.0	1.5	0.0	34.7	0.0	0.0
Innovace*	18.0	0.0	0.0	0.0	18.0	0.0	0.0
Istin	53.8	0.0	0.0	0.0	53.8	0.0	0.0
Lamisil	43.3	0.0	0.0	–1.8	45.9	–0.8	0.0
Livial	19.5	0.0	0.0	0.0	19.5	0.0	0.0
Losec*	49.7	0.0	1.3	–0.9	49.7	–0.4	0.0
Lustral	56.7	0.0	0.0	0.0	56.7	0.0	0.0
Minocin*	5.4	0.0	0.0	–1.9	7.3	–0.1	0.0
Prempak	8.8	0.0	0.0	0.0	8.8	0.0	0.0
Prozac*	45.6	0.0	0.0	0.0	45.6	0.0	0.0
Sandimmun	16.1	0.0	0.0	–1.8	18.2	–0.3	0.0
Seroxat	7.7	0.0	0.0	–22.5	38.9	–8.7	0.0
Ventolin*	–83.2	0.0	0.0	3.7	–83.3	–3.6	0.0
Voltarol*	–2.8	0.0	0.0	0.0	–2.9	0.0	0.0
Zantac*	–2.6	0.0	0.0	–3.6	1.1	–0.1	0.0
Zocor*	26.4	0.0	0.0	0.0	26.4	0.0	0.0

ANNEX B

A DISEASE AREA APPROACH: TRENDS IN ASTHMA PRESCRIBING

CONTENTS

INTRODUCTION

Understanding as to why the NHS medicines bill has been rising may be increased by looking at specific therapeutic areas, from which wider conclusions may be drawn. This section will look at the trends in asthma prescribing over the last decade in an attempt to explore the extent to which this is possible.

ASTHMA MEDICATION LEVELS

The number of prescriptions for asthma preparations[7] in England rose from 16.1 million in 1983 to 29.2 million in 1993 (evaluated on a consistent basis) (see Table 1). This represents an 81 per cent rise, in comparison to a 28 per cent rise for the total number of prescriptions over the same period. The NIC of asthma prescriptions totalled £347 million in 1993, a rise of 157 per cent since 1983 (real terms) (see Table 2). Average NIC per prescription rose by 33 per cent over the same period. Asthma prescriptions accounted for 7 per cent of all NHS prescriptions in 1993 and 11 per cent of the NIC of all prescriptions (Central Health Monitoring Unit, 1995).

Asthma prescriptions per head of population by Regional Health Authority are appreciably higher in the north of England than the South. However, with a similar pattern being shown for all prescriptions, the regional variations may reflect general prescribing patterns (see Section 3) rather than differences in asthma prevalence.

Table 1 **Number of prescriptions dispensed (millions), England, 1983-1993**

	1983 (a) (pharmacist & appliance contractors only)	*1993 (a) (pharmacist & appliance contractors only)*	*1993 (total)*	*% change 1983-1993 (pharmacist & appliance contractors only)*
Total prescriptions	315.3	405.1	445.4	+28
Asthma prescriptions	16.1	29.2	31.3	+81

Notes:
1. The basis of the prescriptions statistics was changed in 1991. Data for 1983(a) and 1993(a) include prescriptions dispensed by pharmacists and appliance contractors only. Data for 1993 (total) also include prescriptions dispensed by dispensing doctors and personal administration. 1983 data are based on fees only whereas 1993 data are based on items.
2. Based on the BNF, sections 3.1-3.3, September 1992.

Source: Central Health Monitoring Unit, 1995.

