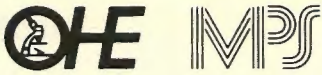

Pharmaceuticals in seven nations

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Office of Health Economics

The Office of Health Economics was founded in1962 by the Association of the British Pharmaceutical Industry. Its terms of reference are:

To undertake research on the economic aspects of medical care.

To investigate other health and social problems.

To collect data from other countries.

To publish results, data and conclusions relevant to the above.

The Office of Health Economics welcomes financial support and discussions on research problems with any persons or bodies interested in its work.

Introduction

This Report has been prepared by the Office of Health Economics (OHE) in Great Britain at the suggestion of and in close collaboration with Medizinisch Pharmazeutische Studiengesellschaft (MPS) in the Federal Republic of Germany. OHE is funded entirely by the Association of the British Pharmaceutical Industry and MPS by seven research-based companies in Germany. The Report describes the modern research-based pharmaceutical industry, with particular reference to its structure and activities in seven countries – the Federal Republic of Germany, France, Italy, Japan, Switzerland, the United Kingdom and the United States. The reason for the choice of these seven countries, which account for three-quarters of world pharmaceutical production, will become obvious in reading the Report.

The Report, which draws heavily on the findings of a special questionnaire survey conducted by OHE, discusses the performance of the pharmaceutical industry, its contribution to national well-being in both social and economic terms and the factors which have been responsible for its success. It is particularly topical because the industry is under scrutiny and attack by both national governments and international agencies in many parts of the world. The industry is also subject to criticism by consumerist groups, which often do not recognise its achievements. Nor do they understand the conditions which are necessary for the pharmaceutical industry to continue to make a positive contribution to society in the future.

The pharmaceutical industry is characteristic of a small group of high technology industries which are becoming increasingly important to the economic prosperity of the advanced nations of the world.[1] These industries need political understanding if they are to make their full contribution to the health and to the well-being of the countries in which they are based. They cannot flourish if they are enmeshed in deliberately hostile constraints.

In recent months pharmaceutical industries have too often been attacked for their profitable success. If these attacks were to continue, particularly in Europe, the prosperity from these high technology industries could be seriously endangered. International competition in and between these industries is strong and vigorous. But if the consumerist criticisms of them lead to punitive government regulation – as seems to be happening particularly in the United Kingdom – the appropriate international competitive environment will be destroyed. As a result, the potential improvements in the quality of life from high technology – that is, from pharmaceutical research – will be endangered.

The Report deliberately concentrates on the problems and performance of the pharmaceutical industry in advanced countries. The quite different

1 For further discussion of this issue the reader's attention is drawn to *Pharmaceuticals among the Sunrise Industries* (the proceedings of an OHE symposium) to be published during the summer of 1985.

problems of supplying medicines to the Third World have been extensively discussed elsewhere (see, for example, *Medicines, Health and the Poor World* published by OHE in 1982) and fall outside the scope of this particular Report. Similarly, no reference is made to the substantial contribution of the pharmaceutical industry to animal health and well-being. Instead the analysis concentrates on the social and economic factors concerned with human medicines. The hope of the authors is that those who read this Report will have a clearer idea of the value of the pharmaceutical industry to those nations which have fostered its growth and prosperity. In consequence, they hope to persuade national governments and international agencies to look favourably on the pharmaceutical industry, and to maintain policies which will allow the industry to make an even greater social and economic contribution in the future.

The Structure of the Industry

HISTORICAL BACKGROUND

The research-based pharmaceutical industry as it exists in the 1980s is less than fifty years old. Up to the 1930s, medicines consisted primarily of naturally occurring medicinal compounds, the so-called galenicals, which had first been formulated by the Greek physician Galen in the second century AD. There were very few synthetic pharmaceutical chemicals – Aspirin, developed by the Bayer company at the end of the last century and Salvarsan by Hoechst for the treatment of syphilis, were notable exceptions. Although many other pure medicinal compounds, such as atropine and morphine, were in use, they were all extracted from vegetable sources rather than being chemically synthesised. It was not until the 1930s that the 'chemotherapeutic revolution' started. The two seminal developments were the synthesis of Prontosil in the laboratories of IG Farben in Germany and of 'M and B 693' in the laboratories of May and Baker in Britain. These early antibacterial substances started to revolutionise the practice of medicine.

The outbreak of the Second World War stimulated the search for other anti-infective compounds; at the same time the therapeutic potential of penicillin, the antibacterial activity of which had been identified by Fleming in 1929, was realised by Florey and Chain. However, the large-scale commercial production of penicillin was eventually effected not in the United Kingdom but in the United States, where industry was less disrupted by wartime conditions. This development in the United States was quickly followed by the discovery and marketing of broader-spectrum antibiotics such as oxytetracycline and chlortetracycline, which were discovered and developed by Pfizer and Cyanamid respectively. Both of these giant chemical corporations had fermentation expertise which enabled them to produce these new antibiotics in large quantities. They were able quickly to make these drugs available worldwide and set a new pattern in positive marketing methods to promote usage. The high overhead costs of the fermentation production process necessitated their achieving a substantial volume of sales as quickly as possible.

Over the next few years, the modern research-based pharmaceutical industry rapidly evolved. This development was founded on the products of synthetic pharmaceutical chemical research and development. The companies entering this new market were either traditional pharmaceutical companies from the galenical era or chemical companies which could see the potential of diversifying into the new synthetic pharmaceutical market. The development of the industry took place in many countries at this stage, but the largest and most successful companies were concentrated in the United States and in the Federal Republic of Germany, France, Italy, Switzerland and the United Kingdom.

Following the example of the United States chemical companies, the largest enterprises based in the other five countries rapidly developed multi-

national businesses. As the cost of pharmaceutical innovation escalated, it became increasingly essential to have markets on an international scale. Initially, many companies licensed their innovations to competitors in other countries; but as the industry grew such companies were able more and more to establish worldwide subsidiaries, first marketing their medicines and then packaging and finally producing them locally. Thus the modern multinational pharmaceutical industry came into existence between 1940 and 1980, with Japan joining the original six innovating countries as a major source of new pharmaceutical preparations during the 1970s. This Report therefore concentrates on the seven nations which have emerged as the major source of new pharmaceutical chemical entities over the past forty years.

OUTPUT

Chart 1 shows that the seven countries covered in this Report represented about 80 per cent of the total economy of the OECD countries, and just under 65 per cent of the total world economy in 1982. Within the total output of the seven study nations, the share of pharmaceuticals increased from just over 0.8 per cent in 1970 to slightly more than 1.0 per cent in 1982 (Chart 2).

Table 1 shows the percentage of gross domestic product accounted for by pharmaceuticals in each country. It is highest in Switzerland and Japan. Overall, the seven study nations accounted for 73.5 per cent of world pharmaceutical production in 1982. This share had been slightly higher in 1980 at 79.5 per cent. (The exchange rates used in each year to convert local currencies to Deutschmarks are contained in Table 2.)

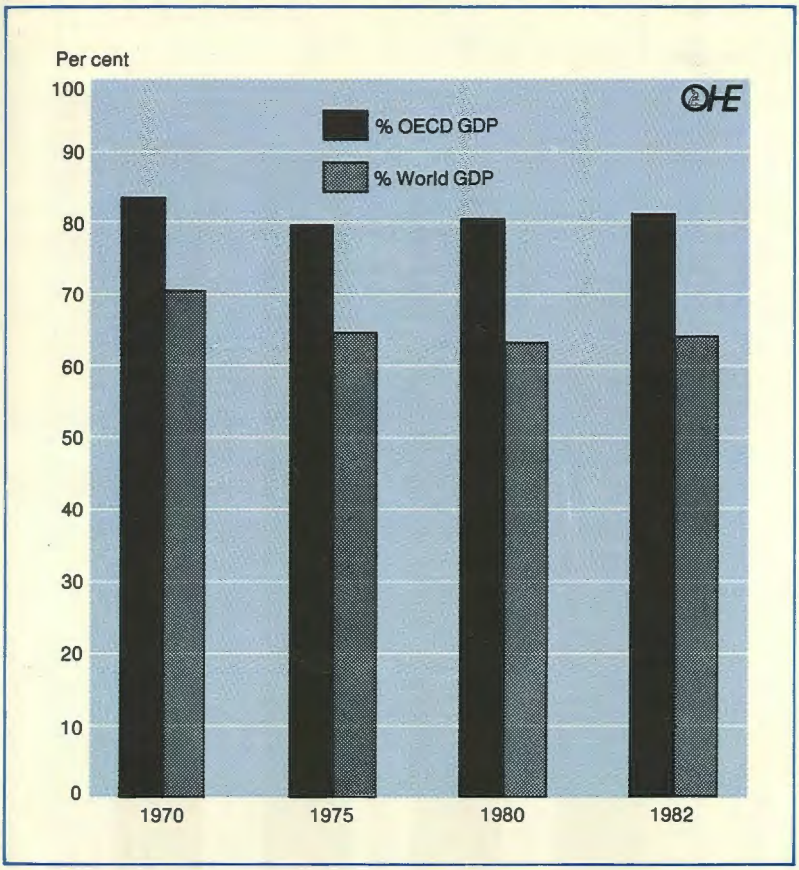
Table 3 shows pharmaceutical output in the seven countries in millions of Deutschmarks over 1970–82. It also provides an index of growth over this period calculated at current and constant prices. Table 4 shows the

Table 1 **Gross domestic product in each of the seven study nations and the proportion attributable to pharmaceuticals.**

	GDP at market prices – DM billion				*Pharmaceutical output as % of GDP (in local currencies)*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	675	1,027	1,481	1,603	0.93	1.07	1.02	1.05
France	517	833	1,191	1,312	0.90	0.89	0.90	0.95
Italy	366	472	719	843	1.03	1.02	0.80	0.92
Japan	747	1,226	1,899	2,579	1.40	1.21	1.48	1.50
Switzerland	77	134	185	234	2.45	2.19	2.36	2.35
UK	447	571	957	1,147	0.89	1.03	0.98	1.10
USA	3,594	3,761	4,700	7,335	0.62	0.80	0.83	0.82
Total above	6,422	8,023	11,132	15,052	0.83	0.96	1.01	1.02
					Seven countries			
As % OECD	83	80	80	81	As % of total World pharmaceuticals			
As % World	70	65	63	64	75	74	79	73

Source GDP data: OECD statistics for 1980 and 1982; IMF for 1970 and 1975.

Chart 1 **Proportion of World and OECD countries gross domestic product accounted for by the seven study nations, at market prices.**



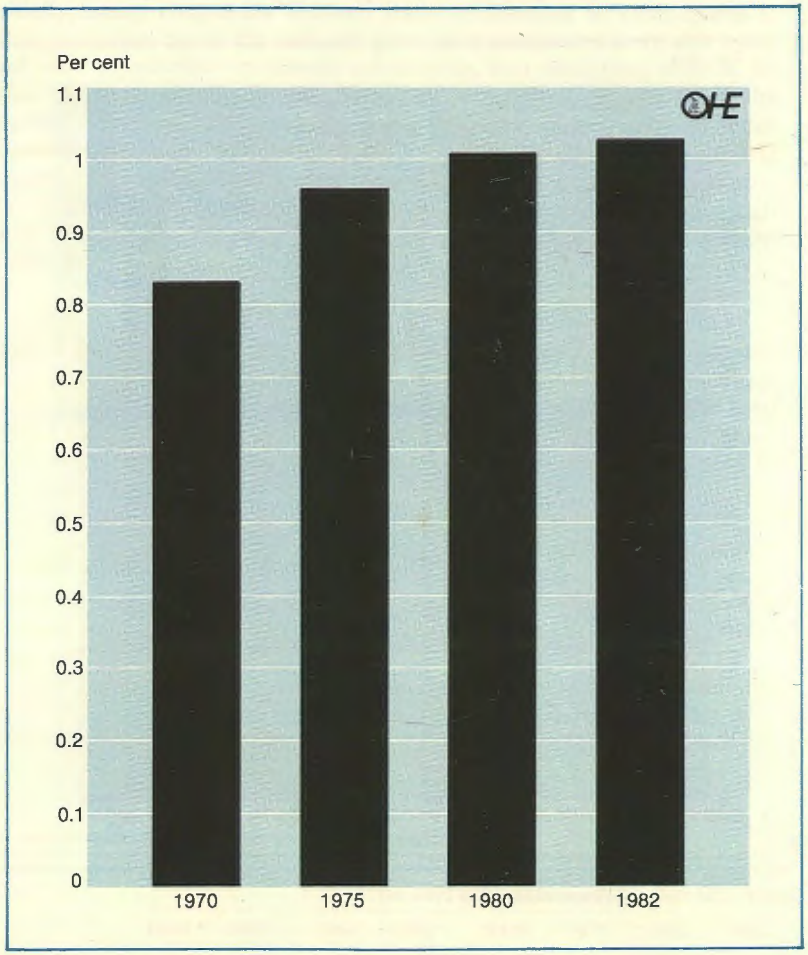
Source International Financial Statistics 1983, IMF.

Table 2 **Exchange rates used in the seven nations study to convert national currencies to Deutschmarks.**

		1970	*1975*	*1980*	*1982*
West Germany	DM	1	1	1	1
France	Fr	1.51	1.74	2.32	2.71
Italy	Lire	171.85	265.50	470.92	557.55
Japan	Yen	98.15	120.75	124.26	102.64
Switzerland	SFr	1.18	1.05	0.92	0.84
UK	£	0.11	0.18	0.24	0.24
USA	$	0.27	0.41	0.55	0.41

Source Daily Telegraphic Transfer Rates, CSO Economic Trends.

Chart 2 **Pharmaceutical output of the seven study nations as a proportion of their combined total gross domestic product.**



Source OHE Survey Data.

distribution of this output between home and export sales for each of the countries. The United States is the leading producer, with Japan in second position. The Federal Republic of Germany, the United Kingdom and France were the next largest producers. The very high proportion of Swiss production represented by exports reflects the small size of the Swiss home market. On the other hand, the small percentage of Japanese output represented by exports reflects the present relatively immature stage of development of the Japanese pharmaceutical industry. France and Italy in

Table 3 **The value of and index numbers for pharmaceutical (ethical, OTC and veterinary) output at current and constant prices, 1970–82.**

	Output (DM million) at current prices				*Output 1970 = 100 at current prices*				*Output 1970 = 100** at constant prices*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	6,309	11,022	15,083	16,770	100	175	239	266	100	130	145	145
France	4,631	7,435	10,735	12,408	100	161	232	268	100	121	142	151
Italy	3,758	4,798	5,730	7,760	100	128	152	206	100	115	113	130
Japan†	10,444	14,840	28,023	38,776	100	142	268	371	100	101	144	152
Switzerland	1,881*	2,927*	4,365*	5,501*	100	156	232	292	100	95	111	114
UK	3,977	5,891	9,340	12,652	100	148	235	318	100	129	135	150
USA*	22,412*	30,027*	38,817*	60,410*	100	134	173	270	100	144	164	163

Table 4 **Domestic and export sales of pharmaceuticals (ethical, OTC and veterinary) as proportions of output.**

	Output (DM million) at current prices				*% home sales*				*% exports*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	6,309	11,022	15,083	16,770	72	76	73	70	28	24	27	30
France	4,631	7,435	10,735	12,408	82	79	75	73	18	21	25	27
Italy	3,758	4,798	5,730	7,760	85	81	78	78	15	19	22	22
Japan†	10,444	14,840	28,023	38,776	98	98	98	98	2	2	2	2
Switzerland	1,881*	2,927*	4,365*	5,501*	36	30	33	31	64	70	67	69
UK	3,977	5,891	9,340	12,652	69	66	66	67	31	34	34	33
USA	22,412*	30,027*	38,817*	60,410*	93	93	90	91	7	7	10	9

Source OHE Survey Data.

Notes Unless otherwise stated, all output figures relate to production of ethical, OTC and vetrinary products. It is also assumed that output prices are at manufacturers' prices.

† Indicates output of human medicines only.

** As adjusted by a Consumer Price Index, in local currencies.

* OHE Estimate(s).

