BRIEFING PAPER 11

Medicines, the NHS and Europe

Balancing the public's interests

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and
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Contents

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David Taylor
Alan Maynard
April 1990

Introduction

Had British industry as a whole performed as well as the UK pharmaceutical sector in the decades since the end of World War II, this country would now be as economically successful as are Japan and Germany. The products of British based pharmaceutical innovators have done much to relieve ill-health right across the globe, in fields ranging from cancer and heart disease to the arthritic disorders and bacterial and viral infections. In addition, the UK industry now generates a positive balance of trade surplus of over £950 million a year for this country. It spends some £800 million a year on research and development projects conducted in Britain; provides, directly and indirectly, over a third of a million jobs in this country; and invests in capital terms over £400 million a year in the UK. This last sum alone is in excess of the total profits reported from the sale of medicines to the NHS.

However, notwithstanding this exceptional record (cynics might suggest because of it) the pharmaceutical industry is not universally trusted or praised. Some concerns relate to issues like promotion standards, the safety of medicines, and their sometimes exaggerated role relative to other forms of treatment in improving health standards. But many of the most pressing questions raised about the pharmaceutical sector stem more directly from fears that, despite its contributions, the international pharmaceutical industry has enjoyed a protected existence and made unjustifiable profits both here and abroad.

For example, in the UK agencies such as the Treasury still appear to fear that, even with the introduction of indicative drug budgeting in the NHS Family Practitioner Services, there is a danger that the country will pay too much for its medicines in the 1990s. Some authorities argue that a combination of both enhanced market forces affecting the purchase of medicines and tightened supply-side controls on profits and costs such as promotional spending will throughout the foreseeable future be needed to ensure that medicine spending is adequately restrained in the British, and European Community, public's interests.

There are a variety of reasons why decision makers throughout Europe have proved unwilling to rely on ordinary market forces to limit pharmaceutical outlays. They include:

- The perceived 'life and death' nature of the industry's products, with medicines being seen as essential in ways that most goods are not. Some may fear that as a result of this pharmaceutical suppliers can 'charge what they like'.
- The fact that although patients need and consume medicines, it is their doctors who prescribe them, and third parties like the NHS or insurance companies who often pay for them. This distorts normal market relationships.
- The possibility that the patent system, backed by heavy promotional expenditures aimed at prescribers, creates monopoly supply situations which permit excessive profit taking.
- The possibility that medicines regulation, although widely regarded as unavoidable from a safety viewpoint, serves economically to protect the regulated from competition, by discouraging potential new suppliers from entering the market place. That is, regulation has been captured by and favours the regulated.
- Uncertainty over the working of medicines price and profit control schemes, and the suspicion that on occasions companies enjoy unduly 'cosy' relationships with the agencies overseeing them and/or that multinational companies play governments off against one another to gain exceptionally favourable operating conditions.

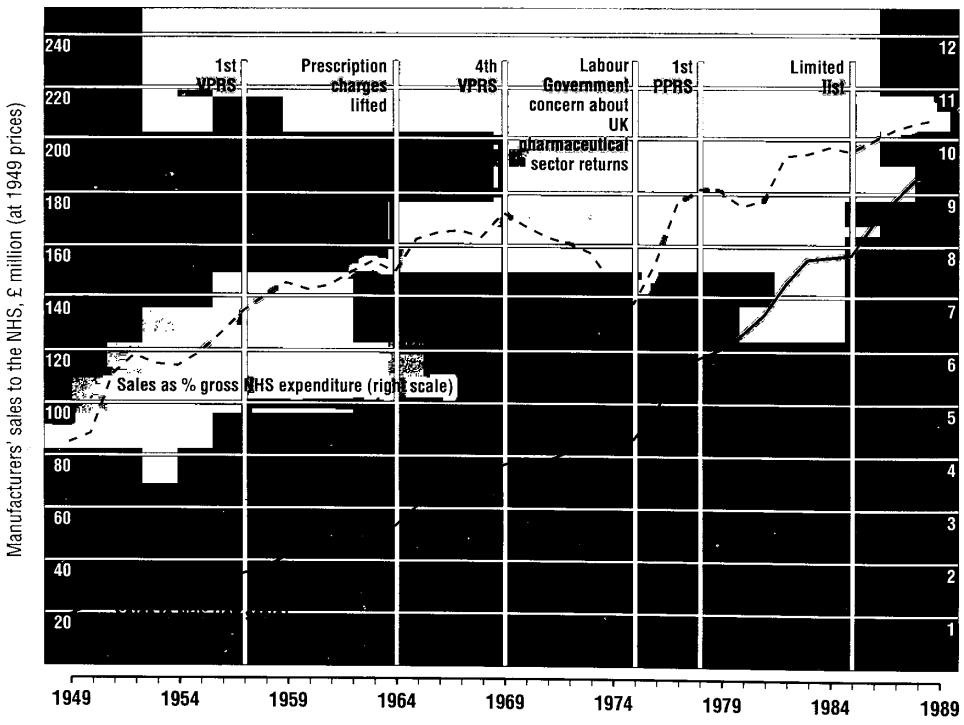
Such concerns may often be ill-founded. Individuals wishing to defend the pharmaceutical industry argue the involvement of government agencies in regulating the cost and quality of medicines is a burden on companies which reduces their commercial freedom and places on them (or may in future place on them) cost and price control disciplines which are harsher than those affecting other comparable sectors. Nevertheless, the fears set out above are commonplace, and it is probably fair to say that the general perception of the pharmaceutical industry in this country does not involve seeing it as being in danger of earning too little, as opposed to too much, money. Impressions of this sort may be supported by pharmaceutical company communications to the stock exchange, designed to encourage potential investors to invest in the pharmaceutical sector.

It is against this background of continuing debate about pharmaceutical expenditure levels and restraints that this King's Fund Institute/ Centre for Health Economics paper examines the development of medicine cost controls in the UK, and looks to the future of such schemes in the more

unified European market of the 1990s. The UK pharmaceutical sector has grown steadily for the last 40 years. But from 1992 onwards (the year in which the current version of the Department of Health's Pharmaceutical Price Regulation Scheme terminates) it may well be subject to radical change. Thus it is timely to note that from both a national and a European policy perspective there is an important public interest at stake in trying to ensure that the positive contributions of a dynamic, cost-effective and innovative pharmaceutical sector are retained to the twenty-first century and beyond.

The countries of the European Community share a positive pharmaceutical trade surplus with the rest of the world of over £3 billion per annum. In the EC as a whole medicine manufacturers provide some 400,000 jobs directly, and probably over a million more indirectly. But despite the obvious value of the parmaceutical sector to Europe, excessive outlays on medicines may distort patterns of health and social care provision to the detriment of the most vulnerable sections of the population. Proposals such as that of the European Commission to extend effective pharmaceutical patent terms to up to 16 years 'on the market' should therefore be balanced against the advantages of further controlling promotion costs and other possibly wasteful expenditures. It is realistic to estimate that several billion bounds could be cut from domestic EC pharmaceutical spending by the more rational selection and use of drugs. The challenge is to achieve such savings for use elsewhere in health care without harming the Community's pharmaceutical research and manufacturing base.

Figure 1 Manufacturers' medicines sales to the NHS, UK 1949–89 (at 1949 prices) and the percentage of NHS resources spent on medicines.



Source: Department of Health, ABPI

The pharmaceutical industry and the NHS

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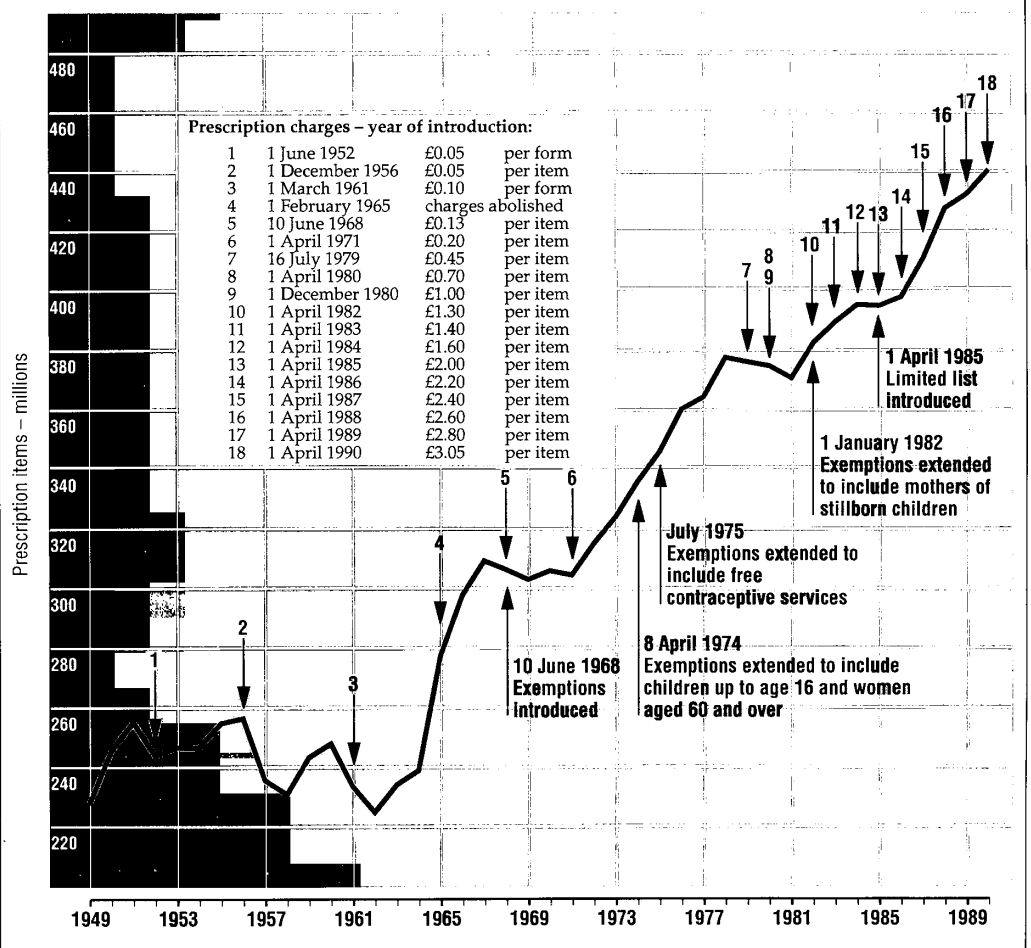
Figure 1 outlines the increasing cost of health service supplied medicines since 1949, and shows also the percentage of total NHS resources devoted to them. The proportion of NHS resources utilised for pharmaceutical purchases (hospital and community, in manufacturers' prices) has doubled, from around five to approximately ten per cent, in the last four decades. This corresponds to a rise in the proportion of UK GNP spent on NHS pharmaceuticals from 0.2 per cent to 0.6 per cent, a roughly nine fold increase in spending in inflation adjusted terms. (In addition, about 0.15 per cent of GNP is now spent on over-the-counter medicines, costed in retail prices).