Table 2 **Cost of asthma prescriptions, England, 1983-1993**

	1983	*1993*	*Real % change*
NIC of prescriptions (£000's)	79,985	346,509	157
Average NIC per prescription (£'s)	4.96	11.09	33

Notes:
1. Asthma prescriptions based on British National Formulary sections 3.1, 3.2 and 3.3
2. Figures for 1983 are based on fees and on a sample of 1 in 200 prescriptions dispensed by community pharmacists and appliance contractors only. Figures for 1994 are based on items and cover all prescriptions dispensed by community pharmacists, appliance contractors, dispensing doctors and prescriptions submitted by prescribing doctors for items personally administered.
3. Adjusted by GDP deflator.

Source: Department of Health.

7. Some medicines may not have been prescribed for asthma, but to treat other, primarily respiratory, diseases. Data excludes peak flow meters.

- **Rising asthma prevalence**

There is little comprehensive data on asthma prevalence, although surveys suggest that regular medical supervision is required for 4-6 per cent of children and for around 4 per cent of adults (Central Health Monitoring Unit, 1995). This corresponds to approximately 2.45 million sufferers in the UK at present.

Several studies have indicated increasing prevalence. Strachan and Anderson (1992) reported a statistically significant increase in the prevalence of wheezing in 7 to 8 year old children, as reported by parents, from 11.1 per cent in 1978 to 12.8 per cent in 1991 ($p<0.05$). Based on the evidence of questionnaires completed by parents of 2,510 children in 1964 and 3,403 children in 1989 Ninan and Russell (1992) estimated the prevalence of wheeze to have risen from 10.4 per cent to 19.8 per cent. The reported diagnosis of asthma rose from 4.1 per cent to 10.2 per cent. Although much of this rise may be attributable to an increase in recognition or labelling, the evidence from these studies, as well as others (Mitchell et al, 1983; Hill et al, 1989; Burr et al; 1989) suggests that the true prevalence of asthma is rising.

Further evidence of the increased burden of asthma is provided by the latest morbidity survey, 1991-2, which estimates a patient consulting rate of 42.5 per 1,000 person years at risk (see Table 3), indicating an annual total of 2.5 million people contacting their GP for asthma annually (OPCS, 1995). 1.7 million of these people were consulting their GP for asthma for the first time. An estimated 5.3 million consultations for asthma were made in 1994. The previous morbidity survey, 1981-2, indicated a patient consulting rate of 17.8 per 1,000, with 1 million people contacting their GP annually (OPCS, 1985). The 139 per cent increase in the patient consulting rate between 1981/2 and 1991/2 followed an 85 per cent increase between 1971/2 and 1981/2.

Although increased recognition and labelling may have exaggerated the results of epidemiological study findings, it does seem likely that rising asthma prevalence has been the main volume driver of increasing asthma prescribing costs. The available evidence suggests that asthma prevalence will continue to increase and exert upwards pressure on the medicines bill.

Table 3 **Patient consulting rate for asthma (per 1,000 people at risk), England and Wales, 1972-1992**

	1971/2	*1981/2*	*1991/2*	*% change 71/72-81/82*	*% change 81/82-91/92*
Males	10.6	20.0	42.9	+89	+115
Females	8.6	15.9	42.2	+85	+165
Total	9.6	17.8	42.5	+85	+139

Source: OPCS Morbidity Statistics from General Practice, 1979, 1986, 1995.

- **Market penetration of more expensive new asthma products**

The 94 per cent increase in the total number of asthma prescription items dispensed between 1983 and 1993 was mainly due to the growth in the number of inhaled corticosteroids and selective beta (2) – adrenoceptor stimulants, the two largest components of aggregated asthma prescribing levels (see Figure 1).

Expert opinion and guidelines from bodies such as the British Thoracic Society have promoted the use of these medicines as a key element in asthma management. Use of inhaled corticosteroids increases prescribing costs in two ways. Firstly, their employment is seen more as a complement to, rather than replacement of, existing treatment to control asthma attacks. The net effect is therefore to increase the total number of prescriptions for anti-asthma medication. Secondly, the average cost of a corticosteroid prescription exceeds that of other forms of asthma treatmet (see Table 4). In volume terms corticosteroid medicines increased their share of total asthma prescriptions from 12 per cent in 1983 to 27 per cent in 1993. The relatively higher cost of corticosteroid medicines meant the increase, in cash terms, was from 17 per cent to 50 per cent.