Table 5 **The structure of the pharmaceutical industry in each of the seven study nations.**

	No of companies	*No of large companies*	*% ownership (related to sales)*				
			Own	*European*	*USA*	*Japan*	*Other*
West Germany*	530	38	57	24	18	0	1
France	320	40	57	20	22	0	1
Italy	345	30	47	47	6	0	0
Japan*	400	81	83	9	8	0	0
Switzerland	250	4	100	0	0	0	0
UK	212	24	46	21	33	0	0
USA	950	57	70	30	0	0	0

Source OHE Estimates.

Notes * Figures for % ownership relate to all companies.
0 Indicates nil or negligible.

Table 6 **Share of national pharmaceutical markets attributable to companies originating from each of the seven study nations, 1983, percentages.**

		Companies						
Market	*Local*	*US*	*German*	*UK*	*French*	*Italian*	*Swiss*	*Japanese*
France	53	20	11	5	53	<1	7	<1
West Germany	56	18	56	4	3	1	11	<1
Italy	46	17	15	7	3	46	10	—
Japan	85	8	4	1	—	—	3	85
USA	82	82	4	5	—	<1	8	—
UK	36	38	9	36	3	<1	8	—
Switzerland	50	16	13	6	5	—	50	<1

Source OHE Estimates.

particular considerably increased their percentage of output which was exported between 1970 and 1982. However, the Federal Republic of Germany and the United Kingdom still exported a higher percentage of their output in 1982, despite the increases in other countries.

Table 5 shows the structure of the industry in each of the countries. The relatively small number of pharmaceutical firms in the United Kingdom and Switzerland is notable. In contrast the Federal Republic of Germany and the United States have a very much larger number of pharmaceutical manufacturers. The definition of a 'large' company is not consistent between the different countries, but in each case apart from Switzerland it is clear that the industry has a highly diversified structure and this is one of the factors underlying the competitiveness of the market.

Table 5 also gives a breakdown of the ownership of the large firms by nationality. Japan stands out because of the exceptionally high degree of local ownership. Switzerland, of course, has no 'large' foreign pharmaceutical firms because of the small size of its domestic market. Italy and the United Kingdom have the largest proportion of foreign firms operating in their countries. In the former case they are predominantly other European

firms but in the United Kingdom the largest proportion of overseas firms are from the United States.

Table 6 shows the breakdown of the national pharmaceutical markets according to the national ownership of the suppliers. Local manufacturers dominate the Japanese and the United States markets. At the other extreme, market penetration by foreign companies is greatest in the United Kingdom where manufacturers from the United States, for example, account for 38 per cent of sales. The very low penetration of both Japanese and Italian medicines into other countries is a notable point which will emerge again later on in the Report.

EMPLOYMENT

Table 7 shows employment in the pharmaceutical industry in each of the seven countries. It is notable that employment has risen much more slowly than output, at both current and constant prices (Table 3). Thus productivity in the industry has constantly risen. This is most noticeable in the Federal Republic of Germany and the United Kingdom, where employment in 1982 was either lower than or approximately equal to the levels recorded in 1970. Table 7 also reveals that a high proportion of pharmaceutical industry employees – between 15 and 20 per cent – have a scientific or technical qualification. This reflects the technological character of the industry.

In addition to direct employment, pharmaceutical production also creates employment in supplier industries, such as basic chemicals, packaging and equipment manufacture. The German industry has estimated that about 120,000 Germans are employed in this way; the French that 60,000 are so employed; and the UK industry 100,000. In addition to direct employment the industry therefore provides a substantial degree of indirect employment.

INTERNATIONAL TRADE

Table 8 shows pharmaceutical exports and imports for each of the seven countries for the years 1970, 1975, 1980 and 1982. The much later entry of Japan into pharmaceuticals explains why it has a negative balance of trade, that is, it is a net importer. As its own pharmaceutical consumption has risen, so its negative trade balance has also increased.

Italy has only a very modest positive trade balance, which has shown no increase (measured in Deutschmarks at current prices) since 1975. Each of the other five countries steadily increased its trade balance between 1970 and 1980. Table 9 shows the increase as an index with 1970 as the base year. The biggest increase has been in France.

Table 10 shows trade balance index numbers based on local currencies. From these data it is clear that each of the seven nations, with the exception of Japan, has in fact experienced a healthy improvement in its positive pharmaceutical trade balance over time. The less encouraging picture painted by the data in Table 9 therefore reflects the impact of currency fluctuations.

Table 7 **Number of employees in the pharmaceutical industry in the seven study nations.**

	Total employed				*% with scientific/technical qualification*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	76,000	72,000	69,806	73,166	NA	NA	9.9	10.3
France	60,500	64,257	64,363††	65,000§	NA	NA	NA	16.0§
Italy	51,436	59,482	60,801††	61,328	NA	NA	NA	NA
Japan	103,912	129,663††	155,415	170,500§	6.8§	6.8§	6.8	7.0§
Switzerland	35,000†	39,500†	39,000†	39,000†	15–20	15–20	15–20	15–20
UK	71,000	76,000	72,000	72,000	20	24	23	22
USA	148,900	166,600	189,866††	199,200	7.5	9.4	11.8††	12.7
Total	546,748	607,502	651,271	680,194	11*	12*	13*	13*

Source OHE Survey Data.

Notes § = Estimated figure(s).
† = Approximate figure(s).
NA = Not available.
†† = Interpolated figures (OHE).
* Indicates weighted percentage (OHE).

Table 8 **International trade in pharmaceuticals: exports and imports by the seven study nations, DM millions.**

	Exports				*Imports*				*Trade balance*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	1,790	2,603	4,128	5,087	637	1,306	2,345	2,825	1,153	1,297	1,783	2,261
France	839	1,559	2,720	3,315	525	839	1,273	1,684	314	720	1,447	1,631
Italy	562	933	1,249	1,682	520	835	1,186	1,594	41	98	64	88
Japan	241	304	536	738	789	1,081	1,952	3,028	–549	–777	–1,416	–2,290
Switzerland	1,200	2,060	2,935	3,781	286	419	747	964	914	1,641	2,188	2,817
UK	1,223	2,028	3,150	4,140	295	528	939	1,589	928	1,500	2,211	2,551
USA	1,540	2,152	3,699	5,720	318	582	1,459	2,259	1,222	1,569	2,240	3,462

Source UN Commodity Trade Statistics and Annual World Trade Statistics, 1982.

Note These figures may differ from those reported in respective countries because of variations in classification between domestic countries and that of United Nations (ie Standard International Trade Classification).

Table 9 **International trade in pharmaceuticals: exports and imports by the seven study nations; index numbers based on conversions to Deutschmarks, 1970 = 100.**

	Exports				*Imports*				*Trade balance*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	100	145	231	284	100	205	368	444	100	112	155	196
France	100	186	324	395	100	160	243	321	100	230	461	520
Italy	100	166	222	299	100	160	228	306	100	236	153	213
Japan	100	126	223	307	100	137	247	384	100	–142	–258	–417
Switzerland	100	172	245	315	100	147	261	337	100	179	239	308
UK	100	166	257	338	100	179	318	538	100	162	238	275
USA	100	140	240	371	100	183	458	710	100	128	183	283

Source UN Commodity Trade Statistics and Annual World Trade Statistics, 1982.

Table 10 **International trade in pharmaceuticals: exports and imports by the seven study nations; index numbers based on local currencies, 1970 = 100.***

	Exports				*Imports*				*Trade balance*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	100	145	231	284	100	205	368	444	100	112	155	196
France	100	214	497	706	100	184	372	573	100	264	707	929
Italy	100	257	610	971	100	248	625	994	100	364	420	690
Japan	100	156	282	321	100	169	313	401	100	–174	–327	–437
Switzerland	100	152	190	223	100	130	203	239	100	159	186	218
UK	100	266	532	698	100	287	657	1,110	100	259	492	567
USA	100	208	482	559	100	272	920	1,068	100	191	368	426

Source UN Commodity Trade Statistics and Annual World Trade Statistics, 1982.

Note *Before adjustment for inflation.

PROFITS

It is notoriously difficult to obtain reliable and meaningful figures for profits and profitability in the pharmaceutical industry. This difficulty principally arises because the pharmaceutical business of a company frequently forms only a part of a larger organisation engaged in a variety of non-pharmaceutical activities as well.

However, an attempt has been made to overcome these problems, and very limited data are shown for six countries in Table 11. The principal point to emerge is that France, Japan and the Federal Republic of Germany recorded much lower rates of return in 1981 and 1982 than the other countries. The exceptionally low rate of return for France is not surprising because of the very low pharmaceutical prices imposed by the French authorities. However, Table 12 gives the sales, operating margins (before interest) and percentage profitability for Rhone-Poulenc Santé between 1977 and 1983. These data presumably indicate a sharp contrast between the greater profitability of a large company and the much lower profitability of the majority of small companies. The same pattern is true in the UK, and probably other countries.

The highest rates of profit are earned in Switzerland and the United States. This finding would have been predicted in view of the political and economic factors operating in these countries which are discussed later in this Report.

For the United Kingdom, figures showing profitability on sales of medicines used under the National Health Service are available because all companies have, since 1967, submitted to government financial details relating to their operations in both home and export markets. Table 13 shows the rates of profits earned, both for sales to the National Health Service and for total sales of NHS medicines both at home and overseas. Several points emerge from these data. The first is the fall in profitability of sales of NHS medicines since the 1960s. The second is the generally higher profit on sales of NHS medicines than for the pharmaceutical industry as a whole (which includes nationally advertised and veterinary products). The third is the lower profit on home sales to the NHS than on total sales including exports (that is, exports are more profitable). And finally, the profitability of sales to the National Health Service was marginally higher than total pharmaceutical industry profit in 1970 and marginally lower than total pharmaceutical industry profit in 1982.

CAPITAL INVESTMENT

In common with information on profitability, only limited data are available to show the way in which industry uses its profits to invest in future growth. However, figures for the United Kingdom are available each year with regard to the assets employed in the prescription medicine business and for the profits earned from it. These come from the Annual Financial Returns submitted by companies to the British government. From the difference in assets employed from year to year, a figure for net capital formation can be calculated. This, of course, is made up of new investment

Table 11 **Pharmaceutical profitability before tax expressed as a percentage of output.**

	1970	*1975*	*1982*
France	—	—	4.0
Japan	—	—	8.1
Switzerland	—	—	18.1
West Germany	—	—	8.7*
UK	12.0	11.3	13.6
USA	—	23.6	18.8

Source OHE Survey Data.
Note *1981.

Table 12 **Sales and operating margins for the Health Division of Rhone-Poulenc, French Francs millions.**

	Net sales	*Operating margin*	
			%
1977	3,782	477	12.6
1978	4,531	588	13.0
1979	5,015	629	12.5
1980	5,762	569	9.9
1981	6,882	770	11.1
1982	7,897	652	8.3
1983	9,908	1,138	11.5

Source Published Annual Reports.

Table 13 **Profitability on the sales of pharmaceuticals by the UK industry 1967–1982.**

	Total industry profitability as in Table 11	*Profitability on sales to the NHS*	*Profitability of total sales of NHS medicine*
1967	—	19.7	22.3
1968	—	16.1	20.7
1969	—	14.8	19.1
1970	12.0	13.7	17.9
1971	—	14.0	17.8
1972	—	14.4	16.5
1973	—	13.3	17.7
1974	11.3	11.3	18.9
1975	—	11.6	16.9
1976	—	12.2	19.9
1977	—	13.8	20.5
1978	—	14.1	20.7
1979	—	10.9	16.7
1980	—	12.1	15.0
1981	—	13.6	16.7
1982	13.6	12.5	17.8

Source NHS Annual Financial Returns and Table 11.

minus depreciation on existing assets, and is therefore lower than the actual amount of new money invested in the business.

Nevertheless Table 14 shows that for the mid-1970s net capital formation generally accounted for over 70 per cent of profits earned. These profits are before tax. By the 1980s, however, new capital formation had fallen to around 50 per cent of profits. Relating this to the figures in Table 13 suggests that lower overall profitability may have been associated with less willingness for the pharmaceutical industry to reinvest its profits in capital growth.

Similar figures are shown for Rhone-Poulenc Santé in France in Table 15. In this case capital expenditure has tended to rise as a percentage of profits since the 1970s. The particular situation of the French industry will be discussed later.

TAXATION

Tables 16 and 17 give estimates of the taxation paid by the pharmaceutical industry in each of the countries covered by this study. These estimates have been calculated by taking the output figures for the industry and applying the average rates of taxation and social security payments pre-

Table 14 **Profits and capital formation on home and export sales of UK 'NHS medicines', 1974–82, £ millions.**

	(1) Assets employed	*(2) Net capital formation*	*(3) Total profits before tax*	*(4) Percentage of (2) on (3)*
1974	407.8	—	87.5	—
1975	501.2	93.4	108.0	86.5
1976	616.1	114.9	156.1	73.6
1977	763.5	147.4	205.9	71.6
1978	879.1	115.6	249.5	46.3
1979	1,046.1	167.0	218.9	76.3
1980	1,169.6	123.5	215.2	57.4
1981	1,307.0	137.4	296.7	46.3
1982	1,517.2	210.2	372.4	56.4

Source NHS Annual Financial Returns.

Table 15 **Profits earned and capital expenditure by the Health Division of Rhone-Poulenc, French Francs millions.**

	Percentage profit	*Profits before interest*	*Capital expenditure*	*Percentage*
1977	12.6	477	204	42.8
1978	13.0	588	149	25.3
1979	12.5	629	225	35.8
1980	9.9	569	345	60.6
1981	11.1	770	440	57.1
1982	8.3	652	475	72.9
1983	11.5	1,138	639	56.2

Source Published Annual Reports.

Table 16 **Estimated taxation paid by the pharmaceutical industry in each of the seven study nations, Deutschmarks millions.**

	Estimated total taxes paid by pharmaceutical industry*				*Estimated income tax† and social security§ paid by pharmaceutical industry*				*Estimated profit tax†† paid by pharmaceutical industry*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	1,552	3,152	4,540	5,333	1,035	2,182	3,092	3,371	139	187	317	335
France	1,079	1,926	3,317	3,871	750	1,361	2,244	2,643	139	201	333	397
Italy	677	1,017	1,484	2,149	530	830	1,169	1,707	60	77	115	163
Japan	1,410	2,538	5,549	8,053	689	1,306	2,998	4,414	491	742	1,457	2,052
Switzerland	337	700	1,043	1,287	209	436	655	809	60	105	127	160
UK	990	1,544	2,242	3,201	684	1,196	1,625	2,227	191	171	346	569
USA	4,953	6,666	9,549	14,982	3,339	4,474	6,754	10,753	919	1,141	1,397	1,873

Source OHE estimates.

Notes *Including employment tax, capital tax, corporation tax and social security payments (employers + employees).
†Income tax of employees paid by the industry.
††Including capital tax.
§Employers' contributions to social security.

Table 17 **Estimated taxation paid by the pharmaceutical industry in each of the seven study nations, Deutschmarks millions.**

	Estimated total taxes paid by pharmaceutical industry (Index)*				*Estimated income tax† and Social Security§ paid by pharmaceutical industry (Index)*				*Estimated profit tax†† paid by pharmaceutical industry (Index)*			
	1970	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*	*1970*	*1975*	*1980*	*1982*
West Germany	1,552 (100)	3,152 (203)	4,540 (293)	5,333 (344)	1,035 (100)	2,182 (211)	3,092 (299)	3,371 (326)	132 (100)	176 (133)	302 (228)	319 (240)
France	1,079 (100)	1,926 (178)	3,317 (307)	3,871 (359)	750 (100)	1,361 (181)	2,244 (299)	2,643 (352)	125 (100)	178 (143)	301 (240)	347 (278)
Italy	677 (100)	1,017 (150)	1,484 (219)	2,149 (318)	530 (100)	830 (157)	1,169 (221)	1,707 (322)	53 (100)	72 (137)	109 (207)	155 (295)
Japan	1,410 (100)	2,538 (180)	5,549 (394)	8,053 (571)	689 (100)	1,306 (189)	2,998 (435)	4,414 (640)	470 (100)	712 (152)	1,401 (298)	1,975 (420)
Switzerland	337 (100)	700 (208)	1,043 (310)	1,287 (382)	209 (100)	436 (209)	655 (314)	809 (387)	47 (100)	88 (187)	100 (214)	127 (269)
UK	990 (100)	1,544 (156)	2,242 (226)	3,201 (323)	684 (100)	1,196 (175)	1,625 (238)	2,227 (326)	155 (100)	153 (99)	327 (211)	519 (334)
USA	4,953 (100)	6,666 (135)	9,549 (193)	14,982 (302)	3,339 (100)	4,474 (134)	6,754 (202)	10,753 (322)	807 (100)	1,021 (127)	1,242 (154)	1,691 (210)

Source OHE estimates.