Figure 2 indicates the volume growth in Family Practitioner Service prescription items dispensed annually since the same year. The latter have accounted fairly consistently for about 80 per cent of all NHS medicine costs since the early 1960s, despite the growing use of community rather than institutional services. (During the last three years, however, the hospital sector share of the NHS medicines bill has dropped somewhat, to approximately 17 per cent in 1989/90.)

Figure 2 NHS prescription charges and the number of items dispensed by community pharmacists, UK 1950–1989.



Source: Robert Chew, OHE 1989

Given the dramatic expansion of the range of medicines available over this period, coupled with factors like population ageing, such figures do not appear surprising. Certainly in terms of absolute per capita outlay UK pharmaceutical spending is well below that reported in countries like Germany, France, Italy, the US, and Japan (Redwood, 1987; Burstall, 1990a). Yet it may also be observed that in unit terms UK medicine prices are at or somewhat above the middle of the European Community range (Harrison, 1990; Touche Ross, 1989). It is volume prescribing and dispensing which are low in the UK compared with nations like France and Italy (Szuba, 1986; Burstall, 1988). Furthermore, a minority of advanced nations, such as Holland, Norway and Denmark, appear to spend significantly less of their (albeit higher) GNPs on pharmaceuticals than does the UK (ABPI 1988).

The development of the British approach to pharmaceutical cost control can be divided into four phases. These are outlined below, after which the main policy objectives involved and lessons to be drawn are briefly considered.

The re-establishment of brand name prescribing, 1948-57

During the second World War defence regulations enabled the government to control pharmaceutical prices, together with those of other goods. The pressures of the conflict also led to the production of a National War Formulary. In the immediate post-war period the government of the day was reluctant to give up its medicine price control powers, particularly in the light of the formation in 1948 of the NHS and the resultant prospect of an increased demand for 'free' medicines paid for with public money. However, the government was also sensitive to the potential of the pharmaceutical sector to contribute to Britain's 'export drive'. It was therefore sympathetic to the then newly established Association of the British Pharmaceutical Industry's arguments against restricting the use of brand names within the NHS, lest this inhibit the UK industry's sales performance in other parts of the world.

Thus from the start the UK's post-war approach to its pharmaceutical sector was ambiguous (Lang, 1973). This perhaps helps to explain some of the apparent contradictions in the records of the period. On the one hand a special committee was established in 1949 (the 'Cohen' committee) to monitor and restrain the use of unduly expensive drugs in the NHS; the Chief Medical Officer in 1950 advised in favour of generic prescribing; prescription charges were introduced in 1952; and the Public Accounts Committee repeatedly questioned the cost of prescribed medicines in the early 1950s. But on the other hand spending on medicines continued to grow, and by mid 1957 a half of all NHS medicines were prescribed by their brand names. The proportion so prescribed in 1949 was under 20 per cent.

In retrospect these trends can be seen to be related to the surge of innovation taking place at that time. In addition, the report of a committee of enquiry published in 1956 (the 'Guillebaud Report') revealed that the cost of the NHS in fact fell as a proportion of GNP in the first half of the 1950s. This to a degree relieved fears that the creation of the NHS would lead to unlimited, open-ended spending. Nevertheless, elements within the Treasury together with politicians on both the left and the right continued to express concern about NHS medicine costs. It was the continuing political worry that the 'free' NHS was 'pouring medicines down the throats' of the British in ever increasing volumes and at ever increasing cost that led, after negotiations between the Ministry of Health and the ABPI which started in 1954, to the introduction of the first Voluntary Price Regulation Scheme (VPRS) in 1957 — see Box 1.

From the first VPRS to the Sainsbury Report revisions, 1957-1969

As Figure 1 (page 6) shows, the introduction of the first VPRS in 1957 made little or no impact on the inflation adjusted NHS medicine spending trend observable from the mid 1950s onwards. This was partly because the new scheme was only gradually introduced (Luce, 1987). Even so, informed observers might have predicted that its impact would be limited, given that arguably the most significant means of checking prices introduced by the scheme was 'the export criterion'. This applied to products when 20 per cent or more of their output was exported, and restricted their domestic price to no more than the weighted average of the export price. But export prices tended anyway to be higher than home prices. Further, the scheme permitted a three year price freedom period for new products, during which suppliers could take as much profit as the market would bear.

There were other elements within the first VPRS which helped to check price rises. Yet it was in the main remarkably unrestrictive, given the background to its genesis. The explanation for this appears to be that in private the civil service and political decision makers concerned were not particularly disturbed by the domestic pharmaceutical spending figures, and were more influenced by a desire to increase the country's positive balance of trade in medicines. (See Figure 3, page 10.) It is also possible that in creating a scheme demanding negotiation between the

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THE EVOLUTION OF THE PPRS, AND ITS UNDERLYING ECONOMIC RATIONALE

The two sides participating in the VPRS/PPRS system have always acknowledged that its objectives include both holding down NHS medicine spending and maintaining an efficient, dynamic, UK based pharmaceutical industry. The introduction of the latest, 1986, version of the scheme explains that its purposes are to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices.
- Promote a strong and profitable pharmaceutical industry in the United Kingdom capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines.
- Encourage in the United Kingdom the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

The VPRS/PPRS has undergone many changes since 1957. Over the last three and a half decades, however, a number of consistent elements have emerged. These include:

- The PPRS provides an overall framework within which individual companies negotiate privately with the Department of Health over the details of their particular trading relationship.

  The main focus of the scheme is, notwithstanding the occasional product specific intervention, the limitation of the total profit each company can make in a year from selling medicines to the NHS. Ceiling earnings are based on the amount of capital employed in NHS production, and in relation to this base costs incurred in all elements of a company's activities are controlled.
- The working of the PPRS usually involves determining the proportion of companies' capital operating in the UK devoted to home medicines as opposed to other production. The assumptions made in this context have an important influence on all other calculations subsequently made in relation to the scheme. Companies which merely import into the UK and have little or no capital base have their permitted profits calculated in relation to their sales. The nominally allowed rate is about 4-5 per cent.
- The PPRS permits (indirect) government access to data relating to companies' international transfer pricing policies, as well as (directly) to national level accounts showing expenditures on activities like promotion and research. The PPRS has tended to permit relatively high levels of outlay on the latter, but is relatively restrictive as to the former. About 20 per cent of the pharmaceutical industry's NHS earnings are said to be spent on research, compared to about 10 per cent for promotional outlays.
- Companies may be allowed to retain additional 'grey area' profits of (currently) up to 50 per cent above their basic target levels where these have been generated as a result of innovation or improved efficiency. Otherwise excess profits and 'fines' (incurred as a result of more than permitted promotion outlays which are now both 'clawed back' and counted as additional profit) are retrieved by the Department of Health either in the form of direct repayments or NHS price reductions or increase restraints.

Part of the economic logic of the VPRS/PPRS has related to the alleged difficulties of fairly allocating to particular products costs in an industry with relatively low levels of direct production expenditure (only 30-40 per cent of total outlays in the case of research based companies in the UK). The picture is further complicated by the fact that the marginal costs of medicine production are often only a small fraction of average supply costs, and the implications this has for consumer wellbeing. A cost control approach which focuses on overall company by company profit and cost levels, rather than medicine spending by individual prescribers calculated at average prices, may well have important advantages for communities with strong domestic pharmaceutical sectors.

The naive use of average costs might in some circumstances deny consumers in need of the benefits of medicines substantial welfare gains, for relatively little true saving to the community. This observation has significant implications in relation to both the future working of NHS medicine budget schemes, and the approaches which might one day be taken to the Europe wide control of medicines spending.

Ministry of Health and the industry trade association in the UK, the ABPI, the government was hoping in time to establish a voluntary system of self policing within the British based pharmaceutical sector which would enable it to exercise an acceptable degree of control over all aspects of the industry's activities via indirect rather than direct methods. (The ABPI published its first Code of Advertising Practice in 1958.)

Despite renegotiations of the original VPRS in 1961 and 1964 (which began to introduce the idea of controlling companies' overall profits) it remained largely unchanged during its first decade. The NHS's expenditure on medicines continued to grow at a rate slightly above that of NHS spending generally, while exports increased rapidly. However, the relationship between government and the industry remained punctuated by crises. For example, in the early 1960s considerable conflict arose over the issue of patent protection and the importation ordered by the then Minister of Health, Enoch Powell, of 'cheap' generic antibiotics for NHS use from Poland and Italy, despite the fact that valid patents for the substances in question were in force in the UK.