An insight into the market penetration of new products was gained by the study of 21 asthma preparations in the UK market, based on sales, between 1980 and 1992 (see Figure 2) (Office of Health Economics, Intercontinental Medical Statistics). The wholesale market increased, in nominal terms, more than six-fold during these years, from £58 million to £374 million (even when adjusted by the GDP deflator sales grew more than three-fold). Products launched after 1980 accounted for 81 per cent of this total cash growth. Although products launched pre 1981 experienced a diminishing market share, they still exhibited steady cash sales growth during the 1980-92 period (see Figure 2). Indeed, expenditure on such products doubled between 1984 and 1992.

The effect of the newer inhalers on asthma prescribing costs was particularly pronounced (see Figure 3) due to their much higher cost in relation to old inhalers (the cost ratio of new to old inhalers was 3.4 in 1980 and 4.1 in 1992). Analysis of brand inhalers, which are available in 15 of the 21 compounds studied, demonstrates the significant replacement of products over time (see Figure 4). Much of the replacement is attributable to line extension in the form of a more effective delivery system. Branded inhaler products launched after 1980 increased their share of the total asthma sales market to 50 per cent over the study period (new chemical entities 14 per cent, line extensions 36 per cent).

Product mix effects are clearly a key driver of rising expenditure in the asthma market. The effect of product mix has been particularly influential due to the large differences in price between 'old' and 'new' inhalers – the fastest growing section of the asthma market. Product mix is likely to continue to be a main driver of asthma prescribing costs as the market share of branded inhalers is

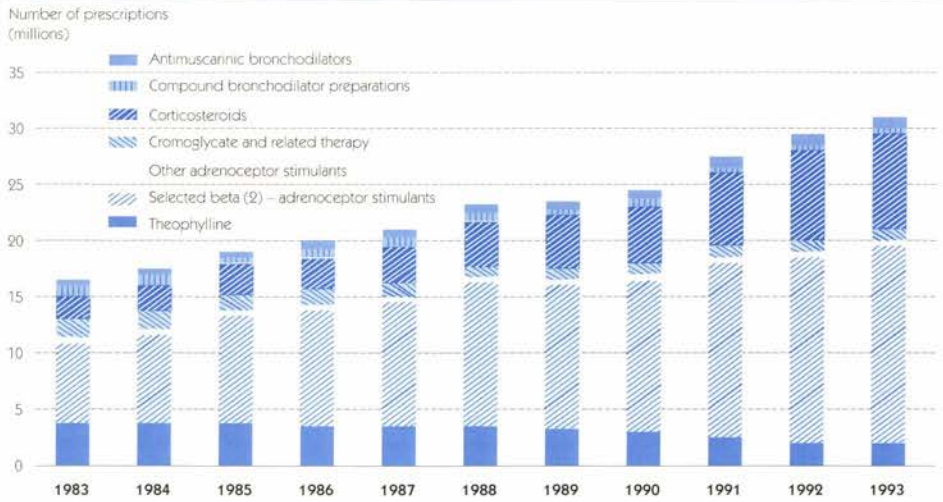
Table 4 **Number and NIC of asthma prescriptions dispensed by therapeutic group, England, 1983-1993**