Notes *Including employment tax, capital tax, corporation tax and social security payments (employers + employees).
†Income tax of employees paid by the industry.
††Excluding capital tax.
§Employers' contributions to Social Security.

vailing in each of the countries. Although this methodology yields theoretical figures, independent calculations for both the Federal Republic of Germany and the United Kingdom corroborate the estimates shown for these two countries. The important point is that, although the individual figures may not be precisely correct, the pharmaceutical manufacturers undoubtedly make a major contribution to the national exchequer in each country, both directly and also through their employees' tax contributions.

The Pattern of Innovation

Innovation is the life-blood of the research-based pharmaceutical industry. It has also provided the foundation for unprecedented therapeutic advance over the last fifty years and is widely seen as the key to future progress in the treatment of today's disabling diseases. This section reviews the innovative performance of the pharmaceutical industry in the seven major industrial nations with which this Report is concerned.

EXPENDITURE ON RESEARCH AND DEVELOPMENT

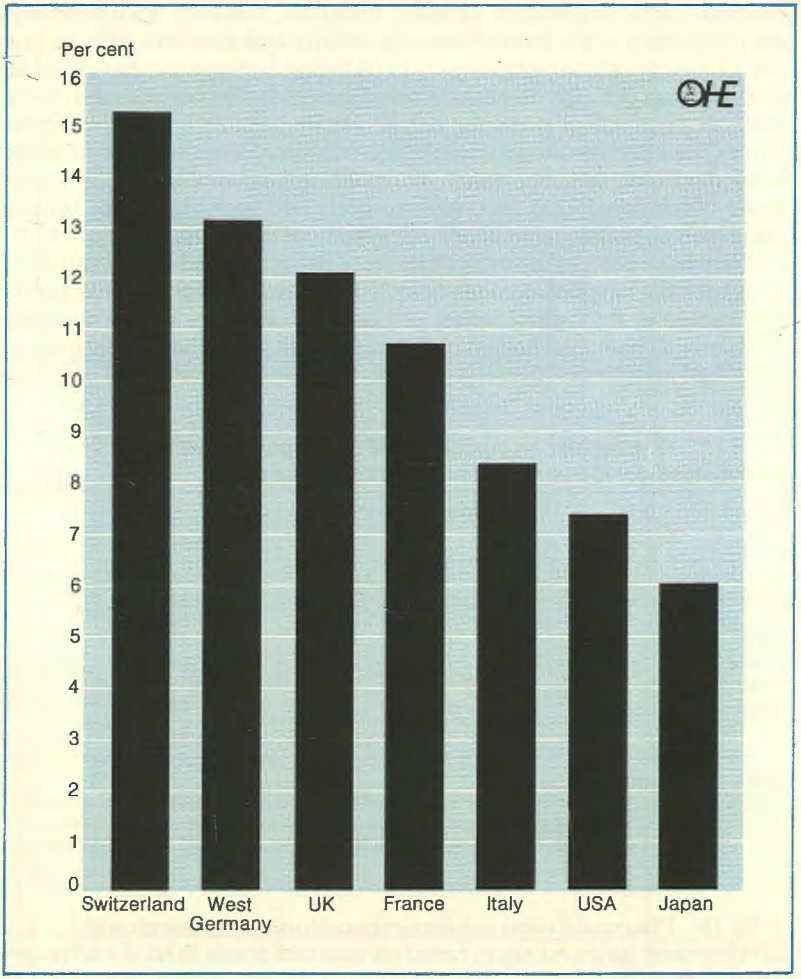
The importance of innovation to the health of the research-based pharmaceutical industry is indicated by the volume of funds channelled into research and development. The most up-to-date information available is shown in Table 18 and indicates that together the Federal Republic of Germany, UK, USA, France, Japan, Italy and Switzerland spent an estimated DM 13.3 billion on this activity in 1982. These seven nations account for three-quarters of the world pharmaceutical industry's expenditure on the search for new and improved medicines. Overall the seven nations allocate a sum equivalent to 8.6 per cent of their collective output value to research and development. The proportions for individual nations are contained in Chart 3, showing that the Swiss, German and UK industries spend considerably more, with proportions of 15.2 per cent, 13.1 per cent and 12.1 per cent respectively.

The United States is the major contributor to research spending (Table 18). In 1982 it accounted for 33 per cent of the total and spent approximately twice as much as Japan, the second highest spender. It is noteworthy, however, that the dominance of the United States has diminished over time. In 1964 the United States contributed an estimated 63 per cent of the seven nation spend on research and development. Yet by the mid-1970s this proportion had dropped to 37 per cent.

These figures have, of course, to be treated with caution. There are considerable difficulties in compiling national data that are both accurate and comparable. Inevitably there is some degree of inconsistency in the content of the R and D expenditure figures made available by various international organisations. Few of the latter specify, for example, whether or not research spending on veterinary products or over-the-counter medicines is included in the national totals. Equally, there is uncertainty with regard to the inclusion or otherwise of capital investments in research facilities. The distorting effect of these factors is, however, unlikely to be great. Instead, the major problem confronting an international comparison of R and D spending over time stems from exchange rates fluctuations and shifts in the domestic purchasing power of the various national currencies.

In order to overcome this problem, Table 19 shows real R and D spending growth in each of the seven nations over the period 1970–82. For the group as a whole, spending increased by an average of 49 per cent. Yet it is

Chart 3 **National pharmaceutical industry expenditures on research and development as a percentage of output.**



Source OHE Survey Data.

clear that there are significant variations about this mean. At one extreme, spending by companies based in the UK increased by 132 per cent. At the other, expenditure in Italy rose in real terms by only 25 per cent.

THE OUTPUT FROM RESEARCH SPENDING

The productivity of research and development expenditures can be gauged in a number of different ways. The number of compounds

synthesised, screening tests undertaken, patents filed and scientific articles published are all measures which have been employed in studies of pharmaceutical innovation. In many instances, however, such indicators are a reflection of the level of research activity and shed little light on output. Consequently, attention needs to be focused on product introductions and, more specifically, on new chemical entities (NCEs) rather than reformulations or modified presentations of existing pharmaceutical preparations. (The latter distinction should not, of course, be interpreted as in any sense devaluing the importance of new formulations. Changes in dosage, mode of administration and other respects can have significant benefits via improved patient compliance and enhanced therapeutic efficacy.)

There have been many investigations of national trends in NCE introductions over the past two decades or so. The Pharmaceutical Manufacturers' Association in the United States, MPS in West Germany and Steward and Wibberley (1980) and Ravenscroft and Walker (1983) in Britain have all published analyses in this respect. Unfortunately, comparison of these and

Table 18 **Expenditure on research and development by the pharmaceutical industry, Deutschmarks millions.**

	Deutschmarks (millions)			
	1964	*1970*	*1975*	*1982*
United States	1,122	2,038	2,196	4,433
United Kingdom	115	253	452	1,526
West Germany	159	600	1,100	2,200
Italy	60	192	279	647
France	111	298	586	1,330
Switzerland	118*	338	476	836
Japan	107	380	788	2,336
	1,792	4,099	5,877	13,308

Source OHE Survey Data.
Note *R & D expenditure in 1964 by Switzerland is not available. However, if it is assumed that Swiss spending growth between 1964 and 1970 matched the average for each of the other six nations included in the table, then a figure of DM118 may be estimated for 1964.

Table 19 **Pharmaceutical industry expenditures on research and development: index numbers based on constant prices in local currencies, 1970 = 100.***

	1970	*1975*	*1980*	*1982*
West Germany	100	116	140	155
France	100	111	128	140
Italy	100	97	98	125
Japan	100	110	149	137
Switzerland	100	92	99	127
United Kingdom	100	135	204	232
United States	100	111	127	129

Source OHE Survey Data.
Note *At constant prices (adjusted by an average earnings index) in local currencies.

Table 20 **New substances according to inventor countries, 1961–1980.**

Year of first introduction	*USA*	*France*	*FR Germany*	*Japan*	*Italy*	*Switzerland*	*Eastern Block*	*Great Britain*	*Scandinavia*	*Benelux*	*Spain*	*Austria*	*Other countries**	*Annual new introductions*
1961	31(1)	12	11	7	4	12(1)	3	6(1)	4(1)	2	—	3	—	93
1962	20	21	15	4	7	8	—	4	5	7	—	—	2	93
1963	22(1)	21	17(1)	12	2	7	2	9	4	2	1	1	—	99
1964	15	8	14	8	4	6	5	4	2	1	—	2	1	70
1965	13	14	10	13	6	7	2	4	1	1	—	2	—	73
1966	22	19	7	8	3	3	8	4	3	4	1	1	1	84
1967	20(1)	19	8	7	5	8	9	5(1)	3	—	1	3	—	87
1968	20(2)	17(1)	12(1)	7	7(1)	5(1)	5	4	3	3	2	1	1	84
1969	18(1)	23	11	5	9	3	9	3(1)	2	3	—	—	—	85
1970	21(1)	18	7(1)	7	1	6	4	2	2	1	1	2	—	71
1971	25	16	5	11	7	6	9	2	3	4	1	—	2	91
1972	14	13	4	9	9	3	8	3	1	2	—	—	1	67
1973	10	18	14(1)	1	8	9(1)	9	3	1	2	3	—	—	77
1974	17(1)	13	9(1)	14	4	5	4	4	3	2	2	1	—	77
1975	15	7	12	8	5	8(1)	11	4	1(1)	1	2	—	—	73
1976	17(1)	8	9(1)	2	7	2	5	3	5	1	1	1	—	60
1977	14	6	13	7	11	3	1	6	2	—	2	1	1	67
1978	12	10	7(1)	7	4	4(1)	2	4	2	2	1	—	—	54
1979	14	6	7	7	7	—	1	—	1	—	2	—	—	45
1980	13(1)	2	9(1)	11(1)	9	4(2)	—	—	2(1)	—	1	—	—	48
	353(10)	271(1)	201(8)	155(1)	119(1)	109(7)	97	74(3)	50(3)	38	21	18	9	1,498

Source Reis-Arndt 1982.

Notes *Argentina, Australia, India, Canada, Portugal.
Figures in brackets signify substances developed simultaneously in two countries. The figure in parentheses is included in the preceding number of substances.

Table 21 **New substances according to inventor countries, 1961–80, absolute and relative figures in 5-year periods.**

Period of first introductions	*USA*	*France*	*FR Germany*	*Japan*	*Italy*	*Switzerland*	*Eastern Block*	*Great Britain*	*Scandinavia*	*Benelux*	*Spain*	*Austria*	*Other countries**	*Total first introductions*	*Yearly average for first introductions*
1961–65															
absolute	101	76	67	44	23	40	12	27	16	13	1	8	3	428	
	(2)		(1)			(1)		(1)	(1)						
relative	24	18	16	10	5	9	3	6	4	3	<1	2	<1	100%	85.6
1966–70															
absolute	101	96	45	34	25	25	35	18	13	11	5	7	2	411	
	(5)	(1)	(2)		(1)	(1)		(2)							
relative	25	23	11	8	6	6	8	4	3	3	1	2	<1	100%	82.2
1971–75															
absolute	81	67	44	43	33	31	41	16	9	11	8	1	3	385	
	(1)		(2)			(2)									
relative	21	17	12	11	9	8	10	4	2	3	2	<1	<1	100%	77.0
1976–80															
absolute	70	32	45	34	38	13	9	13	12	3	7	2	1	274	
	(2)		(3)	(1)		(3)			(1)						
relative	25	12	16	12	14	5	3	5	4	1	3	<1	<1	100%	54.8
1961–80															
absolute	353	271	201	155	119	109	97	74	50	38	21	18	9	1,498	
	(10)	(1)	(8)	(1)	(1)	(7)		(3)	(3)						
relative	25	18	14	10	8	7	6	5	3	2	1	1	<1	100%	74.9

Source Reis-Arndt 1982.

Notes *Argentina, Australia, India, Canada, Portugal.
Figures in brackets signify substances developed simultaneously in two countries. The figure in parentheses is included in the preceding number of substances.

other national trends is hindered by problems arising out of the use of different definitions of a new chemical entity. However, this setback is overcome by the ongoing study of Reis-Arndt. The most recent publication from this author (Reis-Arndt 1982) reveals that 1,498 new chemical entities were introduced onto the pharmaceutical market worldwide over the period 1961 to 1980.

Table 20 provides a breakdown of this overall figure by year of introduction and country of invention. The major point to emerge is that the annual total of NCEs reaching the world market has declined dramatically – from 93 in 1961 to 48 in 1980. If the annual averages for periods of five years are considered in order to avoid sharp year to year fluctuations, the data show a reduction from 85.6 during 1961–65 to 54.8 over 1976–80 (Table 21).

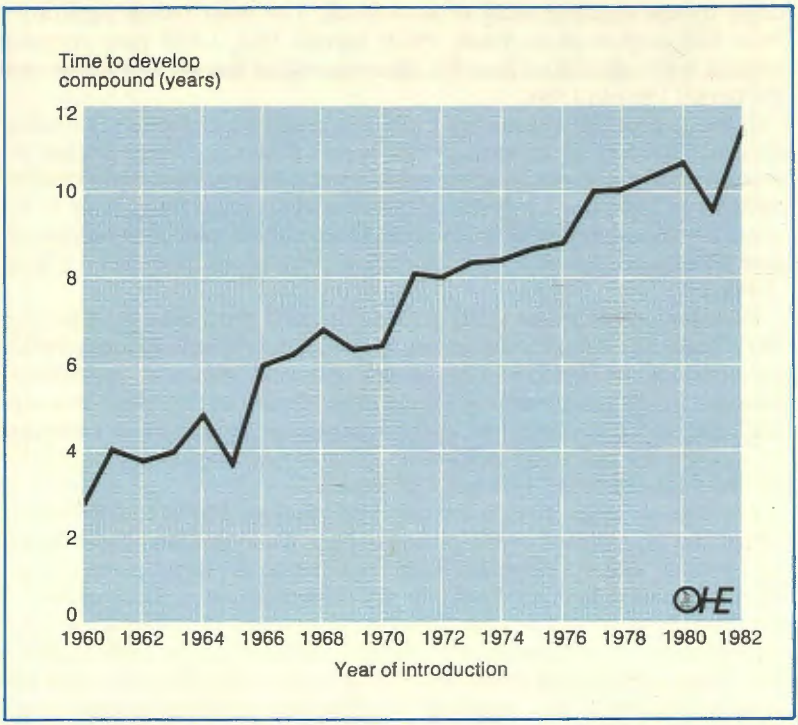
Focusing on the seven study nations the data show that together they have been, and continue to be, the major source of new pharmaceutical preparations. In 1961–65, the group of seven launched, on average, almost 75 NCEs each year onto the world market. By 1976–80, this total had fallen to 47. Nevertheless, in the latter period these nations continued to account for the same proportion of world NCE introductions as that recorded for 1961–65 – that is, 88 per cent.

There is no single reason for the declining trend in NCE introductions which has taken place over a period of time when national expenditures on research and development have escalated at an unprecedented rate. The explanation lies principally in the changing nature and duration of the drug development process. The Pharmaceutical Manufacturers' Association in the United States, for example, observed in its 1980 Factbook that 'from seven to ten years now elapse between the discovery of a new drug and the FDA's final approval. This may be compared with an average of approximately two years prior to the 1962 Amendments to the Food, Drug and Cosmetic Act.'

A similar pattern has been reported from the United Kingdom. In a review of trends in pharmaceutical innovation since 1960, the Office of Health Economics (1983) reported that the development phase facing a major new chemical entity in its transition from initial discovery to marketing now extends over 10 years or more; in the early 1960s, it was not unusual for a similar project to be completed within a period of approximately three years (Chart 4). And, finally, in a recently published study of the German experience, Thesing (1984) has reported that the overall average duration of research and development work on new substances undertaken by companies belonging to MPS has increased from between 2.3 and 5 years in 1964 to between 9 and 13 years in 1981 (Table 22).