At about the same time the thalidomide scandal broke, undermining public confidence in the safety of new medicines and creating political demands for more control (Box 2, page 11). With specific reference to the operation of the VPRS

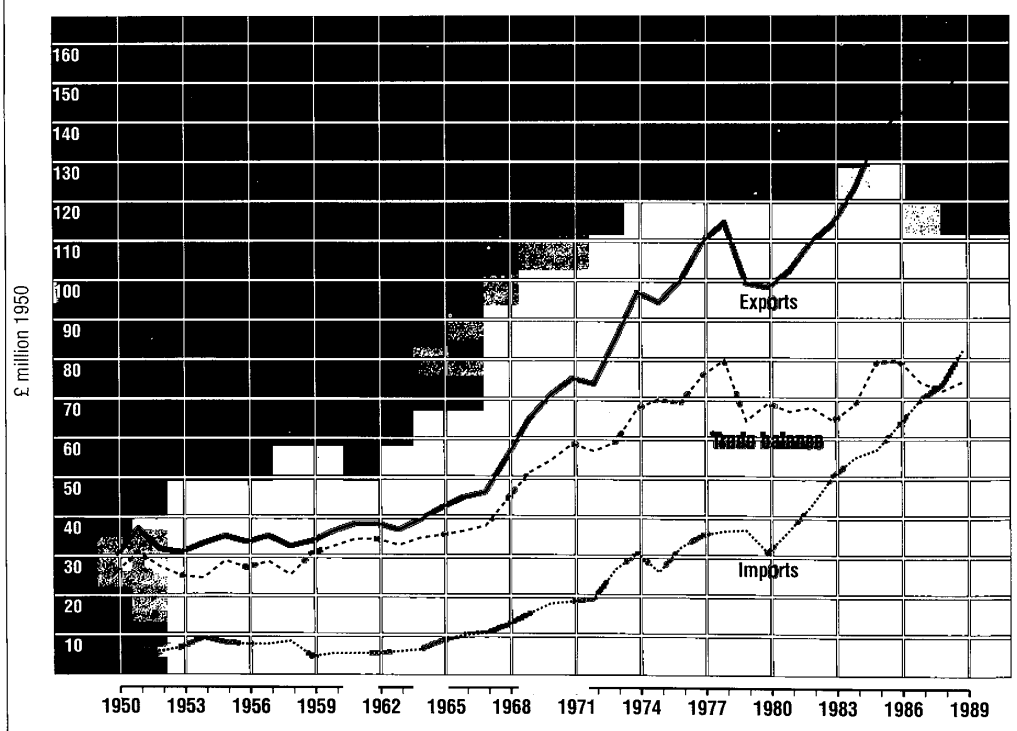
there was concern that certain companies (including both major Swiss and US corporations) objected to some aspects of the scheme and were refusing to modify their prices. This resulted in some governmental dismay, and criticisms of the ABPI to the effect that it was 'toothless'. Subsequently the government took statutory powers (via the 1964 Emergency — Re-enactment and Repeal — Act) to enforce if necessary greater compliance with the VPRS, at least in relation to the information demanded by the state of pharmaceutical companies trading in Britain (Sargent, 1983).

The return of a Labour administration in 1964 was followed in the next year by establishment of the 'Sainsbury' Committee of enquiry into the relationship between the NHS and the pharmaceutical industry, and later in that year by the publication of the report of the McGregor Committee. This last proposed that some types of branded medicines be placed in special categories, whereby doctors prescribing them might be asked to justify their actions. It focused attention on the relative efficacy of medicines, and questioned strongly the desirability of many combination drug products.

The industry protested against these recommendations. However, the Sainsbury Report, when it came, posed an even greater challenge to pharmaceutical industry in the UK (HMSO, 1967). This argued that much more rigorous scrutiny of company costs, profits and prices was required. It also advocated a reduction in intellectual property (patent) protection for pharmaceuticals, and called for a ban on the registration of new brand names for medicines in the UK. Although the Minister of Health decided not to accept all the Sainsbury proposals, his response made it clear that the Government was resolved to do more to control drug costs, and in particular the high promotion expenditures described in the report. These events led to the more far reaching, fourth, revision of the VPRS in 1969.

Before turning to the latter, however, one other aspect of the working of the NHS pharmaceutical market in the late 1960s should be noted. In February 1965 the then Labour government abolished prescription charges, which at that time stood at two shillings (£0.10). In the following two to three years the number of NHS prescription items dispensed, which since the introduction of a charge in 1952 had been kept relatively stable at around 240 million (UK), rose to over 300 million. Inflation adjusted NHS pharmaceutical costs also exceeded projected levels. Prescription charges were re-introduced in

Figure 3 UK pharmaceutical trade at 1950 prices, 1950–1989.



Source: H M Customs and Excise

2

THE LICENSING OF MEDICINES

Before the thalidomide tragedy prescription medicines needed no special licensing in Britain - such products were put on the market at the discretion of the companies concerned. But following the understandable increase in public, manufacturer and political concern levels at the start of the 1960s, a voluntary system of safety scrutiny and marketing approval (conducted under the auspices of the 'Dunlop' committee) was introduced in 1964. Following this the 1967 Medicines Act led to the establishment of the Department of Health as the statutory medicines licensing agency in the UK; it also created the Medicines Commission and its 'section 4' committees, such as the Committee on the Safety of Medicines. (In substance, these arrangements came into force in 1971.)

Recently a restructured body, known as the UK Medicine's Control Agency (MCA) has been set up to deal with all aspects of medicines licensing in this country. It is to have within it six self-sufficient 'businesses' which themselves will contain separate units, dealing with topics ranging from the regulation of clinical trials to European medicine licensing issues.

At the EC level the Committee on Proprietary Medicinal Products (the CPMP) already has a role in relation to granting community wide marketing approvals for some classes of pharmaceutical product. It is intended that by 1993 a European Agency for the Evaluation of Medicines will be established. However, it is not envisaged at present that EC bodies will obviate the need for national level medicines licensing arrangements. The overall costs of such activities will therefore tend to remain higher than they might otherwise be, although it could also be argued that failure to spend sufficiently on such functions might itself lead to high costs. Unsafe products harm consumers, while the commercial consequences of biased or otherwise distorted licensing decisions could harm companies' finances and national economies, as well as patient interests.

1968, and the demand for items again stabilised in volume terms.

This series of events served to emphasise the perhaps surprising extent to which consumers are sensitive to the price of some, if not all, prescription items. (This may to a degree exist because there is substitution between certain NHS supplied and self-purchased over-the-counter medicines, as and when one group is cheaper to the paying consumer than the other.) Yet perhaps the most important point to stress is that when prescription charges were re-imposed in 1968 significant exemptions were introduced. These were extended during the 1970s to include all women over 60 and men over 65 and children under 16, together with unemployed individuals and certain others in receipt of benefits and/or with special health needs. This meant that the application of prescription charges subsequently lost much of its ability to restrain volume demand for medicines, a point which may not always have been clearly understood in the late 1970s and early 1980s.

From the revised VPRS to the PPRS and 1979 election

Like the VPRS of previous years, the agreement made between the ABPI and the Department of Health and Social Security which came in to force in 1969 made explicit its twin goals of ensuring 'reasonable' NHS medicine prices and promoting a 'strong and profitable' British pharmaceutical industry. Like former versions of the VPRS it involved the ABPI directly in as much as the trade association was responsible for representing its members in negotiating the overall terms of the scheme; the day to day working of the VPRS demanded (as does the PPRS today) separate, detailed dealings between individual companies and the Department.

But unlike the three previous VPRSs the 1969 settlement required each company involved to submit detailed — and even to the ABPI confidential — Annual Financial Returns (AFRs) to the Department. These include(d) breakdowns of sales, costs and capital employed, enabling officials to take into account items such as promotional outlays and transfer costs between affiliated concerns when assessing the reasonableness of pharmaceutical prices and profits. It introduced a firmer control system over NHS medicine suppliers, which no longer relied mainly on the ABPI using its 'good offices' to encourage companies to co-operate and supply information to the DHSS in a voluntary manner. The new VPRS gave government more powers to influence both product prices and aggregated company profits from sales to the NHS. As Figure 1 (page 6) shows, there was from 1969 onwards a decline in the rate of growth of NHS pharmaceutical spending, and a marked drop in the proportion of health service money going on pharmaceuticals. By 1975 the latter had fallen to a nadir of a little under seven per cent, a similar proportion to that recorded in late 1950s when the VPRS was first established.

Although the industry-side committee responsible for negotiating the 1969 VPRS had included a number of influential figures (including, for instance, Paul Girolami, the chief executive to-be of Glaxo, now Britain's most successful pharmaceutical enterprise — Turner 1988) the new scheme, perhaps not surprisingly, soon became a matter of serious concern to many companies. It was argued on the one hand that by agreeing to supply AFRs the industry may have saved itself

from more draconian intervention. But on the other its decreased rate of earnings increase during the early 1970s, when the Heath government was in power and both health service spending and inflation generally were accelerating fast, seemed to many an excessive price to pay.

The conflict between a major Swiss company and the DHSS over the pricing of benzodiazepine products was to a substantial degree a test of the enforceability of the new VPRS, although it also involved matters relating to intellectual property protection and the granting of 'licences of right' to competitors wishing to produce patented specialties. This test of strength (which involved heavy use of mass media on the government side) was not resolved until 1975: a settlement was finally agreed on Armistice day of that year.

Following the Labour victory in the election of 1974 medicine spending continued to decline as a proportion of all NHS outlays. However, by 1976 the Government had become concerned that UK pharmaceutical industry earnings and profits had fallen to an 'unduly low' point. Despite restrictions on public spending a clear acceleration in absolute, inflation adjusted, NHS pharmaceutical spending and in the proportion of NHS outlays going on pharmaceuticals was observable in the middle of the decade, although associated with this came the introduction of more specific controls on promotion spending. (Mention of the latter had been dropped in the 1972 VPRS, which slightly modified the 1969 agreement.)

Other events of significance to the UK pharmaceutical sector and its relationship with its single major domestic customer, the NHS, in the late 1970s included: a) in 1977 the government re-established statutory powers to fix the price of products, including medicines, supplied to the NHS, were this to prove necessary b) in 1978 the renegotiation of the VPRS resulted in its title being changed to simply the Pharmaceutical Price Regulation Scheme (the PPRS) and c) in 1978, following the establishment of the European Patents Convention in 1977 and the UK Patents Act of that year, patent terms were increased from 16 to 20 years. This change was of more importance to pharmaceutical innovators than any other sector of industry (Box 3), albeit that transitional arrangements relating to existing patents were to become a further focus of contention in the 1980s.