	Bronchodilators BNF 3.1			*Corticosteroids BNF 3.2*			*Cromoglycate and related therapy BNF 3.3*		
	No RXs	*NIC (£000s)*	*Average NIC (£)*	*No RXs*	*NIC (£000s)*	*Average NIC (£)*	*No RXs*	*NIC (£000s)*	*Average NIC (£)*
1983	12,729	50,304	3.95	1,881	13,731	7.30	1,510	15,950	10.56
1984	13,552	54,185	4.00	2,129	18,344	8.61	1,528	16,591	10.86
1985	14,885	59,819	4.02	2,486	23,726	9.54	1,481	17,005	11.48
1986	15,699	65,835	4.19	2,919	31,710	10.86	1,427	17,779	12.46
1987	16,269	71,390	4.39	3,426	41,877	12.22	1,300	17,578	13.52
1988	17,399	86,948	5.00	4,031	61,021	15.14	1,207	17,738	14.70
1989	17,481	95,072	5.44	4,392	71,369	16.25	1,083	16,955	15.65
1990	18,422	107,078	5.81	5,040	86,988	17.26	998	16,365	16.40
1991	20,393	130,486	6.40	6,266	112,413	17.94	984	15,957	16.22
1992	20,925	144,338	6.90	7,414	142,522	19.22	925	16,449	17.78
1993	21,783	155,641	7.15	8,526	172,887	20.28	938	17,980	19.17

Notes:
1. The data up to 1990 are not consistent with data from 1991 onwards. Figures for 1983-90 are based on fees and on a sample of 1 in 200 prescriptions dispensed by community pharmacists and appliance contractors only. Figures for 1991-94 are based on items and cover all prescriptions dispensed by community pharmacists, appliance contractors, dispensing doctors and prescriptions submitted by prescribing doctors for items personally administered.
2. The NIC refers to the cost of the drug before discounts and does not include any dispensing costs or fees.
3. Therapeutic classes are based on the British National Formulary (September 1993).

Source: Department of Health, Statistics Division 1E.

Figure 1 **Prescriptions for asthma preparations by BNF section**



Notes:
1. Based on the British National Formulary (BNF), sections 3.1-3.3, September 1992
2. 1983 to 1993 data are based on fees only and cover prescriptions dispensed by community pharmacists and appliance contractors only. 1991 to 1993 data are based on items and cover all prescriptions dispensed by community pharmacists and appliance contractors, dispensing doctors, and personal administration.

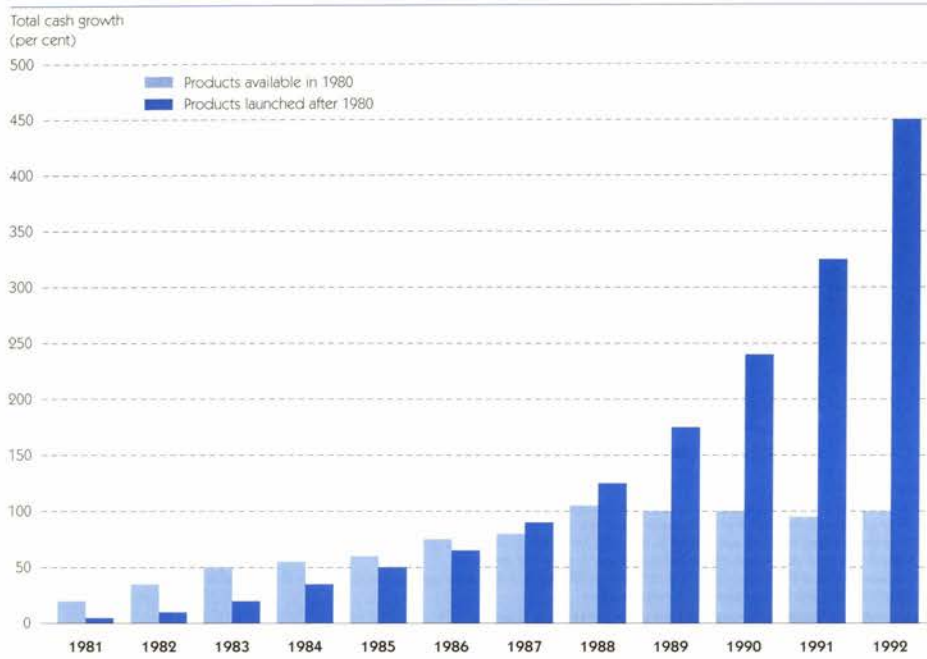
Source: Central Health Monitoring Unit, 1995.

increasing and the cost ratio of 'new' to 'old' inhalers is still rising.