Several factors affect this trend, notably the proliferation of regulatory requirements governing the testing and marketing of new medicines which followed the discovery of the teratogenic effects of thalidomide in the early 1960s. Development times have also lengthened as a consequence of the 'therapeutic transition' that has been taking place since the 1960s. Throughout the preceding phase of pharmacological advance anti-

Chart 4 **Increase in development times for new chemical entities marketed in the United Kingdom, 1960–82.**



Source Ravenscroft and Walker 1983.

infective medicines had, in numerical terms at least, predominated. Their employment usually involves the administration of a short course of treatment, which has as its target the removal of specific disease organisms from the body and thus the restoration of health. As a consequence testing prior to marketing was correspondingly straightforward. Since the mid-1960s, however, pharmacological intervention has been increasingly directed at diseases where the goal of therapy, in the present state of knowledge, is the long-term prevention or control of symptoms: cures are not yet available. Inevitably, the shift towards treatments requiring prolonged drug administration has been accompanied by a commensurate extension of drug testing.

The effect of these and other factors – for example, the increasing need to employ ever more sophisticated research techniques and the fact that solving the medical problems of today poses a much more formidable challenge than was the case 20 years ago – has been greatly to increase the cost of developing a new chemical entity. The nature of pharmaceutical

Table 22 **Duration of research and development work on new active chemicals developed by member companies of Germany's MPS.**

Year	*Pre-Clinical phase*	*Clinical phase*	*Registration*	*Overall development time*
1964	1–2	1.2–3	0.3–1	2.3–5
1981	2–10	3–9	0.6–1	9–13

Source: Thesing 1984.

research is such that it is virtually impossible to isolate the costs arising specifically from the development of a particular new drug but available figures make it clear that they have risen substantially above the £2 to £3 million estimated for the UK for the first half of 1960s. In a consultative document published in 1981, the Pharmaceutical Sector Committee of the Chemicals Economic Development Council reported that the 'cost of developing a successful major drug can now be £50 million or more'. If the unavoidably large number of failures which accompany the evolution of one successful product is also taken into account, this sum may in fact be nearer £90 million (Dench 1981). These figures reflect the experience of the UK but there would appear to be broad international agreement that costs now range between DM 150 million and DM 300 million (see, for example, Thesing 1984).

Thus it is clear that substantial increases in R and D expenditures have been necessary to accommodate the increasing cost of developing a single new medicine. As a result the sustained growth in resources allocated to R and D has not been accompanied by any corresponding acceleration in the number of new medicines becoming available for patient use. Indeed, in terms of new chemical entities, the reverse has been true since the early 1960s.

NATIONAL TRENDS

More detailed analysis of the data contained in Tables 20 and 21 show that the overall pattern of decline in NCE introductions has been common to the majority of the seven study nations. Italy, however, provides the exception: average annual introductions over the 5 year period 1976–80 were 65 per cent up on the corresponding total for 1961–65.

It is also noteworthy that the United States, in spite of a 31 per cent drop in its average annual output[2] over 1961/65–1976/80, continued to produce the largest number of NCEs of the seven nations. Indeed, the United States marginally increased its share of the seven nations' output over the period under consideration from 26 to 29 per cent. In part this gain is a reflection of the considerably more pronounced decline in French NCE productivity: average annual introductions fell from 15.2 in 1961–65 when France was second only to the United States in terms of NCE output

2 Products developed in conjunction with other nations have been excluded from this analysis.

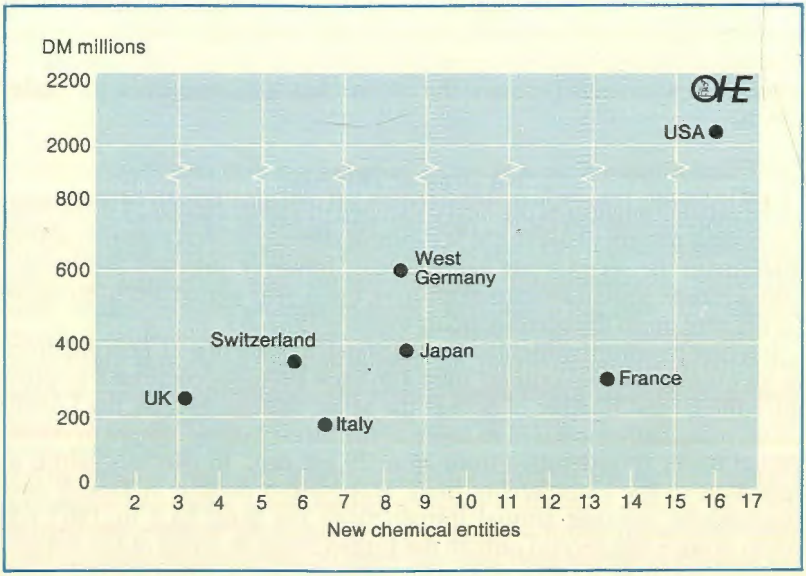
to 6.4 in 1976–80 when she fell behind Germany, Japan and Italy as well as the United States.

Yet perhaps the most unexpected finding to emerge from Tables 20 and 21 is the high level of NCE output achieved by France until the mid-1970s, especially when considered against the research and development expenditures set out in Table 18. The latter indicates that French spending on this function has only once, in the years shown, been at a level sufficient to place France higher than fifth among the seven nations.

The 'exceptional' performance of France is again highlighted in Chart 5 which compares national expenditures in the search for new medicines in 1970 with the NCE data for the succeeding five year period. In broad terms, there appears to be a positive relationship between the two variables: increased levels of research and development spending are associated with greater NCE productivity. France until the mid-1970s and subsequently Italy (Chart 6) clearly depart from this pattern and would appear at first sight to be more efficient in their investments in the search for and development of new medicines than the other nations, including the United States.

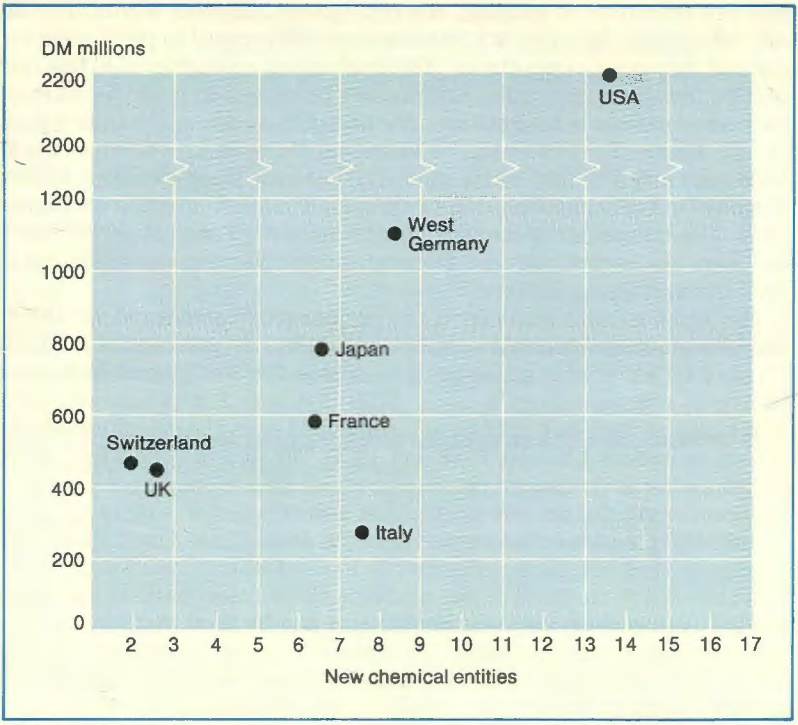
However, two major qualifications modify this conclusion. The first concerns the quality and comparability of the data upon which the assertion is founded. On the one hand, the national expenditure figures are not only

Chart 5 **National spending on research and development in 1970 (in Deutschmarks millions) and average annual NCE output over the period 1971–75.**



Sources Tables 18 and 21.

Chart 6 **National spending on research and development in 1975 (in Deutschmarks millions) and average annual NCE output over the period 1976–80.**



Source Tables 18 and 21.

subject to the limitations referred to earlier in this section of the Report but also include all pharmaceutical R and D spending, that is by both indigenous companies and by those operating in the country in question but with corporate headquarters located elsewhere. On the other hand, the NCE data derived from the Reis-Arndt study, although seemingly representing national NCE outputs, are in fact company-based. Thus the figures showing, for example, NCEs invented in the Federal Republic of Germany will include products developed by German companies in all countries and not just in Germany. Further, the German data will exclude products 'invented' in Germany if the research and development work was undertaken by a company whose origins lie in another country. Thus in order to draw any conclusions from the bringing together of these two sets of data it has to be assumed that a high proportion of any nation's R and D spending is attributable to indigenous companies and that the latter predominantly develop their new medicines in their own country. The validity of

these assumptions is likely to vary from one country to another and over time (see Burstall and Dunning 1985).

The second more serious qualification concerns the fact that the NCE data are reflections of quantity and not 'quality'. In other words, they do not differentiate between NCE introductions with regard to their commercial and therapeutic importance. The levels of success achieved in this respect by the seven innovating nations may be gauged in broad terms from four other sources of information. The first of these is a study, undertaken by the Centre for the Study of Industrial Innovation (Pharmaceutical Working Party 1973) in which some 470 products were identified as new chemical entities introduced onto the world market between 1958 and 1970. The compounds were ranked in terms of their market performance and were also sorted into one of five categories reflecting an assessment of their therapeutic significance.

The seven nations included in the present study accounted for 388 of the 470 products identified – that is, more than 80 per cent of the total (Table 23). Within this group the pre-eminence of the United States as a source of new medicines is clear. With 204 NCEs the US accounted for slightly more than half of the total introduced onto the world market by the seven nations between 1958 and 1970. The US was almost four times as productive as its nearest rival, Switzerland. (It is of interest to note that France is credited with only 23 products over this period, a figure which is substantially less than that suggested by the data of Reis-Arndt. Part of the explanation for this discrepancy may lie in short-falls in 'case finding'.)

If attention is confined to the products of the seven nations for which market performance data are available, it can be seen that only the US, Switzerland, UK and the Federal Republic of Germany generated products which were classifiable in the top two performance groups. Again the US was predominant: thus 15 per cent of its classifiable NCEs appeared in one or other of the top two market performance groupings. For the Federal Republic of Germany this figure was 12 per cent, Switzerland 11 per cent and the UK 8 per cent.

The CSII study also assessed these products from the perspective of therapeutic worth. Confining attention to the 358 products for which appropriate data were available, Table 23 indicates that with the exception of Italy and Japan, each of the seven nations 'invented' one product or more which were regarded as extremely therapeutically significant. Once more, the United States dominated: in total almost one NCE in 10 (that is, 33 products) was classified in the top therapeutic group and half of these were invented in the United States. France, on the other hand, contributed only two products to this grouping.

A second guide to the 'success' of national innovative endeavours may be derived from the Reis-Arndt data. In 1975, the author published a paper showing the extent of international market penetration achieved by new chemical entities introduced for the first time over 1961–73 (Reis-Arndt 1975). Table 24 indicates that international marketing information was available for 597 (67 per cent) of the 889 NCEs introduced by the US,

Table 23 **Market performance and therapeutic assessment of new pharmaceutical chemical compounds introduced by the seven study nations over the period 1958–70.**

		Per cent of compounds in each category											
		Market Performance						*Therapeutic assessment by UK experts*					
Country of origin	*Total No of compounds*	*No of products for which market data available*	*Category* 1	2	3	4	5	*No of products for which therapeutic data available*	*Category* 1	2	3	4	5
United States	204	191	3	12	11	31	43	199	8	12	18	29	34
Switzerland	54	45	0	11	11	38	40	42	12	10	21	29	29
United Kingdom	51	39	3	5	18	15	59	46	20	26	11	22	22
West Germany	35	34	0	12	27	21	39	33	3	19	16	28	34
France	23	21	0	0	14	48	38	18	11	17	11	28	33
Italy	17	13	0	0	8	31	62	16	0	13	19	44	25
Japan	4	4	0	0	50	50	0	4	0	25	25	50	0

Source Pharmaceutical Working Party 1973.

Table 24 **New chemical entity introductions over 1961–73: number of countries in which products introduced.**

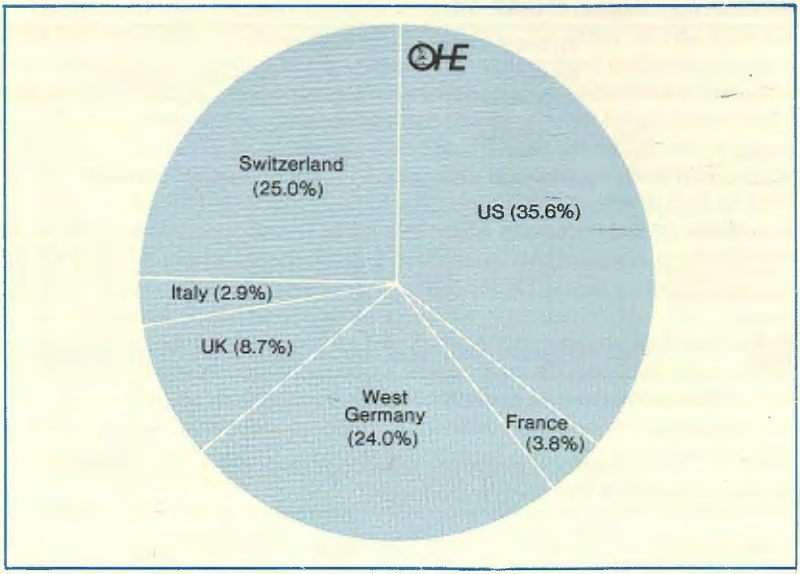
Country of origin of developing company	*A Total discovered over 1961–73*	*B No for which market penetration data available*	*C No of products introduced in more than 40 markets*	*Col C as % of Col B*
United States	247	181	37	20.4
France	213	99	4	4.0
West Germany	133	107	25	23.4
United Kingdom	52	35	9	25.7
Japan	98	40	—	—
Italy	66	58	3	5.2
Switzerland	80	77	26	33.8
	889	597	104	17.4

Source Reis-Arndt 1975.

UK, the Federal Republic of Germany, France, Italy, Japan and Switzerland over this period. The Table shows wide variations in market penetration between the countries. Thus at least 20 per cent of US, German, Swiss and UK innovations were introduced onto more than 40 markets. Yet only 4 per cent of French innovations achieved this degree of penetration.

Chart 7 presents the data from another perspective and shows that of the 104 products introduced by the seven nations onto more than 40 markets, 36 per cent were from the US, 25 per cent from Switzerland, 24 per cent from Germany and 9 per cent from the UK. French and Italian companies each accounted for less than 4 per cent of the total. The principal conclusion to be drawn from the Reis-Arndt data is, therefore, that although French companies were prolific innovators up until at least the mid-1970s, relatively few of their products were widely introduced onto

Chart 7 **New chemical entities introduced onto 40 or more markets analysed by inventor nation.**



Source Reis-Arndt 1975.

the international pharmaceutical market. Of course, this observation may reflect marketing objectives and policies but, in view of the CSII data reported above, it also seems likely that 'qualitative' considerations are important.

The third source of information is concerned with the degree of penetration by the seven innovating nations into each other's pharmaceutical markets. Table 6 shows that companies of United States origin, for example, not only dominated their own domestic market – accounting for 82 per cent of pharmacy and hospital sales – but also captured 38 and 20 per cent respectively of the UK and French markets in 1983. These companies' products were also strong in the German and Italian markets where they accounted for 18 and 17 per cent of sales. French companies, in spite of a numerical innovative record second only to that of the United States, do not appear to have achieved the same level of success within the other six advanced nations. Although dominating their own market with a 53 per cent share of sales, French companies accounted for only 5 per cent or less of sales in the pharmaceutical markets of the US, UK, the Federal Republic of Germany, Japan, Switzerland and Italy.