From 1979 onwards — the Thatcher era

Towards the end of the most recent Labour administration's existence the rate of increase in NHS pharmaceutical spending throttled back, so that in 1978/79 it resumed a trend more or less on line with that set in the 1960s (Figure 1, page 6).

3

PATENT PROTECTION FOR MEDICINES IN BRITAIN AND EUROPE

Innovative companies which invest heavily in research and development would, without patent protection, be vulnerable to competition from lower cost copyists. This, it is generally accepted, is particularly so in the pharmaceutical sector. The reasons for this include:

- **The costs of researching, licensing and informing the market about a new medicine's uses are usually high relative to its production costs. This gives non-innovative producers a strong economic incentive to move into the market as rapidly as possible, to exploit opportunities for supra-normal profit taking.**
- **To date, at least, competent manufacturers can relatively easily reproduce innovative medicines. Unlike, say, an aircraft which has thousands or millions of parts and is difficult to assemble, the active ingredient of a high-tech medicine is usually only one, albeit complex, chemical substance. As new biological products and more complex medicine delivery systems enter the market the balance of this argument may shift somewhat, but viable opportunities for copyists will remain.**
- **Following from the above, the opportunities for simply re-presenting valuable products to the market in slightly modified forms each year (a form of innovator protection seen in consumer electronics and many other commercial fields) are very much restricted in the pharmaceutical context, for ethical, legal and technical reasons.**

Alongside the theoretical arguments in support of intervening in the working of an unregulated free market to support medicines innovation by adequate intellectual property protection, lobbyists for pharmaceutical interests can show that since the introduction of extended safety testing (and more complicated research programmes) in the 1960s effective medicine patent terms have been significantly eroded. Indeed, despite the 1977 European Patent Convention and the increase of all patent durations to 20 years from the date of filing in most EC nations, medicine innovators typically enjoy only about half this term 'on-the-market'.

As the discussion in the main text (pages 17, 21 and 24) indicates, EC authorities have shown some sympathy to the industry's calls for patent restoration. Although the innovative pharmaceutical sector has to date been highly profitable, it is possible that without enhanced intellectual property provisions its future financial position in a more competitive European market would become precarious.

With the election of a Conservative government committed to strict public expenditure control in May 1979, the most likely prospect was a return to still tighter NHS medicine spending control. This outlook was apparently confirmed by the almost immediate introduction of increased prescription charges, in July 1979.

The effect of the latter was to halt the steady increase in the number of NHS prescription items dispensed which took place during the administrations of Wilson and Callaghan. They had not raised charges (Figure 2, page 7). However, because by the late 1970s a very significant proportion of the people likely to be high volume drug users were exempt from payments, this effect was relatively short lived. Despite 11 further increases in prescription charges during the last 11 years the prescription item volume trend resumed growth in 1981 .

One aspect of the consequent skew in consumption patterns which has developed is that today well over 40 per cent of NHS dispensed prescription items are for people over retirement age; in 1979 the equivalent proportion was one third. Precise data are not available, but prescription take up by less well off working age people liable to charges may have fallen significantly in some localities. (Overall consumption in the population under retirement age, which includes children, unemployed and other exempt users, stayed constant at about five items per head in England during the 1980s — OHE, 1989).

It was perhaps in part because of the limited value of prescription charges as a prescription volume restraint that NHS pharmaceutical outlays began to rise at an unexpected rate in the early 1980s. Yet working of the PPRS should have modified the effect of volume increases in the domestic market to a substantial degree, had volume growth been the only factor involved. (That is, the NHS should have incurred extra outlays somewhere between the marginal and the average supply cost of the additional items consumed.) Another significant element was the sudden downturn of UK pharmaceutical exports in 1979, related primarily to events in Nigeria and Iran, and the what by UK pharmaceutical industry standards was a disappointing export performance in 1980 and 1981. To the extent that the latter influenced the balance of capital allocation in the company by company PPRS negotiations, export disappointments could have helped increase NHS prices and so contributed to the unexpected rise in NHS resources going on medicines observed in and around 1982.

In addition, the basic profits allowed at that time by the PPRS — about 25 per cent on capital — had not been adjusted downwards to take account of the falling rate of inflation in the early 1980s. Whatever the cause of the spending increases, however, the result was easily observed. Government-industry relations became strained. This was not least because a rise in 'parallel imports' from Europe encouraged by sterling's strength meant that some UK based companies suffered decreased domestic incomes at the start of the 1980s, even though the national 'drugs bill' had gone up. Earnings of dealers buying medicines 'cheap' abroad and selling at full NHS prices in the UK helped fuel the communication gap between the pharmaceutical industry and the government, which after the 1983 general election turned into a communication crisis. A freeze on medicines prices was first imposed, followed by selected price cuts. These alone disrupted the normal activities of those running the PPRS. Then in 1984/85 came the conflict over the 'limited list'.

The latter affected just a few categories of medicines for which over-the-counter alternatives were generally available. (The major exception was benzodiazepine sedatives.) Had it been introduced as originally suggested by the government, its chief effect may well have been to force consumers of all ages to pay for medicines themselves, rather than to cut overall pharmaceutical industry earnings. But it was fought vigorously by both the BMA and ABPI and its members, not just because of immediate economic fears but also because it cut right across the tradition of negotiation between the trade association and the DHSS established through the VPRS/PPRS. In not consulting ABPI before acting publicly, Ministers were in effect saying that it was a 'broken reed', and implying that they would in future act unilaterally to set national pharmaceutical costs. In not consulting the BMA, Norman Fowler and Kenneth Clarke were challenging medical authority within the NHS.

The resulting sharp public dispute injured all the combatants. The government was questioned on its commitment to the health service, and the ABPI on its political judgement. But following Kenneth Clarke's move to the Department of Trade 'normal' relations were eventually resumed, and both sides could point to some positive outcomes. Seen through Departmental eyes, the proportion of medicines prescribed and/or dispensed in brand form took a steep fall from its late 1970s/early 1980s peak of nearly 90 per cent to about 70 per cent post 1985. And the escalation of NHS medicines spending was halted in 1984 and 1985. Since then growth in spending has not brought NHS outlays back on to the 1975-1982 trend line, indicating that real savings have been achieved on a recurrent basis.

Seen from an industry viewpoint, its objections to arbitrary intervention in the NHS pharmaceutical market place were clearly registered, and the subsequent 1986 renegotiation of the PPRS was not unsatisfactory. For example,

an adjustment was made to the level of promotion costs fundable from profit which was of benefit to relatively hard-pressed middle sized companies competing with larger concerns. At the same time an adjustment was made to the PPRS's so-called 'grey area', allowing more profit to be made over and above the basic target level by firms producing new medicines or achieving efficiency savings (ABPI/DHSS, 1986). Arrangements were made for dealing with transfer pricing problems which appear to have satisfied both the Department of Health and concerned sections of industry.

Since then the main developments to affect the NHS pharmaceutical sector relate to the publication of the White Papers 'Promoting Better Health' (HMSO, 1987) and 'Working for Patients' (HMSO, 1989). The first of these augured major changes in the Family Practitioner Services in particular, and the second in the NHS as a whole. The latter reforms involve an increased separation between care purchasing and care provision. More effective budgeting and case management systems are intended to create more discriminating demand side behaviour within the NHS. Increased provider plurality and competition is designed to help boost supply side responsiveness.

As far as medicines supply is concerned, the developments expected include more widespread voluntary (Clarke, 1990) use of GP practice level (and perhaps eventually locality wide) formularies and the introduction of indicative drug budgets, described in Box 4. These last will, the government has repeatedly said, be flexible. But they should nevertheless help focus more family doctor, Family Practitioner Committee/Family Health Service Authority and Regional Health Authority attention on the costs of medicine used in the community. And general practitioners who opt to hold funds at the practice level will be operating with cash limited resources which if not spent on medicines can be devoted to other forms of patient care, and vice-versa.

The detailed implications of these new arrangements are not examined here. But looking generally at the history of pharmaceutical profit and cost regulation in the UK and its likely future both in this country and the European Community as a whole, such moves suggest the possibility of further major changes after 1992. The latter is not only the year in which the existing PPRS agreement is due to be renegotiated; it is also that in which, in theory at least, a European single market is due to be established. Some questions relating to the future of medicines cost control are examined later in this paper, following a brief look at the lessons to be learnt from the last four decades of NHS medicine cost control in Britain.

4

INDICATIVE DRUG AND PRACTICE BUDGETS

The post 'Working for Patients' reforms are set to influence Family Practitioner Service medicine spending levels via two main mechanisms after April 1991. For the majority of GPs indicative drug budgets, determined by Regional Health Authorities and Family Health Service Authorities, will provide a new impetus for them to be aware of the costs of their prescribing. Supported by improved PACT (prescribing analysis and cost) data, they may have to account for excess spending to their local FHSAs, which in turn will have to account to Regions if they exceed target levels.

In the case of family doctors in fund holding practices, they and their partners will have specific amounts of cash allocated to them for a range of defined functions, including prescribing. If they do not spend all of the proportion allocated for pharmaceuticals on such items, the sum released can be used for other forms of care and/or practice enhancement. It should be noted that the moneys devoted to practice budgets will be drawn via a separate, cash-limited, Parliamentary vote. The resources used to pay for 'indicative budget' medicine spending will not, however, be drawn from the cash limited hospital and community health service vote; despite the new role of Regions the traditional 'open-ended' FPS vote will continue to fund GP prescribed medicines.

For those concerned that the new arrangements could drive medicine spending down to such low levels that NHS patients might be deprived of the medicines they need the latter arrangement should be reassuring. Ministers have repeatedly stated that NHS patients will not be adversely affected by the new arrangements, and that both practice budget and indicative budget scheme family doctors who 'over spend' pharmaceutical allocations for justifiable reasons will not be penalized.