SUMMARY

The asthma medication market was studied in order to determine whether analysing one therapeutic area would allow greater understanding of the factors impacting upon medicines expenditure growth generally. The analysis demonstrated that the significant increase in asthma prescribing, measured both in terms of volume and cost, appears to be the result of a variety of factors. These include therapeutic innovation, the greater cost of new therapies, population growth, increasing asthma prevalence, greater awareness of asthma, and changing treatment patterns. Weighting the importance of these factors for past and future asthma medication expenditure growth is problematic, though, partly due to the difficulty in isolating their impact and the uncertainty over the level of asthma prevalence.

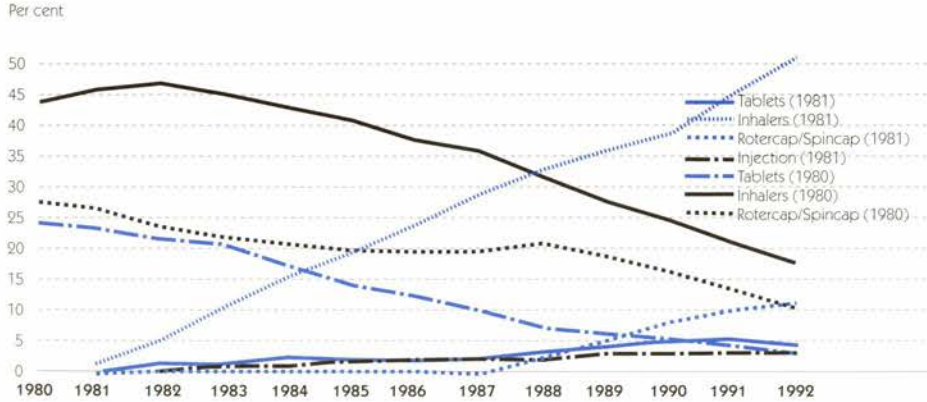
Figure 2 **Increase in sales (£) of asthmatic preparations – percentage of products 1) available in 1980 and 2) launched after 1980, UK, 1980-1992**



Notes:
1. Based on the sales of 21 compounds (see Appendix 1).
2. Pack size is based on 1992 pack quantity and one inhaler is treated as one pack. Thus, the results presented above can only be treated as broad indications of the movements of new or old products.

Source: Office of Health Economics, Intercontinental Medical Statistics.