Data published by the European Federation of Pharmaceutical Industries' Associations provide the final means of assessing the significance of the products developed by the world's seven leading innovating nations. Table 25 shows the proportion of the world pharmaceutical market

Table 25 **The 100 leading international pharmaceutical products in 1980 analysed by the introducing company's country of origin.**

Country of origin	*Number of products*	*% of world market*	*% of 100 product sales*
100 leading products	100	24.1	100.0
United States	35	9.5	39.4
United Kingdom	14	4.2	17.4
West Germany	14	3.3	13.7
Switzerland	12	2.5	10.4
Japan	8	1.7	7.0
France	3	0.6	2.5
Italy	2	0.4	1.7
Belgium	2	0.3	1.2
Canada	2	0.3	1.2
Denmark	1	0.3	1.2
Russia	1	0.3	1.2
Sweden	1	0.1	0.4
Unclassifiable	5	0.7	

Source EFPIA 1984.

accounted for by the leading 100 products identified on the basis of their sales values. Once again, the dominance of products developed by US companies is self-evident. In 1980, the United States had 35 products in the top 100 and these achieved sales values which summed to almost 10 per cent of the world market. France, on the other hand, had only three products in the leading 100 and these accounted for less than 1 per cent of the world market.

The factors contributing to these international patterns of innovation and innovative success will be discussed in the following section.

SOCIAL SECURITY SYSTEMS AND REIMBURSEMENT

In all seven countries there are some arrangements for pharmaceuticals to be reimbursed under social security schemes which exist to cover part or all of the population.

The United Kingdom lies at one extreme, with a centrally tax-funded National Health Service which is fully controlled by the national government. In Japan and the other four European countries there are health insurance schemes which cover virtually all the population. These are financed by a variety of insurance funds and treatment is provided by government, charitable and private health care organisations.

The United States is the exception to the general pattern, in that the nation's two publicly funded health care schemes – Medicare and Medicaid – covered just 43 per cent of medical expenditures in 1979. Only 50 million out of the total population of 220 million were covered by these two schemes. The remainder of the expenditure, by the great majority of the population, is either covered by private insurance or involves direct patient payments for treatment received. Thus the United States alone, among the seven countries studied, has a substantial private market for medical care. In the other six countries the bulk of health care expenses are prepaid through collective health care schemes.

Focusing on pharmaceutical reimbursement, each of the seven study nations except the United States covers part of the cost of the pharmaceuticals supplied to patients on doctors' prescriptions. However, in each case patients have to pay a proportion of the cost of all or some of the medicines which they receive.

In the Federal Republic of Germany the patient pays a fixed charge of 2 DM for each medicine prescribed. However, children are exempt from this charge. Overall, 92 per cent of the total cost of medicines is covered by reimbursement. In France, medicines are reimbursed either 40 per cent, 70 per cent, 80 per cent or 100 per cent according to their therapeutic category. Most medicines are either 70 per cent reimbursed or 100 per cent reimbursed. The latter accounted for 42 per cent of the total cost of medicines reimbursed in the first half of 1984 (*Scrip* 1984). However, in France patients frequently take out additional insurance, so that their personal payments are also covered by separate private insurance.

In Italy, reimbursement covers 15 per cent of the retail cost of the medicine plus 1,000 lira. This represents 70 per cent of the total cost of medicines reimbursed. In Japan, 70 per cent of the price of medicines is reimbursed although some patients are exempt from paying even 30 per cent of the cost. In Switzerland, about 50 per cent is reimbursed.

In the United Kingdom, patients pay a fixed charge of £2 per item prescribed, but 78 per cent of prescriptions are exempt from this charge, either because of the age or indigence of the patient, or because he or she is suffering from one of a number of specified diseases. Overall, 94 per cent of the cost of all prescribed medicines is reimbursed.

In the United States, the Medicaid programme pays the cost of medicines for the indigent population covered under this scheme. For the remainder, patients generally pay the full cost of their medicines privately. Thus, with the exception of the United States, reimbursement under the national social security systems is an important factor affecting the pharmaceutical market. In the United States the majority of the market is still 'private'.

In France, the patient nevertheless pays for the full price for the medicine and then has his payment reimbursed. In other countries the patient receives the medicine in return for the 'prescription charge' and the pharmacist receives the remainder of the price of the medicine direct from the social security system. The data presented later concerning pharmaceutical consumption suggest that patterns of reimbursement are not, in practice, a major factor affecting pharmaceutical consumption.

PATENT SYSTEMS

In each of the seven countries pharmaceuticals are covered by patents. In general, two types of patent protection are available. One covers the actual substance itself – a 'product' patent – the other covers only the method of manufacture – a 'process' patent. The latter provides only very weak protection for the innovator, as it is often possible to produce his novel medicinal chemical by a different production process, thus circumventing the intended patent protection. In addition, it is extremely difficult to prove that an imitator is actually using the patented production process, particularly if the onus of proof in this respect lies with the original patent holder.

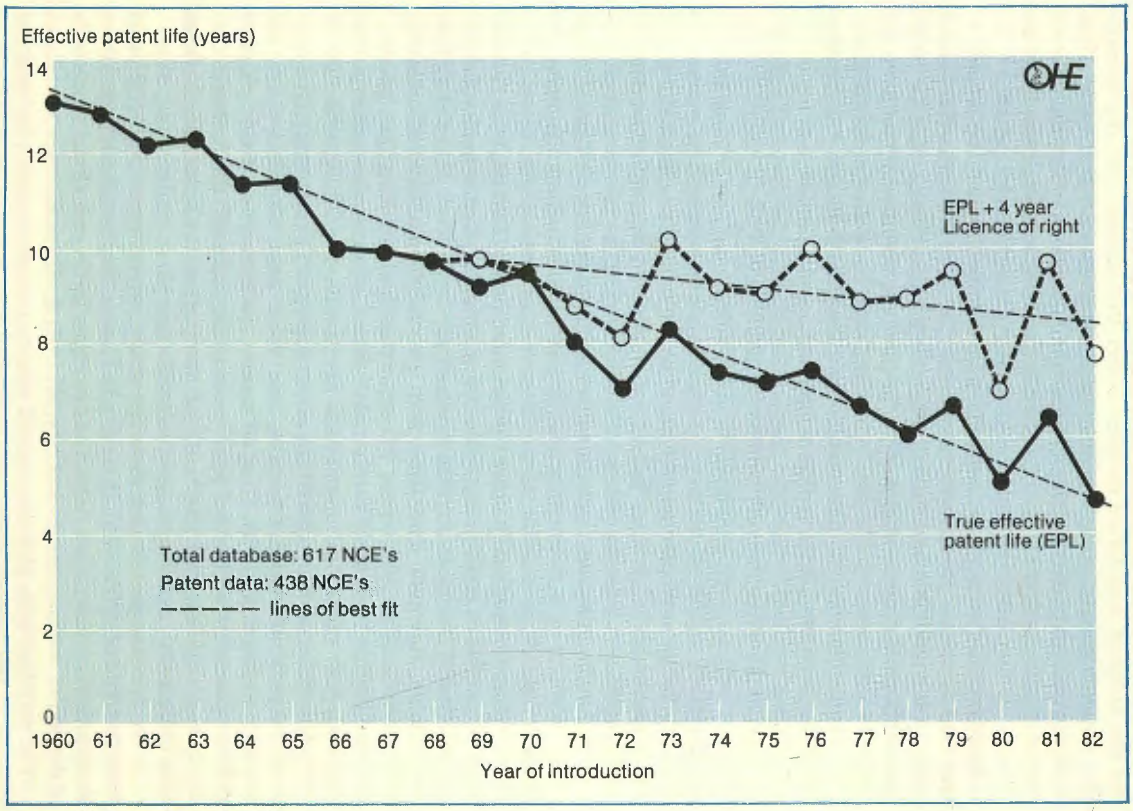
Until the 1950s, most countries relied only on process patent for pharmaceuticals. However, since then, with the exception of Italy, all countries in the study have for at least twenty years had the stronger 'product' patents. Before 1978, Italy continued to rely only on process patents, thus enabling pharmaceutical imitators to operate freely in Italy. However, in 1978 the Italian Courts ruled that under European Community Law Italy must respect full product patents, and these were introduced into the Italian patent law in 1979. Thus all seven countries now provide effective product patent protection for pharmaceuticals, although the Italian industry is still suffering the aftermath of many years as a source of cheap pharmaceutical copies because of its ineffective patent protection.

In the five European countries in the study, patents now run for 20 years from the date of application. In the United States they last for 17 years from the grant of the patent (see below) and in Japan for 15 years from acceptance of the patent, with a maximum of 20 years from application.

The problem with pharmaceutical patents in recent years has been the erosion of the *effective* duration of cover due to the increasing length of time which it takes for the development of a new medicine prior to marketing. In the United States, new legislation has recently been introduced to allow companies an additional period of patent protection, up to five years, in order to compensate for time lost during development.

The importance of such legislation is illustrated in Chart 8. This shows,

Chart 8 **Trends in effective patent life in the United Kingdom, 1960–82.**



Source Walker and Prentis 1985.

Table 26 **Number of years of patent protection remaining at the time of market introduction (1983).**

	Years
West Germany	6.4 (1981)*
France	13
Italy	8–10
Japan	7–8
Switzerland	11
United Kingdom	8.7 (1982)
United States	9.7

Source OHE Survey Data.

Note *New products here on extra two years effective patent life under current legislation.

for the United Kingdom, that under pre-1977 regulations permitting a 16 year patent term, effective patent life declined from 13.2 years in 1960 to 4.7 years in 1982.[3] Even with the additional four years which will apply to more recently patented products, the effective patent life will still be less than nine years. Table 26 shows estimates for the other six countries of the effective patent life remaining when a new medicine was marketed in 1983. France and Switzerland appear to be in a slightly more favourable position than the other five countries. The possibility cannot be ruled out that this observation reflects errors in what little data are available. Nevertheless, the Federal Republic of Germany, the United Kingdom and the United States have based their estimates on hard quantitative information.

BRAND NAMES AND SALES PROMOTION

The role of brand names and sales promotion for pharmaceuticals is seriously misunderstood. Since the independently conducted research of the economists Chamberlin (1933) and Robinson (1933) in the 1930s it has been recognised that modern economic competition depends on differentiating new products from those already on the market, and then promoting their sales. In the 1940s Schumpeter (1942) extended this idea to include the role of research and innovation. Since then economists have accepted that brand names and sales promotion are just as important a part of the total process of innovation as research and development itself. In innovative markets, such as pharmaceuticals, new products are continually being developed and marketed, rendering earlier innovations obsolete. In the pharmaceutical market, this results in the development of progressively safer and more effective medicines to replace those already in use.

The recent concerns about the safety of medicines have not arisen because new medicines are less safe, but because overall standards of safety have risen to such an extent as to make previously acceptable levels of risk now appear unacceptable. This is one consequence of creative competition, which is stimulated by the brand name system and by the use

3 British patents were extended from 16 to 20 years by the 1977 Patents Act.

of modern marketing methods. For a new pharmaceutical chemical entity, when it is first marketed, the use of a brand name is an essential element in its commercial life. Although in the seven countries under review it is covered by a patent, and hence available only from the company which developed it, it has already been pointed out that the period in which patent protection will be effective is becoming progressively shorter. As soon as the patent expires, perhaps after as little as eight years, the new medicine is dependent on its brand name alone to provide protection for the 'intellectual property' created by the research investment which has been put into it. Thus when effective patent protection is short, companies become heavily dependent on brand names to protect the intellectual property of their past research and to provide finance for their future investment in research. Doctors are naturally conservative, and hence reluctant to adopt new medicines into their routine practice. Therefore the medicine may only be beginning to reach its peak usage at the point when its patent expires and its innovator must depend on its brand name alone to recover his investment.

At that stage, the medicine becomes subject to direct competition from other medicines containing the same active ingredient produced by companies imitating the original innovation. These new 'identical' competitors may either be marketed under competing brand names, or else simply using the product's 'generic' name – the officially approved chemical name for the active ingredient.

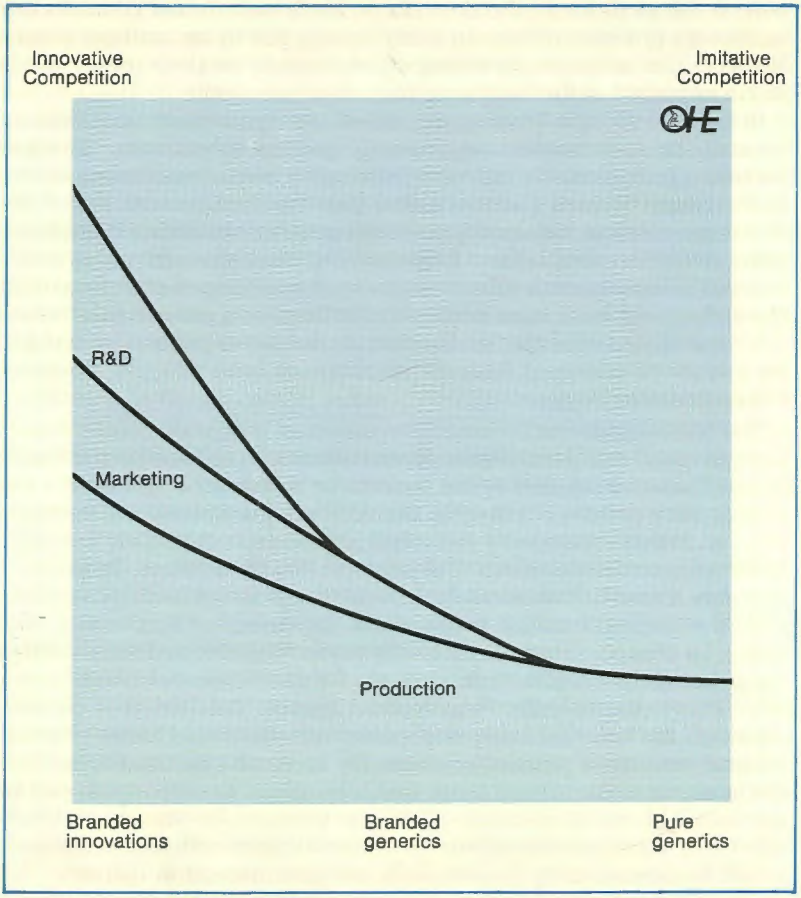
The competing brands are often referred to as 'branded generics'. The medicines marketed under a generic name alone can be referred to as 'pure generics'. The branded generics will be advertised and marketed to doctors in the same way as the original innovation. Pure generics will rely on their price advantage alone in order to gain a share of the market.

Among the seven countries covered in this Report, the United Kingdom is unique in being a substantial 'pure generic' market. A recent study has shown that the United Kingdom is the only major country in Europe in which 'pure generic' medicines feature in the top twenty prescriptions written by doctors (O'Brien 1984). In the other countries so-called 'generic competition' is in effect competition between the original brand and alternative branded medicines containing the same active ingredient but marketed by imitative competitors.

These competing brands are usually sold at a lower price than the original, in order to give them an economic advantage in the pharmaceutical market. This pricing strategy is possible because these competitors have incurred few if any basic pharmaceutical research costs in bringing their products to the market.

Chart 9 gives a diagrammatic representation of the costs which have to be met by innovative competitors on the one hand and companies involved in imitative competition on the other. Pure generics, with neither research nor marketing costs, can be substantially cheaper than original innovations, which have borne heavy research and marketing expenditures in order to achieve their acceptability. Generics exist quite simply

Chart 9 **Costs in different types of pharmaceutical market.**



Source OHE.

only by 'riding on the back' of original innovations. They are essentially copy products exploiting the heavy investment which innovators have put into the development, testing and marketing of genuinely new medicines.

It has been suggested that the role of brand names is often misunderstood, and an interesting example of this situation arose in the United Kingdom in 1982 when a government working party recommended that pharmacists should be permitted to substitute the cheapest generic medicine even in cases where the doctor had prescribed a branded preparation. This recommendation was designed purely to save money for the British National Health Service. Among other important considerations, it ignored the fact that with high technology products such as medicines, the

original manufacturer has an important role to play in providing information on the medicine to the prescribers. Medicines are not common low technology products which can safely be supplied by an imitative manufacturer. The 'software' consisting of information on their proper use is just as important as the 'hardware' of the medicine itself.

In fact in 1983 the British government, after prolonged consideration, rejected the recommendation to permit generic substitution. This was because it recognised the economic importance of the brand name system to the research-based pharmaceutical industry. It is possible that if the British government had decided to permit generic substitution other European countries would have followed this example, and an essential element of the economic infrastructure for the support of pharmaceutical research would have been destroyed. Furthermore, generic substitution could have led to confusion and anxiety on the part of patients, who might have received tablets of dissimilar appearance from different manufacturers on successive occasions.