However, the fact that the bulk of NHS medicine costs will still be carried on a separate, open ended, vote may not have pleased all those responsible for trying to ensure that such public expenditure is adequately controlled. (In the past sources in the Treasury have reportedly estimated that NHS medicine spend savings of £200-£400 million per annum could be effected without harming national interests, although no calculations supporting this conclusion have ever been published.) Also some uncertainty still remains (in April 1990) as to the nature of incentives — and sanctions — which may be introduced to encourage RHAs, FHSAs and GPs to stay within their medicine budgets. Without appropriate managerial and financial provisions the purpose of the new arrangements could well be defeated. For example, the retention of the separate, open, FPS vote as the source of FPS medicine supply funding might even encourage some people in RHAs to 'dump' costs into that area, rather than properly to control it.

Understanding NHS medicines cost control 1948–1992

2

Despite periodic crises and the creation by government of numerous 'expert' enquiries into the relationship between the NHS and the pharmaceutical industry, the most obvious characteristic of the partnership which has existed between the health service and British based drug companies over the last 40 years is its success (NEDO, 1986). As noted previously, Britain has a strong, innovative, pharmaceutical sector, generating one of the world's largest positive balances of trade in medicines. Notwithstanding a relatively fast growth in imports since the start of the 1980s (which has meant that in inflation adjusted terms the UK pharmaceutical trade balance has stayed roughly constant from 1979 onwards) Figure 3 (page 10) shows that the inflation adjusted value of this country's medicine exports now stands at over 50 per cent above the 1980 level, and over 400 per cent above the 1960 figure.

At the same time UK spending per capita on medicines is relatively low in international terms, and is certainly well below that of all other major pharmaceutical producers. Domestic investment in pharmaceutical R and D is high, and spending on promotion expressed as a percentage of all sales to the NHS appears to be only two thirds or less of the equivalent figures recorded in countries such as France, Italy, Germany, Japan and the US.

There are several groups of reasons why even with this record of success there has been such frequently observed tension surrounding NHS pharmaceutical spending and the activities of pharmaceutical companies. At a fairly general level, for example, it is perhaps inevitable that a technology which attracts so much hope and interest, but is often little understood, will generate 'horror stories' as well as misleading 'wonder cure' coverage in the media. The combination of fear of disease, desire for new treatments, uncertainty about safety, and ignorance about how medicines work is a potent one, particularly if mixed with issues of high finance and 'human interest' illustrations of individual distress.

Moreover, as discussed earlier, pharmaceutical markets are subject to many different types of imperfection. That is why all governments in Europe have felt it necessary to intervene in pharmaceutical supply processes in special ways, and why the outlook for the 1990s is one in which new EC regulatory interventions of various types are going to be of great significance.

In the context of the UK in particular, with its directly politically controlled health sector, differences of perceived interest between companies/the industry, consumer interests and the NHS/government are likely to surface in the form of vigorous, adversarial, public debate from time to time. The 'noise' of the latter should not necessarily be taken to be evidence of an unsatisfactory situation; to date, at least, it might rather be considered to have been simply the sound of democracy working to trade off the interests of the various groups involved, and achieve fairly satisfactory results. However, it may be that in the more complex conditions of the 1990s a system which has worked well for Britain as a single unit will not prove so satisfactory for Britain in Europe.

One of the more disturbing conclusions which might be drawn from the record of past decades is that bodies such as the Treasury seem to have relatively little detailed knowledge of how sectors of the economy like pharmaceuticals function. This ignorance has been counter-balanced by expert understanding in those parts of government responsible for health care and hence has not as yet proved too destructive; adversarial interaction between 'public expenditure minimisation' proponents and individuals with more pragmatic attitudes has resulted in mutually acceptable compromise. But in the future it may be that a better informed, less divided, governmental approach will increasingly be seen as essential, if still in practice difficult to attain.

Another set of reasons as to why high tension has often surrounded questions of NHS pharmaceutical supply relates to the fact that at times British governments may not have wished fully to acknowledge the relative success of the NHS in limiting health care costs. Although in the late 1940s/early 1950s it was possible to believe that 'free' NHS provisions would lead to 'excessive' demand for and supply of health services, it has been apparent since the mid 1950s that this is not actually the case. Telling the public and/or concerned labour groups too openly that the NHS is a comparatively effective care rationing and wage limitation agency could on occasions have seemed politically unattractive. Conversely, stressing the rising cost of prescribed medicines may sometimes have seemed a good way of communicating how much is spent on the NHS. Cynics might think it has sometimes also served as

a way of checking the authority and aspirations of professionals in the NHS who might otherwise have demanded greater investment in their activities.

Similarly, the twin motives of the Ministry/Department of Health in wanting to be able effectively to control NHS medicines spending but also to encourage a strong, export oriented, domestic industry may on occasions have led to degrees of public — and health professional — confusion about the objectives of national policy. For instance, the emphasis on voluntary involvement of companies in the VPRS/PPRS and promotional content and cost control arrangements may sometimes have looked like weakness, even though the result has been in many respects desirable from the DoH, and national, standpoint. In reality, the statutory and allied controls available to the UK government have not been as insignificant as the nation's overt tradition of voluntarism might suggest to outsiders.

Indeed, at a representational level it is the industry which, even though it apparently 'made the running' in developing many aspects of the VPRS/PPRS, may in fact have been the frailer partner. A trade association significant enough to help government contain major conflicts with individual companies or groups of companies but too weak usually to act as a lobby powerful enough to enable the industry (or any one cohesive part of the industry) to speak with a strong, universally credible, voice could be a state asset rather than a sectional, private sector, one. Whether or not in future some further reorganisation of research based and generic manufacturing company representation on a national or EC wide basis would prove beneficial to the public or company interests is uncertain.

Finally, the perceived need for secrecy in Departmental/industry/company relations may have fostered amongst some commentators fears of 'under-the-counter' dealing. Despite the praiseworthy achievements of Britain's public health and private pharmaceutical sector collaboration, this could to a degree have led to suspicion and an undermining of public and political confidence (Box 5). Similar doubts have recently been expressed in relation to the working of pharmaceutical promotion regulatory arrangements in the UK (Herxheimer and Collier, 1990).

Commercial confidentiality is, of course, vital in as much as without it fair competition between companies would be impaired. Yet arguably the most important lessons for the future to be drawn from the past of the VPRS/PPRS relate to the options for greater openness regarding public and professional education about all aspects of pharmaceutical sector control. If it is decided that in future it would be in the community's interest to achieve a more balanced political and public understanding of the working of Europe's pharmaceutical sector then more effort to explain and justify the principles and mechanisms of relevant market regulations will become seen as essential.

5

PROFITS AND THE PPRS

From time to time the national press and other news media have carried stories suggesting that profits made from the sale of pharmaceuticals to the NHS have been excessive. On occasions these fears may have resulted from the researches of investigative journalists themselves; at other times they may have come from political or related sources. What is clear that definitive data as to precise levels of profit and costs on medicine sales to the NHS permitted under the PPRS are not publicly available on a company by company basis. However, comparisons with per capita medicine spending levels recorded elsewhere in Europe do not, as discussed in the main text, support the suggestion that British based companies have been particularly 'feather-bedded' by the PPRS.

For the industry as a whole the permitted return on capital employed under the PPRS was set at 16-18.5 per cent in October 1986, and lifted to 17-21 per cent in October 1987. This appears to have allowed an increase in industry earnings from the NHS towards the end of the 1980s, although in 1989 the stabilisation of profit levels, coupled perhaps with factors like an increased general inflation rate and renewed interest in NHS medicine costs, cut back on 'real' NHS medicines spending growth.

Some concern and doubt about the significance of such profit figures, and the extent to which pharmaceutical suppliers may sometimes have motive and opportunity to allow their costs to be relatively high, is perhaps to be expected in so sensitive an area as health care. (And confusion may sometimes be further stimulated by occasional public references made to figures based on companies' aggregated Annual Financial Returns to the Department of Health, which show industry cost and profit figures before adjustments have been made as a result of Departmental/company negotiations.) Yet the 'bottom line' for Britain in relation to its pharmaceutical sector is not seriously to be questioned. If this country did not have its strong domestic pharmaceutical industry it could be £2,000 million per annum or more worse off in balance of trade terms alone.

Looking to the future

13

The European Commission has already issued a number of draft Directives, Directives and Regulations relating to pharmaceuticals. In response, the international pharmaceutical industry has established an increasingly vigorous communication and lobbying effort focused primarily on Brussels; it is probably more advanced than any other part of industry as to its thinking about, and attempts to shape, the future European environment. For some, national governments are increasingly seen as mere 'side-line' players on the European Community stage. To the extent that this is true it raises important questions about the democratic process in Europe, and the accountability of decision takers in the European Commission to the populations, and elected representatives, of nations such as Britain. Despite the activities of some vigorous Brussels based consumer groups, the mechanisms for ensuring that the public's interests are adequately represented and pursued within the EC structure seem on occasions to be of questionable reliability.

In practical terms, progress has to date been relatively slow. But one example of existing EC legislation is the 'transparency Directive', which is designed to ensure that pharmaceutical pricing and patient reimbursement regulations are based on overt principles. This could eventually pave the way to a more unified EC pharmaceutical price/profit control approach. Illustrations of other proposed interventions relate to future systems for registering pharmaceuticals in the EC (including the creation of a European Agency for the Evaluation of Medicinal Products), to the labelling and packaging of products (including the supply of patient information), to the control of pharmaceutical advertising, and to extending pharmaceutical patent protection. This last, for instance, may involve the issue of 'supplementary protection certificates' (SPCs) to provide a total of up to 16 years exclusivity of supply post-marketing approval. It is intended to compensate innovative manufacturers for the time spent testing the safety and efficacy of medicines after the official start of patent protection period, but before the market launch of their products.