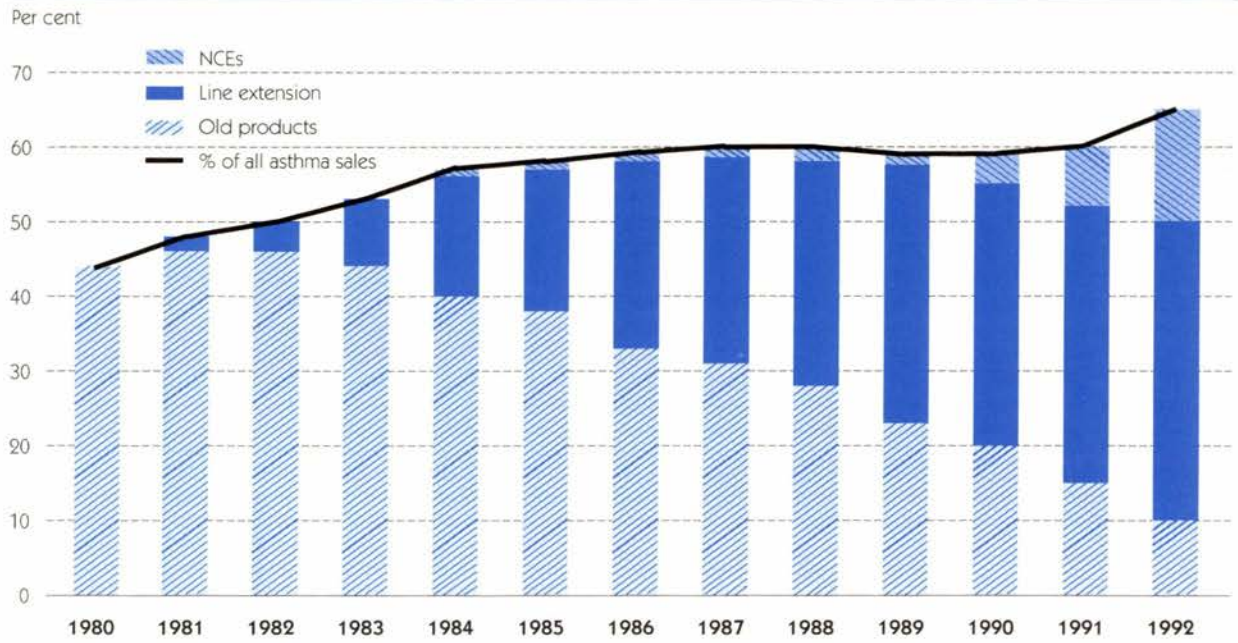
Figure 3 **Asthma products – percentage market share (£) of all asthma products by presentation, UK, 1980-1992**



Notes:
1. Based on the sales of 21 compounds (see Appendix 1).
2. It is assumed that inhalers are priced at one unit pack, which in some cases may not be true. Thus, the results presented above can only be treated as broad indications of the movements of new or old products.
3. It is assumed that pack sizes have remained static throughout the study period, using 1992 as the base unit pack.
4. 1981 = products launched in 1981 or after. 1980 = products already available in 1980.

Source: Office of Health Economics, Intercontinental Medical Statistics.

Figure 4 **Market share (£) of branded inhalers by compounds, UK, 1980-1992**



Notes:
1. Based on the sales of 15 out of 21 compounds for which branded inhalers are available (see Appendix 1).
2. Old products are defined as preparations which were available in 1980 and have been prescribed and dispensed.
3. It is assumed that inhalers are priced at one unit pack, which in some cases may not be true. Thus, the results presented above can only be treated as broad indications of the movements of new or old products.
4. It is assumed that pack sizes have remained static throughout the study period, using 1992 as the base unit pack.
5. Figures shown are percentages of all asthma sales.

Source: Office of Health Economics, Intercontinental Medical Statistics.

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ASTHMA COMPOUNDS USED IN THE ANALYSIS

Aminophylline

Beclomethasone*

Budesonide*

Choline Theophyllinate

Cromoglycate*

Ephedrine

Fenoterol*

Ipratropium*

Isoprenaline*

Ketotifen

Nedocromil*

Orciprenaline*

Oxitropium*

Pirbuterol*

Reproterol*

Rimiterol*

Salbutamol*

Salmeterol*

Terbutaline*

Theophylline

Tulobuterol

*denotes compounds for which brand inhalers are available.

ANNEX C

PRESCRIBING BUDGETS OF FUNDHOLDERS AND NON-FUNDHOLDERS

CONTENTS

BACKGROUND

The 1991 NHS reforms introduced the Practice Budget Scheme and the concept of GP fundholding. Fundholders were granted a prescribing budget and the opportunity to invest any surplus made back in to the practice. Non-fundholders were set an indicative prescribing amount, now called a target budget, in an attempt to contain their expenditure, although no penalties were implemented on practices not achieving their target. It was expected that the introduction of prescribing budgets would help to contain prescribing costs, with GPs becoming more aware of medicine prices[8], and drive the search for more cost-effective prescribing.