The one exception to the otherwise universal recognition of the importance of brand names among the seven nations is to be found in the United States. There substitution by the pharmacist is permitted. However, it has already been pointed out that the United States pharmaceutical market is atypical, in that the majority of it is still private, and not publicly funded as is the case under European and Japanese health schemes. In practice, therefore, in the United States the private patient still generally chooses to have the original branded preparations dispensed for him, rather than opting for cheaper substitutes. It is only under Medicare and Medicaid that the government will sometimes only pay for the cheapest available substitute. This is the so-called 'Maximum Allowable Cost' or 'MAC' scheme. Although the latter is clearly unpopular with the United States pharmaceutical industry, it remains economically acceptable because so much of the market is in the private sector which continues to support and pay for the original branded medicines. If similar schemes for 'Maximum Allowable Costs' were introduced into the universal health schemes in Europe it would be economically disastrous for the pharmaceutical industry. This was recognised by the British government when it rejected the recommendation for bringing generic substitution into the National Health Service.

The British government has, however, imposed severe restrictions on the amount which companies are allowed to spend on sales promotion. These were first introduced by a Labour government in 1978. They required the industry's promotion to be reduced progressively from 14 per cent of sales to 10 per cent. Any overspending would be added back to profits during price negotiations. These controls were then considerably tightened by the Conservative government in 1983. Any overspending on promotion was now to be paid back directly to government, in addition to being added onto profits. Furthermore, the limit on spending has been reduced to 9 per cent of sales from 1985. The restriction is causing very severe difficulties especially for the smaller companies which cannot afford to employ an adequate number of medical representatives to visit all doctors.

CONTROLS ON PRESCRIBING

Every country with a national health insurance scheme or health service is concerned to contain the costs of medical care. In recent years special attention has been paid to the need to contain pharmaceutical costs, even though Chart 10 shows that in the European Community pharmaceutical costs fell as a proportion of total health care costs from 25 per cent in 1965 to 16 per cent in 1979. These percentages include the cost of non-prescribed medicines bought privately by the public and the cost of pharmacists' remuneration. The pharmaceutical industry's share of the total cost of health services is now less than 10 per cent in all countries.

Two principal methods of attempting to control pharmaceutical costs have been introduced. These are either 'positive' or 'negative' lists for medicines which may be reimbursed under the social security schemes. The first sets out a limited list of medicines which are allowed to be reimbursed. The second sets out a list of medicines which will *not* be reimbursed. In the absence of either a positive or negative list, all medicines normally prescribed by doctors will be reimbursed under the social security scheme. Table 27 summarises the position in the seven countries. Only Japan still gives doctors complete prescribing freedom. In Britain proposals were announced in November 1984 to introduce severe restrictions on prescribing freedom for treatments for minor ailments and for anxiety (that is, tranquillisers) from April 1985. Both the medical profession and the pharmaceutical industry in Britain have strongly opposed these measures which go much further than similar restrictions in the Federal Republic of Germany, for example.

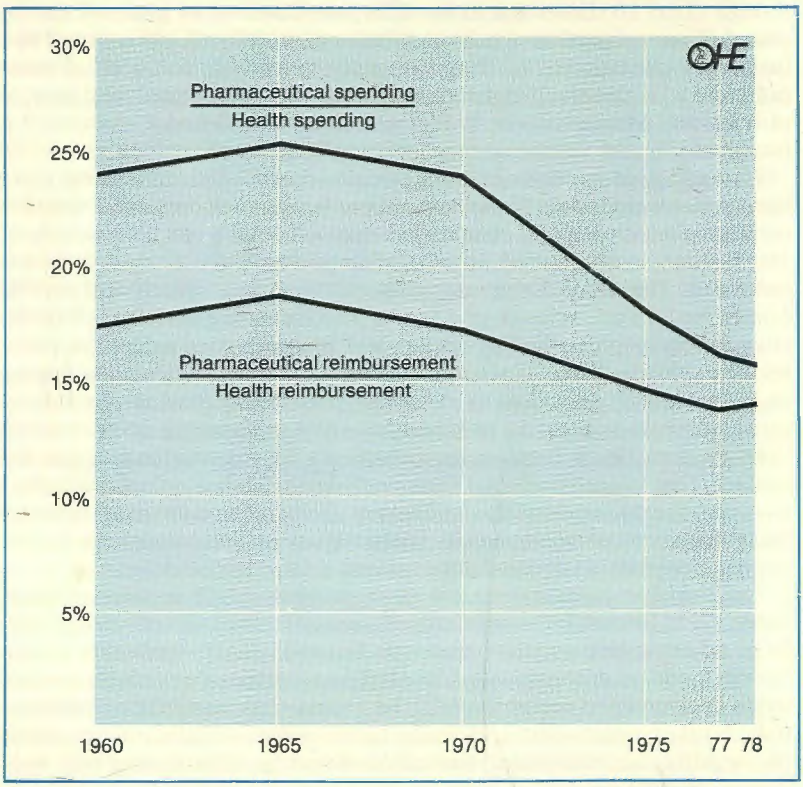
The situation is, however, less clear cut than might be inferred from Table 27. In Britain, for example, medicines advertised directly to the public could never be prescribed under the National Health Service. Nor have 'health foods' or other so-called 'borderline substances' ever been permitted to be prescribed under the NHS. In a sense these restrictions constituted a form of 'negative list'. Similarly, in the Federal Republic of Germany, the negative list includes only indications which could be treated with normal 'household necessities' such as cough and cold preparations and laxatives. In general, it is countries such as those of Scandinavia, Austria and Australia (which have been excluded from the main part of this study)

Table 27 **The existence of 'positive' and 'negative' lists to restrict prescribing in the seven study nations.**

	'Positive List'	*'Negative List'*
West Germany	No	Yes
France	Yes	No
Italy	Yes	No
Japan	No	No
Switzerland	Yes	No
United Kingdom	No	Yes
United States	Under Medicare and Medicaid in some States only	

Source OHE Survey Data.

Chart 10 **Pharmaceutical expenditure as a proportion of total health spending and reimbursement of pharmaceuticals as a proportion of total health care reimbursements in the European Economic Community, 1960–78.**



Source Data compiled by EFPIA.

which have the tightest controls governing the reimbursement of pharmaceuticals under social security schemes. Although both positive and negative lists are unpopular with the pharmaceutical industry, the next section will indicate that they appear to have been ineffective in restricting pharmaceutical expenditures. They could, however, be disastrous if they followed the very restrictive patterns existing in such countries as Austria.

Apart from the positive and negative lists for reimbursement, there are no specific restrictions on prescribing in the seven study nations. However, in most countries doctors are subjected to fairly strong pressures to encourage them to prescribe economically. In the United Kingdom, for example, there was a specific campaign in 1984 to persuade doctors to use generic names in their prescribing, so that pharmacists could dispense the

cheapest available preparation. Similar pressures have also been applied in the Federal Republic of Germany and in Switzerland. By contrast, Japanese doctors have traditionally been regarded as 'almighty', and they would strongly resist any interference with their prescribing freedom.

PRICES

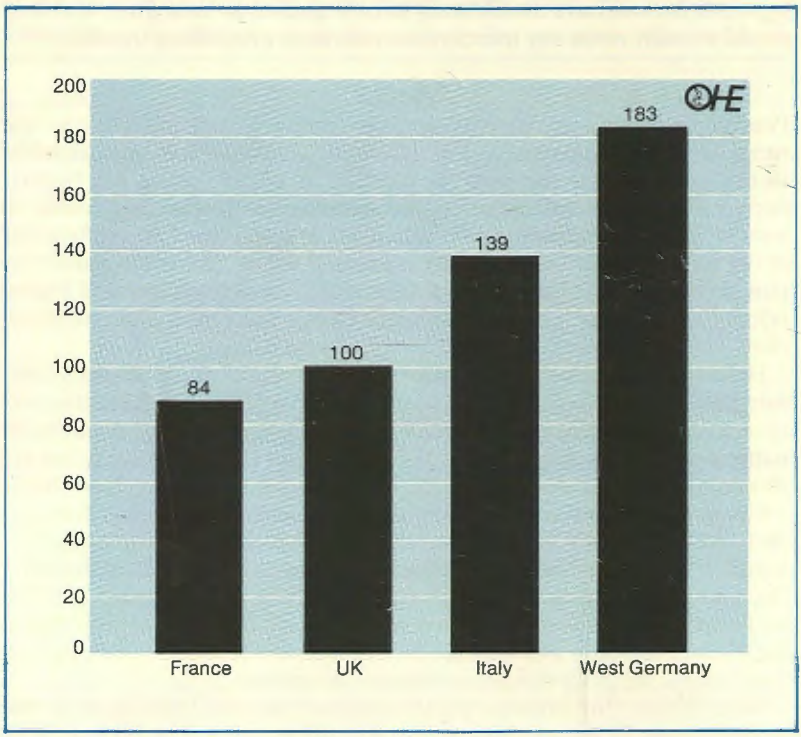
Pharmaceutical price comparisons are extremely difficult because the range of preparations on sale in different countries varies considerably. Hence it is difficult to compare like with like. In addition, currency fluctuations considerably influence individual national prices and 'value of money' differs from country to country. For example, the Federal Republic of Germany is an affluent country compared to the United Kingdom. The purchasing power of the average individual is much greater and higher prices therefore often may reflect higher wage rates more than anything else.

However, it is clear that average pharmaceutical prices do vary considerably from country to country, although not always consistently over time. Chart 11 shows a price comparison covering four of the seven study nations which was carried out in 1974 by Cooper (1975). Italian prices are shown to be above those in the UK. Chart 12 shows a more recent international comparison which covers six of the seven countries. It was carried out in 1982 by HealthEcon, the Swiss economic consultancy, and found that Italy had become cheaper than the UK. The effect of currency fluctuations is illustrated well in Cooper's 1975 study. Whilst at 1974 exchange rates the German prices are shown as 183 compared to 100 in the UK, at 1964 rates of exchange the comparison becomes 103 as against 100. That is, the price difference virtually disappears.

Nevertheless, the outstanding conclusion from the 1982 study is that price controls in France, Italy and to a lesser extent the UK have reduced prices below the economic levels applying in Germany and Switzerland. The level of prices in Japan reflects both the strength of the yen and the fact that Japan has consistently supported its home-based industry in order to strengthen its future worldwide development. Recent price reductions in Japan have not significantly altered this general situation. The overall picture of international prices in Europe is supported by two further studies, one conducted in 1981 by Prognos, the Swiss Consultancy (Table 28) and the other based on 1983 data published by WHO (Table 29).

One of the most serious consequences of the effects of price controls implicit in Chart 12 has been the encouragement of so-called 'parallel imports'. This is the practice whereby opportunists buy in the cheap French and Italian markets and then sell these goods in competition with the original manufacturer in higher priced markets such as the Federal Republic of Germany and the United Kingdom. This practice increases the proportion of a manufacturer's sales in low-priced markets and reduces his returns from sales in higher priced markets. The benefit goes to the opportunist distributor, rather than to the public – either directly in price reductions or indirectly as funds to finance pharmaceutical research.

Chart 11 Comparison of pharmaceutical prices in four countries in 1974.



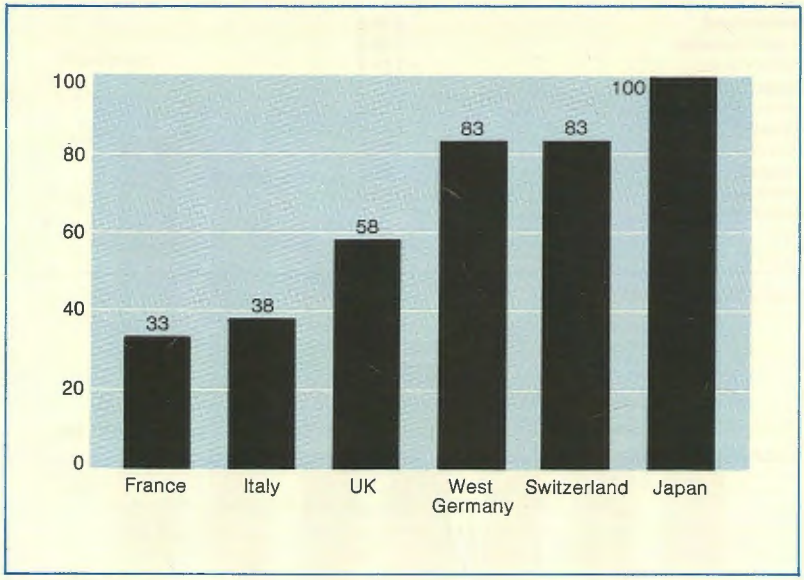
Source Cooper 1975.

LEVELS OF CONSUMPTION

Pharmaceutical prices tell only part of the story in relation to total pharmaceutical expenditure. The other factor is the volume of consumption in different countries. The recent study by O'Brien (1984) examined the number of prescriptions written per head of population in the four largest European countries included in this study. The results are shown in Table 30. However, even this does not complete the story, as it gives no indication of the relative size of each prescription – which could have been for two days' treatment or two months'. The potential significance of this last point is made clear by the per capita drug consumption data shown in Table 31.

Chart 13 shows estimates prepared by the Office of Health Economics of per capita pharmaceutical expenditure in each of the seven countries. Switzerland and Japan come out on top and France is third despite the low

Chart 12 **Comparison of pharmaceutical prices in six countries in 1982.**



Source HealthEcon 1983.

Table 28 **Index of pharmaceutical prices* in selected European nations, 1981.**

West Germany	100
Belgium	69
France	65
United Kingdom	94
Italy	61
Austria	71

Source Prognos 1984.

Note *The study was based on German multinational companies offering the same products in the markets analysed.

French prices. These figures include non-prescribed medicines as well as those provided under the health services. Nevertheless the contrast between this pattern and that of relative prices is remarkable. It seems clear that strict price controls and limited lists do not result in low overall expenditures on medicines.

Table 29 **Price comparisons for a number of selected medicines, 1983.**

Country	*Price Index*
Switzerland	158.4
West Germany	138.4
Netherlands	126.4
United Kingdom	111.3
Denmark	110.1
Finland	105.9
Sweden	100.0
Austria	99.5
Norway	95.0
Belgium	76.9
Italy	64.3
France	57.7

Source Dukes 1984.

Table 30 **Pharmaceutical items prescribed per head of population in four countries in 1982.**

United Kingdom	6.53
France	10.04
West Germany	11.18
Italy	11.26

Source O'Brien 1984.

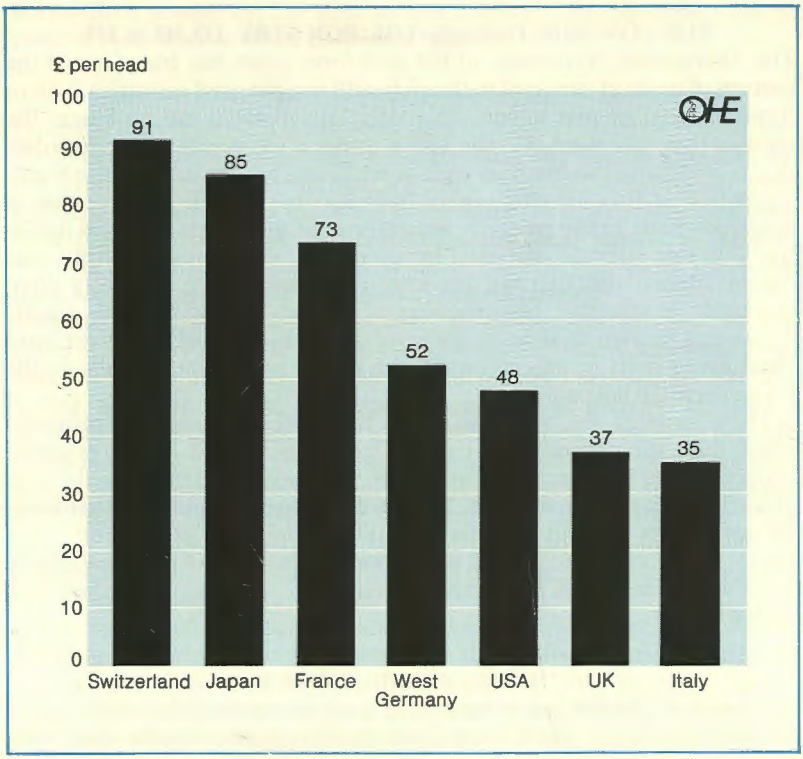
Table 31 **International comparison of drug consumption.**

	*Consumption per head expressed in single doses.**
Belgium	1,304
West Germany	1,004
France	2,129
Great Britain†	1,181
Italy	886
Austria	819
Switzerland§	1,138
Spain	1,297

Source Zentralinstitut für die Kassenärztliche Versorgung 1983.
(Based on issue of medical products by public pharmacies).