This brief paper does not contain detailed analyses of these initiatives. Rather, the remainder of this section highlights some key policy questions linking Britain's pharmaceutical interests with those of the European community as a whole. The objective is to provide an overview of the types of pharmaceutical policy issue which should be resolved in the 1990s.

However, before this there are two preliminary points to be made. First, the central goals of decision makers include the pursuit of a satisfactory balance between citizens' interests in restraining current outlays on medicines, and spending 'enough' on innovation for the future. Also, they need to create and maintain a 'level playing field' in Europe, so that pharmaceutical investments are made on rational, welfare-maximising, criteria rather than the economically inefficient pursuit of local subsidies.

Yet there is no 'scientific' way of deciding the 'right' level of spending on research, and the achievement of a unbiased European-wide pharmaceutical investment market is likely to be very difficult. A spirit of compromise, good will and open communication between all the interested parties will be essential for the attainment of such policy objectives.

Following on from this, it has to be recognised that any gains to be made from the creation of a more unified and efficient European market in this, or any other, area cannot be achieved without costs; some parties will inevitably lose. For example, it is virtually certain that the simplification of medicine licensing and other regulatory controls affecting market entry will help 'foreign' rather than established indigenous companies to increase their European pharmaceutical market penetration. With Japan in particular likely to extend its share of the global pharmaceutical market in the 1990s, this is a matter of concern to some commentators. However, it should be recognised that against possible trading losses Europe will enjoy not only the benefits of competitively successful Japanese medicines but also new capital investment from Japanese companies.

It is also probable that concentrations of existing and future medicines production capability in Europe will lead to local job, and in some cases export, losses. Some observers believe that there is currently up to 75 per cent plant 'overcapacity' in the European pharmaceutical industry (Burstall 1990b), although for the next few years at least political considerations may inhibit drastic rationalisation measures. The point remains, however, that the establishment of a more open and competitive market and the vigorous pursuit of lowest possible cost medicine supplies

by large purchasing agencies (including international wholesalers) will not always be in the interest of communities which benefit from existing patterns of pharmaceutical trade. In Britain's case, and perhaps particularly that of the broadly defined London region which at present can lay good claim to being the pharmaceutical capital of the world, a degree of caution about encouraging unpredictable change might be prudent.

Policy questions

1 Could and should supply side medicine price and profit control systems be replaced by demand-side restraints like health service budgets?

The shift to indicative budgets and practice fund holding in the UK may be taken as evidence of a government intention to become in future less reliant on the PPRS and related supply-side restraints for NHS pharmaceutical cost control. If demand-side interventions can without harming patient interests heighten price competition in the NHS pharmaceutical market place sufficiently to convince government that satisfactory value for money is assured, then medicine price controls might be eliminated altogether in the UK. This could in some respects prove advantageous after 1992.

However, despite the appeal of such a scenario to market economists and sections of the pharmaceutical industry alike, it is not without drawbacks. Setting budgets for health service agencies to spend on pharmaceuticals may be no less of an uncertain and contentious a process than intervening to control supplier prices and profits. Indeed, it could bring additional complications. Apart from politically significant public fears about the health service being unable to afford certain products for certain individuals, there could be some danger that too enthusiastic a cost-saving approach on the part of officials in bodies like RHAs (who are naturally concerned mainly with local health service costs) would result in uneconomic national expenditure savings. (At present, however, general practice medicine costs will not be derived from Regions' budgets.) By contrast, too little control on 'block-buster' innovations might, some fear, lead to considerable profit taking by a few fortunate companies.

In many parts of Europe demand-side only pharmaceutical cost control systems would in practice tend to require very heavy reliance on patient co-payment schemes, with only a limited proportion of products being fully reimbursable. The extent to which such arrangements would represent efficient and effective ways of providing medicines is as yet unproved. Despite some potential advantages — see below — the fact that need for pharmaceuticals is often inversely related to wealth can in practice make fair, easily workable, medicine co-payment systems very difficult, if not impossible, to set up.

For these reasons alone the creation of a pan-Europe free price medicines market moderated only by local service budget restraints and patient payment/product reimbursement variables seems some way distant. However, the working of the European market (coupled with new government price controls) should during the early to mid 1990s reduce pharmaceutical price differentials between EC states, down from the current range of 100 per cent plus to perhaps as little as 20-30 per cent. During this process average European price levels are likely also to fall, although it is impossible to predict the precise outcome.

Looking specifically at the UK it appears probable that the UK pharmaceutical price/profit controls will not be totally eliminated in 1992. Rather, the PPRS might be further narrowed and modified to cover only patent protected or single-source supplied products, and will perhaps become used mainly as a reserve power for identifying product related extremes demanding special intervention rather than as a 'norm' setting device for overall company and industry profits and costs. (It should be stressed, however, that even now the PPRS does not guarantee any company given profit levels — rather, it imposes ceilings.)

2 In what circumstances might extended consumer payments for prescription medicines have desirable effects on patients' wellbeing?

To the extent that prescription charges and other patient part-payment schemes for medicines discourage or prevent poorer individuals from obtaining treatments that they need, they are of course undesirable. But if 'free' medicines such as tranquillisers are sometimes over-prescribed, and if even limited charges help consumers to decide rationally whether or not they wish to use a prescribed medication, then patient payments for medicines may have a positive role over and above their public expenditure implications (Taylor 1987).

In the UK the data presented earlier in this paper show that payment exemptions, particularly for the elderly population, have greatly weakened the impact of prescription charges as compared to the situation prevailing in the 1950s and early 1960s (Box 6). It may thus be that after the 1991/92 general election some revision in domestic UK policy will be considered, although the political factors militating against changes in the NHS's existing arrangements are in this context very considerable.

6

MEDICINES AND THE ELDERLY

Figures recently produced by the Association of the British Pharmaceutical Industry (1990) show that over 41 per cent of all NHS prescription items are for people of state pension age. The number of items supplied per person of working age or below is five per annum. For those aged 65-74 it is 12. And for those aged over 75 it is 24. Given the ageing of the population, the industry trade association suggests the number of prescriptions should continue to increase — 96 per cent of the growth recorded between 1977 and 1988 was related to medicines for the elderly. The ABPI argues that any attempt "to bring downward pressure on expenditure on drugs ... would certainly have implications for the health care of the elderly and more particularly the very elderly".

The Secretary of State for Health, Kenneth Clarke, (1990) has acknowledged the special pharmaceutical needs of older NHS users. But in a speech shortly after the publication of the ABPI's document he commented that "recent research showed that some doctors' records were so deficient that they were seemingly unaware of one-fifth of all the tranquillisers being taken by their elderly patients. Pharmacists considered that 31 per cent of all prescribed medicines taken by the elderly were pharmacologically open to question". (See Cartwright and Smith, 1989.)

The range of possible motives on both sides of this political debate are obvious. What is needed from a public interest viewpoint is an impartial, patient centred, approach to such matters, which looks in an objective way at issues like the impact of prescription charges, the dangers of careless or excessive medicines prescribing, and the degree of unmet overall health care need in the elderly population. The extent to which any British agency is currently equipped to provide this is questionable: it is perhaps a function of the sectional, conflict oriented approach to the health care debate in the UK that such a situation exists.

3 What evidence is there that there are community-wide patterns of 'over' or 'under' prescribing of pharmaceutical products?

The available international figures indicate very marked differences in medicine consumption between high volume use countries such as France and lower pharmaceutical use countries such as Holland and the UK. But in outcome terms it is not (at present at least) possible to identify clear overall patterns of advantage or disadvantage associated with either type of medical culture. Despite concerns such as those mentioned in Box 6 in relation to high volume (repeat) prescribing of medicines like tranquillisers for elderly people, there is insufficient evidence to conclude that either 'too much' or 'too little' prescribing takes place in this country. Broad generalisations involving any such assertion should be treated with great caution. However, the data presented in Tables la and lb throw some light on the nature of high medicine cost/use and low medicine cost/use Family Practitioner Committee areas in England.

Although studies of individual general practitioners have revealed wide discrepancies in prescribing volume even within similar localities, it can be seen that at FPC level variations in medicine costs are not particularly pronounced. Lowest use areas like Oxford, Croydon and Bromley have per capita FPS medicine (net ingredient) costs some 15 per cent below the national average, while highest use localities like Salford and North Tyneside have pharmaceutical cost levels about 25 per cent above the national average.

Examination of data such as FPC 'Jarman scores' (used to measure degrees of deprivation) shows that, as might be expected, higher prescribing costs relate positively with factors such as unemployment and the proportion of elderly people in FPC populations. There also appears to be a negative association (over and above age structure variables) between the proportion of people of new Commonwealth and Pakistani origin in a locality and overall medicine spending. Hence London FPC areas like Camden and Islington and Lambeth, Southwark and Lewisham (which on the Jarman ratings are respectively the second and third most deprived areas in England) appear in the list of lowest pharmaceutical spenders, alongside advantaged counties like Surrey and Hertfordshire.

The overall picture to emerge is that medicine spending is highest in relatively deprived but stable communities in the north of England, which probably combine above average levels of morbidity with well established patterns of GP/patient contact. Low per capita FPC medicine costs, by contrast, are typically found in better off southern localities. The exception relates to the socially atypical inner London areas, where low medicine costs are apparently positively linked with deprivation. The hypothesis that in the capital (and perhaps elsewhere) people with new Commonwealth and Pakistani ethnic origins may be at particular risk of 'under-treatment' – at least in terms of the receipt of dispensed medicines – deserves further investigation.

4 Are special European controls on pharmaceutical advertising content and/or costs needed?

Standards of pharmaceutical promotion, and the costs of such activities to health care providers, have long been controversial matters. It is important to recognise that disseminating complex information to health care providers is bound to be an expensive process, and that companies in competition must try as hard as they can to attract and hold their audiences' attention. An excessively naive or puritan approach to promotion regulation

could undermine the existing successful base for pharmaceutical innovation and dissemination in Europe, or at best distort the competitive process in favour of the status quo.