STUDY FINDINGS

Initial research carried out after the introduction of the NHS reforms indicated that fundholders were spending less on medicines per patient than non-fundholders. In a comparison of GPs' prescribing costs in fundholding and non-fundholding practices before and after implementation of the NHS reforms, Bradlow and Coulter (1993) concluded that fundholding had contributed to a decline in the growth of prescribing costs. Based on the evidence of PACT[9] data, provided from eight fundholding and seven non-fundholding practices in the Oxford region, the authors found that prescribing costs had increased in all practices in the six months after the reforms. However, the net ingredient cost increased 18.7 per cent among non-fundholders and only 12.1 per cent among fundholders. The proportion of generic medicines prescribed increased by 5.5 per cent for fundholders but remained unchanged for non-fundholders. Average cost per item increased 5.1 per cent for fundholders and 11.9 per cent for non-fundholders. Five of the seven fundholding practices made savings on their prescribing budgets, ranging from 2.9 per cent to 10.7 per cent. Savings on the medicines element of their budget ranged from 3.2 per cent to 20 per cent. All the non-fundholding practices overspent their indicative prescribing amounts by up to 20 per cent.

Evidence that fundholding has a dampening effect on prescribing costs was also shown in a study comparing prescribing patterns between a selection of fundholding and non-fundholding practices in north east Scotland (Maxwell et al, 1993). Over a two-year period the cost of medicines per defined daily dose[10] rose an average of 24 per cent in the non-fundholding practices, and between 11 per cent and 16 per cent in fundholding practices. The eight per cent difference in increase in unit cost between fundholders and non-fundholders (based on upper estimate of prescribing cost increase for fundholders) is equivalent to £19,000 a year for a practice of 10,000 patients for the 11 main British National Formulary sections[11].

The ability of fundholders to sustain lower growth rates in expenditure was one aspect of fundholding analysed in a recent England-wide study (Harris and Scrivener, 1996). This study is the most comprenhensive analysis so far undertaken of the fundholding scheme, with the authors analysing item and cost data for all general practices in England in the six years from April 1990 to March 1996. The number of fundholders in each of the five waves studied were 300, 277, 635, 793, and 644, respectively, totalling 2,649. Over the six-year period of the study total prescribing costs increased by 66 per cent in the continuing non-fundholders and by 56-59 per cent for fundholders. The approximate 6 per cent reduction in costs of fundholders compared with non-fundholders began in the first year of fundholding and declined in the second and third years. For subsequent years the relative reduction ceased and the costs of the fundholders ran parallel to those of continuing non-fundholders, although the decrease achieved continued. The relative reduction in costs achieved by fundholders in the first three years after entering the scheme were achieved by lowering the average cost per item rather than by prescribing fewer items. The authors conclude that, in financial terms, fundholding has had some success.

The belief that fundholding has had a dampening effect on the rate of rise of prescribing costs is supported by a 1996 study investigating the variation in prescribing among general practices (Wilson et al). Based on the analysis of prescribing data of 384 practices in the former Mersey region, the authors estimated that fundholders saved £3.71 per prescribing unit compared with non-fundholders, with fundholding itself accounting for £3.57 of this saving. A similar pattern is demonstrated for second and third wave fundholders.

Studies have indicated that the lower average cost per item achieved by fundholders – identified by Harris & Scrivener as the main reason fundholders attained a relative reduction in costs – in the initial phases of the scheme (1990-92) were a result of their increased