Notes *Single doses or units are individual dragées, tablets, suppositories or ampoules or, in the case of ointments, creams or drops, that quantity which the patient uses for each individual application.
†In Great Britain only the prescriptions of general practitioners are supplied by public pharmacies. Internists and other specialists practise in hospitals which also supply outpatients with drugs. For this reason the pharmacy value of 975 for Great Britain was corrected by 35 per cent.
§In Switzerland 30 per cent of general practitioners are authorised to issue the drugs prescribed by them direct to the patient. Therefore the pharmacy value for 875 for Switzerland was corrected by 30 per cent.

Chart 13 **Estimated pharmaceutical consumption per capita in the seven study nations in 1981, £ per head.**



Source OHE Estimates.

Some Comparative Conclusions

THE CONTRIBUTION OF THE INDUSTRY TO HEALTH

The 'therapeutic revolution' of the past forty years has transformed the pattern of medical care and national health in advanced countries such as those covered by this Report. The infectious diseases are no longer the menace they represented in the 1930s. Surgical interventions for disorders of the brain and the heart as well as widening possibilities for the transplantation of diseased vital organs have become feasible only because of advances made in the research laboratories of the pharmaceutical industry. Diseases such as diabetes, hypertension, rheumatoid arthritis and mental illness, although not yet wholly conquered, are now very often amenable to effective pharmacological therapy. In addition to greatly enhancing human well-being these advances in medical treatment have often saved costs in other parts of the health services, especially in the very expensive hospital sector.

These benefits are available on an international basis and countries other than the seven study nations have also shared in the pharmaceutical-based improvements in health. Yet they have tended to do so as 'free-riders' in economic terms. That is, they have obtained the therapeutic advantages without contributing fully to the costs of progress. As a result they have not derived the economic benefits of pharmaceutical innovation which have been experienced by the seven countries described in this Report.

THE ECONOMIC BENEFITS

The seven study nations, representing three-quarters of the world output of pharmaceuticals, share very substantial economic benefits from their innovative activities.

First, Table 7 shows that their pharmaceutical industries provide employment directly for about 680,000 people. Probably as many as a million others are employed in industries which act as suppliers to the pharmaceutical manufacturers. Out of the 680,000, about one-fifth have scientific and technical qualifications. Thus the industry is a major employer of technologically qualified staff in each of these seven countries. Indirectly, again, the pharmaceutical industry supports scientific activities and employment in the universities. Thus it is beneficial for employment, for technology, and for science in the seven countries where the pharmaceutical industry is most active.

Second, Table 8 showed that the pharmaceutical industry accounted for a positive balance of trade of 10.5 thousand million DM in the seven countries combined in 1982. Without Japan's negative figure the total was almost thirteen thousand million DM.

Third, it is estimated in Table 16 that the industry contributed in total 39 thousand million DM in all forms of taxation in 1982.

In each of these three ways the pharmaceutical industry is a 'good

citizen' for the seven countries where it is most active. It brings substantial economic benefits to those countries and has made an important contribution to their prosperity. The next section discusses these benefits from the point of view of some of the individual nations.

THE NATIONAL PICTURE

From the Report so far it is apparent that four out of the seven countries – the Federal Republic of Germany, Switzerland, the United Kingdom and the United States – have formed a central core of the successful international pharmaceutical industry. From Table 24 it was clear that these countries have achieved the greatest international market penetration with successful and important new medicines. On this basis, these four have been the most productive pharmaceutical nations.

Traditionally, since the creation of the modern research-based pharmaceutical industry after the Second World War, the United States has dominated the scene. However, its share of total research expenditure has been falling, as other nations have spent more on this activity. In 1964, it accounted for 63 per cent; by the early 1980s this had fallen to 33 per cent. Switzerland, also, has a very strong historical tradition in pharmaceutical research and production but real growth in its research spending since 1970 has been slower than that experienced in most of the other study nations. Table 19 showed that it was the United Kingdom, followed by the Federal Republic of Germany, which had the largest increase in research spending between 1970 and 1982.

The success of the pharmaceutical industry particularly in the Federal Republic of Germany, in Switzerland, in the United Kingdom and in the United States has been due largely to a good balance being established between the need to encourage a profitable research-based industry and the need to keep pharmaceutical expenditure down to reasonable limits. In Germany, the latter objective has been achieved by putting pressure on doctors to prescribe economically; in Switzerland it has been achieved by price control; in the United Kingdom it has been achieved under the Pharmaceutical Price Regulation Scheme (PPRS) and in the United States it has been encouraged by allowing generic substitution. However, the important point is that – by whatever method – a balance has been achieved. If governments were now to introduce more restrictive measures solely to reduce costs, it could be extremely damaging both to the economic prosperity of the countries and to the well-being of patients.

In Britain, for example, the PPRS has since 1969 controlled the overall profit which companies can earn from their sales to the National Health Service. However, it is a deliberately ambivalent instrument: in its preamble it specifically spells out the importance of maintaining 'a strong, efficient and profitable pharmaceutical industry in the United Kingdom' which should be 'capable of such sustained research and development expenditure and should lead to the future availability of new and improved medicines, both for the National Health Service and for export'. Although there have been frequent vigorous disagreements between the

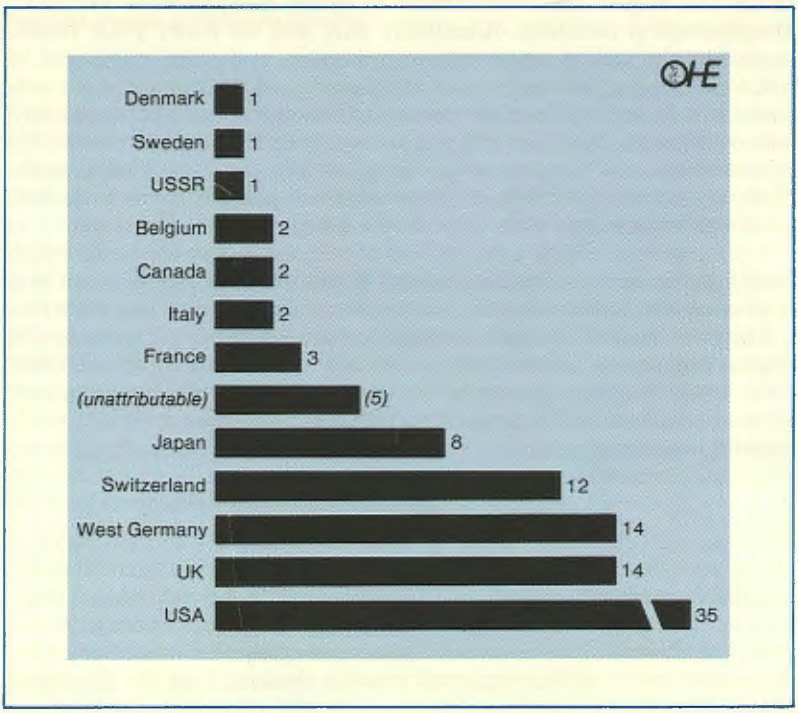
industry and government on the interpretation of these words (notably in 1983 when both price cuts and a price freeze were imposed, and in 1984 with new restrictions on sales promotion and the proposal of a limited list for prescribing) the British government still claims to recognise the importance of a strong pharmaceutical industry. The Federal Republic of Germany, Switzerland and the United States have, until now, similarly recognised the need to balance the economic prosperity of the pharmaceutical industry with the desire to pay no more than reasonable sums for pharmaceutical supplies.

Turning to the other three countries, Italy has on the whole had a rather poor penetration of world markets with its pharmaceutical innovations, and has a much smaller positive balance of trade than countries such as Switzerland and the Federal Republic of Germany.

This relatively poor performance is almost certainly related to its lack of proper patent protection for pharmaceutical innovation before 1978. Although it now has strong product patents, it takes at least ten years between a change in policy towards innovation and the consequent effect on international trade. Thus it remains to be seen whether the change in patent law will help Italy to catch up with the more successful pharmaceutical exporting countries. Yet there must, unfortunately, be some doubt about this because of the imposition of very strict price control on Italian medicines. The consequent low prices in Italy and the low consumption per capita (Chart 13) mean that the prospects for the Italian industry are still not too optimistic.

France provides one of the most fascinating enigmas of the seven countries. It has very strict price control and very low prices, yet its total per capita consumption of pharmaceuticals appears to be among the highest in Europe – more than three times that of the United Kingdom and 50 per cent above that in the Federal Republic of Germany. In the international markets, it has made very little impact with really significant therapeutic or commercially successful innovations. Yet in the early 1970s it had a large number of innovations and its positive pharmaceutical balance of trade remains among the highest of any country. It seems possible that the French industry has had very special support from its government; France's balance of trade in pharmaceuticals may have been increased, for example, by restrictions on imports and by local price controls. In addition, in the 1950s the French laboratories received strong nationalistic protection. Foreign investment in the French industry was severely controlled, and this may account for the survival and success of many small French pharmaceutical companies with limited sales but surprising export success in countries outside Europe. Table 24 showed that very few French innovations sold in more than 40 markets. And Chart 14 (based on Table 25) indicates that in 1980 France was responsible for only three of the leading 100 pharmaceutical products ranked according to sales value in world markets. This total was well behind the United Kingdom and the Federal Republic of Germany. The future for the French pharmaceutical industry is therefore hard to predict, particularly since the government

Chart 14 **Number of pharmaceutical products in the international top 100 (by sales value) attributable to manufacturers originating in selected countries, 1980.**



Source Table 25.

takeover of the major pharmaceutical firms in France.

It has already been pointed out that Japan was the last of the seven countries to enter the field of pharmaceutical innovation. However, Table 18 showed that in 1982 it was the second highest spender on pharmaceutical R and D (after the United States). Chart 14 shows that it was responsible for the fifth largest number of leading products in 1980. These measures of research success and innovative output have still to show up in Japan's figures for international trade. However, there seems no doubt that the Japanese pharmaceutical industry is set to follow the example of its motor cycle, car, camera, watch and electronics industries in making a major impact on world pharmaceutical markets. High local prices for medicines in Japan, despite recent price reductions, and continuing measures of government protection for the local industry support the impression that national policy is geared to promote the international growth of the industry. The implications of this Japanese development will be discussed in the final section of this Report.

The Alternative Scenario

So far this Report has concentrated on seven conspicuously successful pharmaceutical countries. Admittedly Italy was for many years handicapped by the lack of proper patent protection, and is still hampered by restrictive pricing policies. France, too, has a less clear cut picture of international success than the other countries, although it has a strong positive balance of trade. And Japan still has to develop its full potential as a source of pharmaceutical innovation and a major force in international trade. However, overall, the seven countries dominate the picture as far as successful pharmaceutical innovation is concerned.

It is interesting next to turn, by way of contrast, to five countries which have been conspicuously unsuccessful in pharmaceutical innovation, and to examine the way in which adverse government policies have contributed to their failure. The five examples which have been chosen in this respect are Austria, Greece, Spain, Australia and Canada. There are many other examples, such as the Latin American countries where similarly adverse policies have been equally disastrous. The five examples merely illustrate a general principle.

AUSTRIA

In a recent issue of *Scrip* the general secretary of the Association of Austrian Industrialists was reported as saying that the Austrian domestic pharmaceutical industry was 'going increasingly to the wall' (*Scrip* 1984a). Primarily this situation has been created by the pharmaceutical pricing policy in Austria. Pharmaceutical prices are controlled first under a law introduced in 1976. Price approval must be obtained from the Ministry of Health and Environment, and this restricts both the price of locally produced and imported medicines.

However, in addition, the social security scheme applies its own 'price control' by refusing to grant permission for a medicine to be reimbursed unless it also regards the price as 'acceptable'. In practice, the social security authorities ignore the prices already approved by the Health Ministry, and set their own much lower prices. The result is that medicines sold at the already low prices approved by the government are still prohibited under the social security regulations.

Medicines will only be accepted for the social security scheme's 'positive list' if the manufacturer makes a further price reduction. Legal experts consider these arrangements to be illegal under Austrian law, but they nevertheless persist, causing very severe damage to the pharmaceutical industry and depriving social security patients of the benefits of many very important medicines.

In addition, Austria has until now had only weak process patents (*verfahrenspatent*), although product patents are to be introduced in 1987. In practice, however, Austrian pharmaceutical prices are so low, in any case, that generic manufacturers have not generally regarded it as worth-

while to introduce copies of original patented pharmaceuticals. Overall, unless urgent steps are taken to restore reasonable prices under the social security scheme in Austria, the local pharmaceutical industry in that country seems unlikely to survive.

GREECE

The Greek government has been consistently hostile to the pharmaceutical industry. It provides only weak process patent protection, and although on accession to the European Community the Greek government gave an undertaking that it would introduce effective product patents, in accordance with the European Community Patent Laws, it has so far failed to do so.

More seriously, pharmaceutical prices in Greece have been held down, and price increases have been refused despite substantial inflation. Thus in real terms Greek prices have been falling substantially in recent years.

In consequence a number of major international pharmaceutical companies have withdrawn altogether from the Greek market, and their medicines are now available only through local agents. The Greek government has refused to recognise that its behaviour is extremely damaging to the local pharmaceutical industry as well as to the subsidiaries of the international companies operating in Greece.

SPAIN

Spain also has until now had only process patents for pharmaceuticals. As, in addition, the burden of proof of infringement lies with the original patent holder, who must prove that his patented manufacturing process has been used, there is at present no effective protection for pharmaceutical innovation in Spain. After accession to the European Community the Spanish government will introduce full product patent protection for pharmaceuticals. But it still threatens to grant compulsory licences to imitators. Thus in practice Spain may follow the example of Greece, and derive the benefits of the European Community membership without fulfilling the spirit of its membership obligations. In addition, Spain has recently been favouring generic medicines instead of original branded preparations by allowing them more favourable conditions for registration prior to marketing. Finally, Spain also has very restrictive price controls on pharmaceuticals so that Spanish prices are well below the international levels required to finance continued pharmaceutical research and development. Only small overall price increases have recently been permitted and these have been offset by substantial individual price reductions.

AUSTRALIA

Australia is a classic example of a country which is pursuing what economists call a 'free-rider' policy towards its pharmaceutical industry. That is, in the price controls which the Pharmaceutical Benefit Scheme imposes on pharmaceutical manufacturers, the authorities refuse to take account

of the proper share which Australia should contribute to worldwide pharmaceutical research costs. The Australian PBS authorities specifically ask 'why should we pay for pharmaceutical research in Switzerland or Germany or the United States?' Hence Australian prices are among the lowest in any of the advanced countries of the world (Reekie 1984).

In consequence, a number of major international companies have withdrawn their production facilities from Australia. They now import all their preparations from overseas. This reduces the companies' costs, and makes the very low Australian prices more acceptable. However, it increases Australia's negative balance of trade in pharmaceuticals and reduces local Australian employment in the industry. Perhaps most important of all it diminishes Australia's prospects of becoming a technologically advanced nation. It is a short-sighted policy for a country with Australia's national potential for the future to rely so heavily on its mineral resources rather than technology for its prosperity.