The European Commission produced in late 1989 a preliminary draft Directive suggesting a range of controls on pharmaceutical promotion, including restrictions on representatives' activities such as giving samples and other gifts to doctors. The sponsorship of meetings held in attractive locations might if the Directive was implemented also be curtailed. Companies breaking the rules could lose their right to market products.

Not unpredictably, individuals within the pharmaceutical industry reacted adversely to these proposals, arguing that pharmaceutical promotion should not be controlled differently to similar activities in other commercial sectors. Yet some independent economists believe there is good reason to pay special attention to the control of pharmaceutical promotion, over and above particular health related concerns about information quality. In essence this is because of the types of market imperfection noted earlier, and the 'prisoners' dilemma' problems which can occur in relatively price inelastic markets. The danger is that rival medicine manufacturers become trapped in a cycle of ever more expensive competitive promotional spending. If all could cut such outlays together, all would probably retain similar market shares and the prescribers/users may not be any worse informed.

If price sensitivity in the European pharmaceutical market increases in the future such dangers will recede. If so, fears that 'excessive' promotional efforts permit companies to profit unduly from high cost off-patent branded products or innovations of little therapeutic advantage at the ultimate expense of tax or fee paying consumers (who might have been as well off using lower cost, older or generic products) would also be allayed. Yet the fact that in some EC member states the proportion of pharmaceutical company earnings going on promotion appears to be 50 per cent or more above that permitted under the UK PPRS provides some substantive reason for concern.

To the extent that the European medicines market of the 1990s will become increasingly unified some common approach to pharmaceutical promotional practices — and directly or indirectly their costs — would seem attractive from a range of viewpoints. Companies will continue to argue that controls of any sort may prove harmful, especially to those competing against larger, established, rivals. But even as far as overall industry interests are concerned, exclusive reliance on market forces alone to control promotional spending and practice could be damaging. A more attractive policy may be one combining balanced, largely voluntary promotional restraint (backed by legal powers) with market structures designed to help ensure the financial stability of a high quality, responsible, and where appropriate innovative, pharmaceutical sector.

Table 1a High medicine cost English FPC areas (1988/89)

FPC	Spend (£)[1]	UPA score (rank)[2]	
Salford	49.8	15.9	(16)
North Tyneside	49.1	5.4	(30)
Sunderland	46.5	14.6	(18)
Bury	46.5	-1.5	(40)
Barnsley	46.2	-11.8	(71)
Lancashire	45.8	7.2	(28)
Liverpool	45.7	25.6	(9)
Trafford	45.7	-9.8	(62)
Wirral	45.3	2.9	(32)
Wigan	45.1	-2.0	(41)
Isle of Wight	44.7	-4.93	(45)
Dorset	44.3	-10.73	(68)
Sandwell	44.2	11.6	(22)
Rochdale	44.1	26.5	(7)
Walsall	44.0	-4.4	(43)
Wakefield	43.9	-8.3	(56)
Lincolnshire	43.8	-10.4	(65)
Cleveland	43.6	12.8	(20)
Doncaster	43.5	-4.7	(44)
Durham	43.4	2.5	(34)
National Average	39.0		
	Mean	2.8	
	(Ethnic[3]	2.3)	
	(Mean for highest 10	5.6)	

Source: Department of Health

Notes

1 Net ingredient cost of pharmacist and GP dispensed medicines expressed per capita OPCS population.

2 Jarman UPA score, positive scores show above average degrees of deprivation (Rank 1 = most deprived, 90 = least deprived)

3 An element in the Jarman UPA score is based on the percentage of households in each FPC area with heads of new Commonwealth or Pakistani origin.

Table 1b Low medicine cost English FPC areas (1988/89)

FPC	Spend (£)[1]	UPA score (rank)[2]	
Oxford	33.1	-13.0	(74)
Enfield & Haringey	33.4	-6.1	(29)
Croydon	33.5	-8.5	(58)
Bucks	33.6	-15.9	(84)
Bromley	34	-25.9	(88)
Gloucestershire	34.1	-14.9	(82)
Greenwich & Bexley	34.2	-1.0	(39)
Cambridgeshire	34.2	-6.1	(48)
Hertfordshire	34.8	-25.1	(87)
Barnet	34.8	-9.6	(61)
Berkshire	34.9	-14.4	(79)
Northants	35.1	-0.4	(37)
Avon	35.2	-10.8	(68)
Surrey	35.2	-30.9	(90)
Nottinghamshire	35.3	-7.4	(53)
Wiltshire	35.3	-10.6	(67)
Lambeth, Southwark & Lewisham	35.3	39.8	(3)
Merton, Sutton & Wandsworth	35.4	7.6	(27)
Dudley	35.6	-18.9	(85)
Camden & Islington	35.7	41.3	(2)
National Average	39.0		
	Mean	-6.6	
	(Ethnic[3]	7.0)	
	(Mean for lowest 10	-14.4)	

5 Should 'on-the-market' pharmaceutical patent terms be extended?

Proponents of pharmaceutical patent term restoration in Europe can argue convincingly that, compared with other innovative industries, pharmaceutical sector concerns lose approaching ten years worth of potential patent protected earnings because of pre-market safety testing and licensing requirements (Lis and Walker 1989). This may have made innovative concerns more reliant than they otherwise would have been on rapid initial launches and brand name promotion. It might in more severe future market conditions undermine the economic position of innovative pharmaceutical companies. Acceptance of recent EC proposals to restore effective medicine patent terms is, they believe, necessary now to safeguard the European public's long-term interest in a strong research based pharmaceutical sector.

These proposals stem from initiatives taken within the French politico-industrial establishment and from Commission and industry expressed concerns that America and Japan have already taken steps to restore effective pharmaceutical patent terms, to the benefit of their domestic industries. However, neither country has introduced extensions as great as those proposed by the European Commission.

The opponents of such reforms argue that the pharmaceutical industry has been, and remains, more profitable than most other sectors of the economy. The continuing low concentration of the industry in Europe, where despite recent mergers some 2,000 pharmaceutical companies remain in competition, is critics believe evidence of a protected environment. They argue that increasing effective medicine patent terms will only serve to put up drug costs. Otherwise such reform would not be advocated by most research based pharmaceutical companies. (Only one of the latter has suggested publicly that its superior efficiency in bringing forward major new products to markets gives it a competitive edge in times of eroded average patent protection. Some producers of generic medicines also favour relatively short effective patent terms.)

Patent term restoration opponents may also argue that research based companies can today 'build in' additional technical forms of product protection, such as manufacturing process variations or complex, separately patented, delivery systems. However, if this last is true it logically tends to suggest that patent term restoration for medicinal substances per se would not alter overall medicine costs as much as might otherwise be the case. Similarly, if major products have longer than average patent terms the costs of restoration/extension would be less than opponents of reform may fear.

Identifying appropriate trade-offs in this area is not a straightforward matter. As with trying to calculate 'desirable' levels of pharmaceutical research spending, there are no clear answers. However, it is a fact that national outlays on medicines are determined by a wide range of factors. If it is assumed that in planned or semi-planned environments variations in these will over time tend to even each other out in relation to overall spending levels (if only because of government price controls) then the key issues to consider about patent term restoration are its likely consequences regarding market structure, company behaviour, and the balance of income as between therapeutically innovative companies and their competitors. To the extent that patent term restoration can be employed in efforts to help create or maintain a European pharmaceutical market characterised by responsible levels of promotion, useful innovation and successful but not 'unduly' profitable domestic manufacture then it will be in the public interest.

6 What place are generic medicines and formularies likely to have in future medicine cost control strategies?

Generic prescribing and dispensing and the use of formularies may, their proponents claim, help improve medical practice and reduce costs. But against this it is possible that too simplistic or rigid an approach to such techniques could stifle innovation and therapeutic choice and might, in the case of the UK, damage the nation's economy as well as the finances of research based companies. From a British position NHS savings achieved at the cost of significantly increased 'cheap' imports and the undermining of domestic production could prove expensive.

Once again, a reasonable, pragmatic balance has to be achieved — there is no single 'right' answer but a range of possible ways forward. In the UK context calls for generic substitution (ie the dispensing by pharmacists of generic products even if brand name items have been prescribed) appear to have lost strength in the face of the indicative budget proposals. To the extent that this will, from patients' and doctors' viewpoints, protect the integrity of the prescribing process, this is arguably desirable.Greater awareness of the cost implications of prescribing choices engendered by practice and indicative budgets should tend to increase generic prescribing and practice (and perhaps locality) formulary usage, regardless of other factors. Provided that undue economic restraints are not in future placed on prescribers this seems a sensible, practically viable, approach.

An additional support for such trends could be the introduction of regulations permitting doctors to specify the source of generic medicines to be used, and allowing pharmacists to be appropriately remunerated for dispensing them.

The recently formed British Generic Manufacturers Association has advocated reforms of this nature, not least because they could overcome problems of patient recognition of generic medicines as well as increasing prescriber confidence in the use of generic products (Smith, 1990). Although some critics might dismiss 'identified generics' as merely being low cost brands, the potential advantages of having a professionally trusted system for providing off-patent medicines of assured quality from a known source and at near commodity price are clear.

7 Could involvement of non-medical medicine prescribers in care provision be beneficial?

In the UK discussions are already being conducted about the introduction of nurse prescribing, based on a 'limited list' of products. There is also a possibility that in the future extended prescribing rights — and an associated diagnostic role — could be given to pharmacists. There are already a number of 'pharmacist only' medicines (see below) and in countries like Holland pharmacists have long enjoyed a more respected professional status than they do in Britain. Together, extended nurse and pharmacist prescribing would not merely allow the transfer of some work from family doctors to other staff: it could create new patient choices about where and how they can obtain primary care, and introduce competition where previously there was an exclusive, single profession, monopoly.

Innovations such as 'smart cards' could help reduce problems related to medical record continuity, unplanned multiple treatments and resultant drug interactions/contra-indications. However, it is likely that strong objections to any radical extension of prescribing and/or diagnosis by other professions would be raised by some doctors. Controversial counter-claims, such as that general practitioners should become more responsible for dispensing and so enable more primary care patients to enjoy 'one-stop shopping' (Pharmaceutical Journal, 1990), might in future become central to defensive strategies adopted by medical interests.