8. In two studies carried out before the introduction of fundholding Ryan et al. found poor knowledge of pharmaceutical prices amongst GPs in both England and Scotland. In a study of 281 Scottish doctors only one third of GP cost estimates were correct to within 25 per cent of the actual cost (1990). A study of 244 English doctors indicated that they had a marginally worse knowledge of medicine costs than their Scottish counterparts despite receiving much more detailed information on prescribing costs. English GPs have been receiving information on their prescribing costs since the introduction of PACT (prescribing analyses and cost) in 1988/9. Scottish GPs first received such information in 1990 with the introduction of SPA (Scottish Prescribing Analysis). The impact that fundholding has had on GPs' knowledge was examined in a study of 1,000 randomly selected GP principals in England and Scotland (Silcock et al, 1997). Overall, one-third of the price estimates given were accurate (within 25 per cent of the actual cost). Analysis of accuracy by fundholding status indicated few significant differences between groups of GPs, although fundholders were better informed about the prices of cheaper medicines. Fundholders also had more positive attitudes towards cost reduction in principle. It is unclear, though, whether fundholding has raised cost-awareness or whether the more 'cost-aware' GPs have become fundholders.

9. Prescribing analyses and cost data.

10. The World Health Organisation defined daily dose system allows conversion of prescribed substances into equivalent units of a standard defined volume.

11. Each section contains notes on medicines and preparations related to a particular system of the human body or to another main subject.

rate of generic prescribing. Prescribing less expensive preparations, reducing the duration of prescriptions, and prescribing lower doses of some medicines are other methods of lowering the average cost per item. A 1997 study (Baines et al) using prescribing cost data from all general practices in one English Health Authority, Lincolnshire Health, for the financial year 1993/4 indicated that the principal gains in cost control arising from the imposition of budgets have been short-term or 'one-off' as opposed to long-term. Analysis was based upon practices that joined the Practice Budget Scheme during the first three waves and were, therefore, fundholders in the financial year 1993/4 (n = 19) and all the remaining non-fundholding practices (n = 81). The study's main findings were that fundholders' prescribing costs are effectively contained by cash-limited budgets and fundholding practices achieved their lower average costs per ASTRO-PU mainly by increasing generic prescribing, as well as by restricting the volume of medicines they prescribe. As the capacity for increased generic prescribing to realise savings is inevitably limited, it is unclear whether fundholders can produce relatively greater savings beyond the short term.

Stewart-Brown et al (1995) reported upon the prescribing patterns of fundholding practices three years after the introduction of the Practice Budget Scheme. Analysis was based on PACT data for eight first wave fundholding practices and five practices that did not wish to become fundholders in 1990-1 for the financial years 1990-1 (phase 1), 1991-2 (phase 2), and 1993-4 (phase 3). The cost per prescribing unit between phases 1 and 3 rose more among non-fundholders (38.7 per cent) than fundholders (35.8 per cent). However, between phases 2 and 3 the fundholders increased their prescribing costs considerably more than the non-fundholders, 21.2 per cent against 14.6 per cent. At the end of the study fundholding practices had higher total costs. The proportion of generic prescribing increased more in fundholding than non-fundholding practices, but only to the extent that in 1993-4 both forms of practice were prescribing generically to a similar degree.

FUTURE IMPLICATIONS OF FUND-HOLDING

The future impact of fundholding on the medicines bill is unclear. Further research is required to determine whether new practices joining the Practice Budget Scheme realise one-off cost savings or consistently report lower prescribing costs than non-fundholders. It is uncertain whether the fundholding scheme itself, the characteristics of the practices that entered it, or a combination of both, has been responsible for fundholders being relatively lower-cost prescribers. It is also the case that the "appropriateness" of prescribing is not being adaquately assessed. No study investigating the effects of fundholding on prescribing costs has linked prescribing to diagnosis and outcome, or looked at whether 'savings' have been used more effectively elsewhere [an Audit Commisssion study (1994) estimated that NHS medicines expenditure could be reduced by £425 million annually if all GPs prescribed 'rationally']. The need to determine the true impact of the fundholding scheme on medicines expenditure and cost-effective prescribing will become increasingly significant as the fundholding scheme expands. In April 1995 41 per cent of the population in England and Wales were registered with a fundholding practice, although there are significant variations between regions (Audit Commission, 1995). National Association of Health Authorities and Trusts estimate that this figure will rise to over 50 per cent by April 1996.

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