CANADA

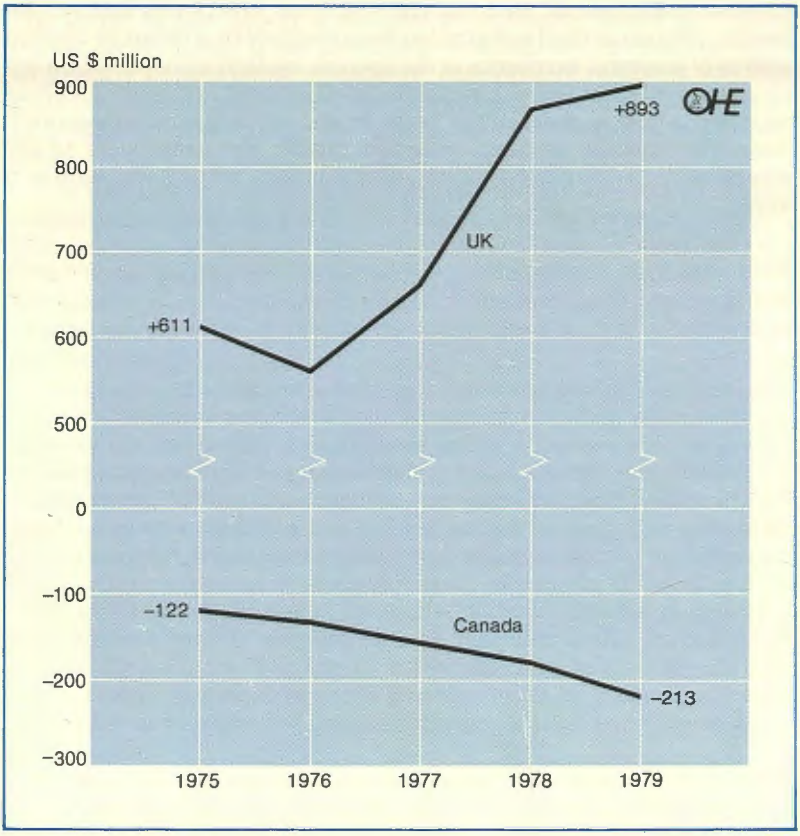
If Australia has been short-sighted in its attitudes to the pharmaceutical industry, Canadian policies have been catastrophically myopic. In the single minded pursuit of a 'cheap-drug policy' the Canadian government has undermined both the system of pharmaceutical patent protection and the use of brand names for medicines.

Canada's postwar government inherited the original British provision in the patent laws which allowed copyists to apply for compulsory licences for pharmaceuticals, and which required the Controller of Patents to grant such licences unless he could see good reasons for refusing to do so. In Britain, this provision of the Patent Law was repealed in 1977. However, Canada, instead of repealing this provision, has instead extended its application to permit importation of copy products as well as their local manufacture. Thus while Britain strengthened its patent protection, the Canadian government substantially weakened the protection afforded to pharmaceutical innovations.

Secondly, under its provincial health insurance plans Canada allowed substitution of generic medicines in place of the original brands prescribed by the doctor. The effect of these substitution laws were strengthened by the introduction of 'Maximum Allowable Cost' provisions into the social security schemes. Thus pharmacists were only reimbursed at the price of the cheap generic copy product; they could not afford to dispense the original brand which had been prescribed.

The effect of these provisions on the Canadian pharmaceutical industry has been disastrous. Canada now carries out no significant pharmaceutical research and much of its pharmaceutical requirements are met by imports. Chart 15 shows the way in which Canada's negative balance of pharmaceutical trade worsened in the late 1970s, while Britain's positive trade balance at the same time improved. The export of generic medicines, which does exist, has not compensated for the much greater increase in imports.

Chart 15 **Comparison of Canadian and UK pharmaceutical trade balances 1975–79.**



Source UN Commodity Trade Statistics.

These five countries illustrate the adverse effect which negative government measures can have on national pharmaceutical industries. It is particularly interesting that over the past year the Canadian government in particular has become very worried about this adverse effect. It has had first a departmental investigation and more recently a Commission of Enquiry conducted by Professor Harry Eastman to investigate what measures Canada could take to undo the damage that has been inflicted on the pharmaceutical industry. The findings of this Commission of Enquiry are still awaited.

Countries which have discouraged their pharmaceutical industries do not just suffer economically. They also lose out in a more indirect way by failing to encourage medical progress in a broader sense. Spain, for

example, is seriously concerned because so many of its most distinguished medical scientists have emigrated to work in the United States. The poor scientific and economic environment which has so seriously harmed the Spanish pharmaceutical industry has been matched by a failure to develop centres of academic excellence in the Spanish medical schools. The United Kingdom and the Federal Republic of Germany are both excellent examples where a close liaison between the successful pharmaceutical companies and the academic research centres has contributed to the general advance of medical science for the benefit of the population as a whole.

A Final Overview

The theme of this Report is not that governments should give special protection or support to the pharmaceutical industry. Special support for an industry implies public investment, development contracts, subsidies, grants and special allowances. The pharmaceutical industry has achieved its present success through the enterprise and investment of the companies engaged in it, and not through government protection.

It is true that governments have created markets for modern drugs in national health systems, but they did not do so to encourage the industry. Their aim was to promote the health and well-being of their citizens – which is also the target of the industry in pursuing therapeutic innovation. The practice of medicine was not created by national health systems; these systems merely put medicines for the many onto a basis of collective community funding.

The practice of medicine is publicly funded: the production of pharmaceuticals, whether innovative or generic, is not. The pharmaceutical industry is a competitive industry: competitive in innovation, competitive in production, competitive in marketing and competitive in efficiency of management. The test of competitive success is profitability and it must be emphasised that profit is a test and not an aim in itself. The aims of the industry are the development, production and marketing of medicines and the consequent provision of employment, of exports, of taxes and the other social responsibilities of corporate industry. That the pursuit of its aims produce profit is no more than an indication of that success which enables the industry to continue to innovate and to grow in economic terms. Failure to produce a profit points to a failure in management, in innovation or in marketing and is an unequivocal indication of an industry in decline.

So long as the pharmaceutical industry can obtain a profitability adequate to finance its future it will continue to innovate in the interests of better medicine and it will continue to direct its policies and skills to more and more of the areas of the world where medicines are needed. The industry does not seek economic privileges through protection and direct support by governments. But the industry is entitled to ask that it should not be actively *discouraged* by governments, which are too intent on cutting the overall cost of medical care.

There have been two ways in which governments have in practice discouraged the success of the industry. The first is by stimulating unnatural competition, for example by favouring cheap generic copies instead of original innovations. The second is by direct regulation to restrict either the volume of sales through social security schemes or the profitability of these sales, through price regulation schemes. The countries which do not have successful pharmaceutical industries, such as Austria, Greece and Australia, have employed both tactics in order to become 'free-riders' in an economic sense. Their tactics endanger the success of the industry

worldwide, because the unfavourable conditions which they have created could spread to the seven successful nations. More ominously, these seven successful countries have themselves recently started to introduce either unnatural competitive conditions or more strictly to regulate the profitability of their pharmaceutical manufacturers. The real danger for the industry, as conditions in other countries illustrate, arises when distorted competition is *combined* with restrictive regulation. This appears to be happening in the United Kingdom and other European countries at present, in a desperate effort to cut public expenditure under the NHS in Britain and the corresponding national health schemes elsewhere.

There can be no question that the well-being of mankind has been enormously enhanced by the innovations of the pharmaceutical laboratories over the past forty years. Premature mortality, especially death from disease in childhood, has been greatly reduced. Suffering from diseases like rheumatoid arthritis, depression and even such generally minor ailments as skin disease has been greatly alleviated. Although much publicity is now given to the 'dangers' of modern medicines, they are in fact very much safer than many of the preparations such as mercury and arsenic which constituted the pharmacopoeia of the 1930s. The risks of surgery have been minimised – despite its increased complexity – by advances in anaesthesia and in antibiotic prophylaxis against post-operative infection.

More recently, medicines have made enormous advances in improving the quality of life for many victims of disease: the pharmaceutical industry is now active, along with economists and clinicians, in developing measures which can quantify these improvements. Such quantitative measurement is important in order to demonstrate more clearly how much the development of modern medicines has contributed to well-being. The cost of medicines should then be seen in perspective against clearly measurable benefits.

However, this Report has concentrated mainly on the economic rather than the medical and social benefits of pharmaceutical innovation. It has shown that, in different ways and to different degrees, the seven countries which are covered by the Report have all benefited substantially from the presence of the multinational pharmaceutical industry within their borders. There is no doubt that the pharmaceutical industry has benefited those countries which have encouraged its development. By contrast, countries which have adopted the most hostile policies towards the industry have largely been denied these benefits.

THE EUROPEAN COMMISSION

From a European point of view, there is a clear message from this Report to the Commission of the European Community and to the European Parliament. Europe is one of three centres of pharmaceutical innovation: Japan and the United States are the others.

Japan in particular is edging its way up in the international league of pharmaceutical innovation. Europe has already faced a threat from other

Japanese industries, and will shortly face a threat from Japanese pharmaceuticals. This is an obvious and in many ways desirable development in relation to world trade. However, it means that the authorities cannot be complacent towards their European pharmaceutical industry.

A recent publication from the European Federation of Pharmaceutical Industries' Associations (1984) emphasised three ways in which the European Commission needed to support the pharmaceutical industry in Europe. These were, reasonable prices, protection of pharmaceutical know-how in the widest sense, and freedom for doctors to prescribe the medicines which they believe best for their patients.

The European Courts have already ruled that the price control schemes in some European countries are an infringement of the Treaty of Rome. However, the European authorities have so far been ineffective in preventing these local governments from imposing unreasonably low prices. France and Italy are specific cases among the seven countries covered by this Report. Italy has until recently had a poor record of pharmaceutical innovation and still has a poor performance in the international pharmaceutical market. In France, the Report has included evidence that pharmaceutical innovation has recently become less fruitful than in the 1960s. Again this could be related to restrictions on French pharmaceutical prices, although attention has been drawn to a number of other factors.

Patent protection is now strong in each of the seven countries studied, although Italy still has to reap the benefits of the reform of its patent law in 1979. However, there are threats to the innovators' know-how in more subtle ways. In particular, imitators could be given access to confidential company data when patents expire and generic imitations become permissible. This could be particularly serious since the delays in initial marketing have so greatly eroded the span of effective patent protection.

The European Commission has, in addition, a particular role to play in ensuring that Greece and Spain and Portugal, when they gain membership, comply with the European patent laws for pharmaceuticals. Doctors' prescribing freedom is also under threat. For example, the recent introduction of restricted prescribing freedom in the Federal Republic of Germany and the United Kingdom are serious threats to the industry. The European Commission should ensure that prescribing freedom, at least for major diseases, is restricted only on the grounds of safety rather than grounds of economy.

THE ROLE OF NATIONAL GOVERNMENTS

Although it is important for the European Commission and Parliament to prevent restrictive controls on the pharmaceutical industry in Europe, it is the individual national governments which have the strongest influence on the success or failure of the industry in their own country. The Japanese and the United States governments both give strong support to their local industry. What is the situation in Europe?

So far, in the Federal Republic of Germany and Switzerland the governments have in different ways given general recognition to the economic

importance of their pharmaceutical industries. It has also been pointed out that the Pharmaceutical Price Regulation Scheme in the United Kingdom is claimed specifically to recognise the need to promote a successful and profitable industry.

However, there are signs that the growing desire to restrict health care spending could tempt each of these three governments to change their policies – price cuts, controls on promotion and curtailed prescribing freedom in Britain; a negative list and increasing pressures on prescribing freedom in Germany; and Swiss price controls are all straws in the wind indicative of a changing climate. One purpose of this Report is to point out the folly of such change. These countries benefit substantially from their pharmaceutical industries and they must not be discouraged. Short term gains from a 'cheap-drug' policy could be enormously damaging in the longer term.

In the other two European countries, restrictive price control has recently been the major problem. In France, this has not reduced overall consumption, and although the recent French record of pharmaceutical innovation has been disappointing, its international trade balance has continued to increase. France has already been described as an enigma: its pharmaceutical future is problematic.

Italy, on the other hand, presents a more gloomy picture. With only recently introduced effective patent protection, its industry is still hampered by price restraint and very low local consumption. It has only a weakly positive balance of trade. The Italian government, more than any other among the seven, needs to modify its attitude towards its pharmaceutical industry if it is to share fully in the economic benefits of pharmaceutical innovation.

Within Europe, the low prices of France and Italy (as well as Greece and Spain) have an impact outside their national boundaries. This is because of the effects of 'parallel imports' which have already been discussed. It has even been suggested that parallel importing could have the effect of importing not only cheap products but also cheap prices into other countries. Price competition exists for prescription medicines. If the lower prices of parallel imports were passed on to the consumer (via the social security schemes) they could undermine the higher price levels existing in countries such as the Federal Republic of Germany, Switzerland and the United Kingdom. This would reduce the funds available for European pharmaceutical research and for investment in the growth of the industry in Europe. Thus national governments which impose 'illegal' price control schemes – in terms of European Community law – are undermining the whole future of the pharmaceutical industry in Europe.

THE INFLUENCE OF PUBLIC OPINION

One of the most serious problems facing the pharmaceutical industry in the 1980s is the development of an increasingly hostile public opinion towards its activities.

To a large extent, this appeared to start as a result of various inter-

national pressure groups attacking the industry for its activities in the Third World. These, it has been pointed out, are outside the scope of this Report. However, the criticisms of the industry have more recently been directed by the same pressure groups against its operations in advanced countries as well.

The criticisms concentrate on the alleged dangers of pharmaceutical products and on the methods used to promote their sales. There are also criticisms of the fact that different prices are charged for the same medicine in different countries. These two latter criticisms reflect a failure to understand the basic economic principles necessary for the development of a research-based industry. From the 1930s onwards, economists have recognised that powerful marketing methods are necessary for modern industry. As far as prices are concerned, these cannot be directly related to production costs for a research-based product. Prices must be set according to the competitive factors in the market, and these will vary substantially from country to country. In addition, in Europe, the situation is confused by the application of 'illegal' price controls. Uniform pharmaceutical prices across Europe will not be achieved for many years to come, if ever.

In general, there is perhaps an element of jealousy in the criticisms levelled at the pharmaceutical industry. This Report has indicated that it is a highly successful industry in the seven countries. It has a remarkable record of innovation, and it has prospered as a consequence. The industry's critics seem to be resentful of this prosperity which is a measure of efficiency and success. They fail to recognise that benefits accrue to the nation as a whole, not just to the employees and shareholders of the pharmaceutical companies. The pharmaceutical industry throughout Europe needs to take more active steps to publicise the benefits which it brings.

If these benefits are not appreciated, and if the voice of the industry's critics goes unchallenged, there is a danger that governments could respond by placing further restrictions on the industry, and thus lose the advantages which the industry yields.

THE PROSPECTS FOR THE FUTURE

Despite national governments' recent measures discouraging the pharmaceutical industry, this Report has on the whole presented an optimistic picture for its future in the Federal Republic of Germany, in France, in Italy, in Japan, in Switzerland, in the United Kingdom and in the United States. No other country represents a serious challenge to the supremacy of these seven in the field of pharmaceutical innovation and in their potential for international pharmaceutical trade.

However, there could be even better things in store. Advances in basic science are now beginning to provide leads to a better understanding of diseases such as early onset diabetes, rheumatoid arthritis, the virus infections (including the common cold), multiple sclerosis, Parkinson's disease and the cancers. In the field of mental illness there is the possibility that senile dementia, which affects 20 per cent of the very elderly, could be

prevented or controlled. If advances in the treatment of these diseases are achieved in the next twenty or thirty years, there is no doubt that the medicines involved will be developed and marketed by the pharmaceutical companies in the same seven countries. With a lead-time of perhaps twenty years between really fundamental research and a marketable product (half of which will be spent in the actual research and development of the specific medicine) no other country is likely to present a serious challenge to the seven before 2020. The economic potential from pharmaceutical innovation between now and then lies in the hands of industry and government in the seven countries.

Hopefully, France and Italy will become more successful, and support more fully the economic framework necessary for the continued development of the pharmaceutical industry. Hopefully, also, the other five nations will avoid steps which will damage their successful pharmaceutical industries. They must not give in to ill-informed critics who seemingly would like to see the pharmaceutical industry's progress held back.

For the rest of the developed world, the prospects on present trends are less favourable. Many countries may continue to pursue their disastrous cheap drug policies, and hence get no share of the world's pharmaceutical prosperity. Although this is an economically selfish and unwise policy for these other countries, it represents only an indirect threat to the seven. The latter represent three-quarters of the total world market, and this share is likely to increase as their future pharmaceutical research programmes yield even more successful innovations.

For its final words this Report takes a phrase from the great English philospher who first set out the principle of scientific method. Francis Bacon wrote nearly three centuries ago: 'Surely every medicine is an innovation and he that will not apply new medicine must expect new evils'.

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