8 Should more medicines be made freely available 'over-the-counter' (OTC)?

There has recently been debate as to the possibility of introducing a single European wide list of non-prescription medicines, although the likelihood of this now seems to have receded. The situation in the EC member states is varied. Britain has at present a fairly liberal position with regard to General Sales List (GSL) OTC medicine sales (available from any outlet) but does not allow pharmacists to provide without medical authorisation medicines like basic antibiotics or H2 antagonists to patients, as do some other European countries. (Denmark has recently pioneered a radical approach to the extended supply of OTC medicines.)

Key points to consider here relate to the distinction between any outlet (GSL) and pharmacist only (P) medicine sales, and the possible advantages to consumers of the former as opposed to the latter. Clearly, if pharmacists offer no important professional service to most consumers over and above those of being competent product stockists, there is little case for granting them retail monopoly powers. Rather, effort and resources should be put into direct consumer education and the spread of 'pharmaceutical literacy', perhaps with a view ultimately to making more (in some cases expensive) products such as H2 antagonists and first line antibiotics available from any convenient source.

But if community pharmacists can in future extend or better demonstrate the special value of their existing professional services to consumers it may be that the public interest will be seen to lie more in the direction of greater P medicine supply. There might even be moves to curtail some existing GSL availability in Britain, in line with a more pharmacy oriented pan-European approach.

9 What are the likely benefits of revised medicine packaging and extended patient information requirements?

In most European countries most if not all medicines are dispensed in manufacturers' original packs (OPD — original pack dispensing). In Britain, by contrast, there has been a much stronger tradition of pharmacists buying in bulk and dispensing in their own containers. This is now likely to change, in part because of medicine manufacturers' policies and in part because of new draft EC requirements. They demand that numerous mandatory items of data be included in both package inserts and product labels.

To the extent that these changes will enhance consumers' knowledge about medicines and their ingredients, they are of course to be welcomed. The use of manufacturers' packs can help ensure product identification, safe storage and correct dose delivery. However, it is possible that a shift to OPD linked to the enclosure of compulsory information inserts with each prescription item could in some circumstances also serve less desirably to inhibit the free flow of goods in Europe, increase pharmacists' storage problems, increase medicine wastage and inflate costs for little or no real return for patients. The public interest policy approach here may therefore be one which does not 'lock' medicine suppliers into only one set of options, and which focuses firmly on the key issues of safety in medicine dispensing and demonstrated effectiveness in drug information provision to consumers.

Conclusions

The success of the pharmaceutical industry in the last 40 to 50 years has been largely a result of research discoveries. Advances in chemistry, biological science and medicine have combined to generate many new opportunities for drug based therapeutic innovations since World War II. In the same way, the global future of the pharmaceutical industry will depend primarily on scientific innovation. However, differences between internal corporate cultures clearly affect individual company performances. And the distribution of the pharmaceutical industry across the world and the rate and nature of its local development may be significantly influenced by medicine price controls, and regulatory interventions in fields such as medicine licensing and promotion. National variations in consumer and prescriber health beliefs and treatment customs are additional relevant factors.

Britain's pharmaceutical sector achievements in the post war period have resulted from a positive — if in part fortuitous — partnership involving representatives of UK based companies, civil servants and central government politicians, NHS based prescribers, and the relatively strong, intellectually rigorous, domestic science and medical communities. Despite periodic overt conflicts and expressed public worries over issues such as medicine safety, this country has provided a stable, reliable, but nevertheless testing and discriminating environment for pharmaceutical innovators to work and invest in. To date, at least, it appears that pharmaceutical companies based in competitive and intelligently regulated environments (rather than merely protective ones) have been those most likely to succeed in global trade (Thomas, 1989; Redwood, 1987).

The 1990s, however, are likely to see radical changes. Alarmist predictions of the sudden dismantling of the British based industry should not be countenanced. No-one who has been in contact with the pharmaceutical industry could have failed to notice its financial strength during the 1970s and 1980s; and no-one who has been in contact with the NHS could fail to be aware of the urgent need for maximum value for money within it. But it is realistic to suggest that reforms in the structure of the health service coupled with the emergence of a more unified European pharmaceutical market and shifts in the focus of world-wide academic research will in time expose Britain's pharmaceutical sector to significant new pressures. For example, the development of Europe-wide medicine wholesaling operations (the regulation of which has recently been addressed by the European Commission) will inevitably sharpen price competition between manufacturers right across the Community, regardless of other factors.

Against this background the material reviewed in this brief report is not sufficient, or intended, to provide definitive insights into what future UK and European policies towards the pharmaceutical sector should be. But it does indicate the broad range of issues which need to be considered during the process of balancing the public's interests. It also contains pointers to what may be learnt from experience of NHS medicine cost control and UK pharmaceutical development efforts, and possible dangers to be avoided in the period of transition into a new European order.

One significant set of issues which has often been overlooked in the mainstream debate about health care development and the better use of medicines is that surrounding the future of community pharmacists, in both the UK and the EC as a whole. During the twentieth century this group has been deprived of its traditional medicines fabrication role, and to a degree is now further threatened by the development of computer based drug information and allied systems. How in future the profession will best be able to contribute to primary care is a matter which needs careful investigation. Ultimately, movement towards either an extended diagnostic and prescribing role for pharmacists (comparable to that played by the progenitors of the family doctors, the apothecaries, in the nineteenth century) or a closer union between the practice of community pharmacy and general medical care provision would seem likely.

Turning to the pharmaceutical industry, the value of the sector to the British community (and that of Europe overall) is such that, arguably, its preservation and further development is too important a matter to be left to private interactions between commercial interests and political decision takers. Ideally, policy formation should also take place on a level above that of the somewhat parochial and adversarial traditions of the past, as sometimes typified even within government by disputes between individuals in the Health Department and Treasury. An open, honest, and informed public debate about British and European pharmaceutical sector options is clearly desirable.

The problem in trying to achieve this is that sectional lobbies of one sort or another may so distort communication that it becomes widely accepted that rational policy determination can only be achieved behind closed doors. In the complex conditions of Europe at the close of the twentieth century there could well be a need for new initiatives designed to help prevent undue secrecy in such fields, and ensure public access to information about how policies are determined.

A clear example of the type of decision which currently needs to be resolved as rationally and equitably as possible is that of whether or not the United Kingdom should use its influence in Europe to support the proposed EC extension of effective pharmaceutical patent terms. Such a move may need to be balanced by more comprehensive pan-European promotional regulations and measures designed to ensure full competition between non-patented products. Provided this is accepted, then the view taken here is that together such reforms would be likely to be beneficial, even though the EC proposals could give pharmaceutical innovators stronger patent protection than they have ever previously enjoyed. In addition to helping to secure the funding of European pharmaceutical research and development in a tougher future market, a balanced package of reforms could increase public and political confidence that health resources are not being wasted on inappropriate activities.

But it should be emphasised that matters such as pharmaceutical patent term restoration cannot — or at least should not — be decided upon by European Commission officials and their selected contacts alone. Full involvement of national level representatives and open, accurate explanations of issues like why a 16 year on-the-market medicine patent term is thought appropriate are needed if the build up of needless suspicions and resentments is to be avoided. If fears that decision making within the EC is controlled by hidden influences and that European Commission officials can exercise or manipulate power without having to be properly accountable were to become widespread then the entire future of the Community would be threatened.

With regard to domestic UK pharmaceutical affairs, the most obviously important development to effect the system in the immediate future will be the introduction of indicative drug and practice budgets for family doctors. Backed by the availability of more comprehensive PACT (prescribing analysis and cost) data, these initiatives appear bound to increase significantly price competition in the NHS medicines market. This should for many reasons prove desirable. But at the same time excessive pressure to create simple cost awareness, rather than prescriber consciousness of differences in both the properties of medicines and patient preferences, could be counter-productive.

For this reason the emerging role of Regional Health Authorities and Family Health Service Authorities in contexts such as the setting and monitoring of indicative medicine budgets and spending levels will need carefully to be observed and guided. Until the characteristics of the new NHS medicines market and the precise objectives of national policy are fully understood at all levels it would seem reasonable to delay any further significant restructuring, such as a shift of the payment channel for community medicines away from the existing 'open' FPS vote to the cash limited HCHS resource pool. Instead, more effort might be made to understand and intervene in specific areas, such as the possible underprovision of medicines in deprived areas of London.

Defining appropriate levels of spending on medicines will in practice always be a difficult and controversial task. One possible way forward, now being vigorously pursued by industry interests, involves the greater use of cost benefit analyses of medicines and other therapeutic regimes (Teeling Smith 1990). But even this approach could leave many questions unanswered, and may open up new areas of uncertainty and dispute. It should not be naively assumed, for instance, that, simply because an existing medicine generates savings in health care, supra-normal producer profit levels are in the public interest. And poorly conducted or deliberately biased economic studies undertaken merely as exercises in 'product advocacy' could of course discredit health economics in general, just as the underfunding of services for people in need may undermine confidence in health service managers and political policy makers.

The final conclusion to draw, therefore, is one which once again emphasises the need for good-will on all sides, amongst politicians, industrialists, consumer representatives, professionals and public servants alike. It may well be that in the health economics context some form of professionally or independently controlled regulatory agency, analogous to those involved in medicine testing and approval, should be introduced. 'Quack' economic figures may be as damaging to community interests as bogus treatments. Yet no mandatory, formal, mechanisms in this or any other field can ever obviate the need for personal integrity, freely exercised. To the extent that medicine producers, prescribers and purchasing agencies share a common interest in working towards the creation of an efficient national and international pharmaceutical market place, as free of bureaucratic regulation as possible, they need all openly to agree appropriate standards of behaviour aimed at promoting maximum consumer (citizen) wellbeing, and to try honestly to live by them.

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