COMMISSION OF THE EUROPEAN COMMUNITIES

studies

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- Trends in expenditure
- Main measures taken and underlying objectives of public intervention in this field

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C O N T E N T S

INTRODUCTION

This study has three purposes :

1. to analyse the trends in expenditure on pharmaceuticals in the countries of the Community;

2. to describe the main measures taken in the different countries which may have a direct or indirect influence on expenditure on pharmaceuticals;

3. to examine the underlying objectives of public intervention in this field and identify when different objectives lead to the same or conflicting policies.

The report brings together in Part I such information as could be obtained on trends in expenditure on pharmaceuticals over the period 1965-1975 and attempts to analyse how far changes in expenditure can be accounted for by changes in prices, by changes in volume and by changes in other variables. Part II is the description of the particular measures considered as liable to influence the trends identified above.

While comparisons are made between the trends in aggregate pharmaceutical consumption in the different countries, no attempt is made to compare the prices of individual products. A different type of study would have been needed to collect and analyse information of this kind.

While we have taken responsibility for the preparation of the report, the design of the study and the preparation of the questionnaire (printed in Annex[1]) were undertaken in collaboration with a committee of experts drawn from each country :

BELGIUM : M. J. COBBAUT
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Inspection des Pharmacies, Luxembourg

NETHERLANDS : M. H. DE LEEUW

U.K. : Prof. B. ABEL-SMITH
Department of Health and Social Security, London

The final report which we have drafted has been seen and approved by each member of the group.

Each expert took responsibility for completing the questionnaire for his own country. In addition this report has been greatly improved by amendments made at a series of meetings where drafts of the report were presented to the committee of experts.

B. ABEL-SMITH

P. GRANDJEAT

PART I

TRENDS IN PHARMACEUTICAL CONSUMPTION (1966-1975)

A. TRENDS IN PHARMACEUTICAL CONSUMPTION IN RELATION TO NATIONAL INCOME, GROSS NATIONAL PRODUCT AND THE COST OF HEALTH SERVICES

To what extent is the consumption of pharmaceuticals increasing in the different countries of the community ?
Has expenditure on pharmaceuticals been increasing to a greater or lesser extent than expenditure on all health services and than the gross national product or national income ?
Has expenditure on prescribed pharmaceuticals been increasing at a faster or slower rate than pharmaceuticals bought without prescription ?
How far is it possible to identify causes ?
For example, how far are the trends explained by changes in quantity or changes in price ?

These are among the questions examined in this chapter.

THE DEFINITION OF PHARMACEUTICAL CONSUMPTION

To calculate the total costs of pharmaceutical consumption, it is necessary to add together the sales of retail pharmacies of pharmaceutical products for human consumption and the cost falling on hospitals of supplying pharmaceuticals both to in-patients and out-patients. Strictly speaking, the cost to hospitals should include all the costs of the hospital pharmacy departments. If the full cost of dispensing pharmaceuticals in hospitals were excluded, the figures for different countries would not be comparable as the proportion of national pharmaceutical consumption supplied both to in-patients and out-patients by hospital pharmacy departments differs among the countries of the Community, as does the extent to which hospitals obtain their supplies from retail pharmacists.

Retail sales of pharmaceuticals for human consumption can be divided into those sold 'over the counter' without prescription and those sold on prescription. These two categories do not necessarily correspond to sales of the types of products which can be bought without prescription because health insurance schemes will pay for them or reimburse part of the cost. Moreover what can be bought without prescription varies in the different countries of the Community.

Only Luxembourg was able to provide statistics of pharmaceutical consumption (by health insurance) which closely conformed to this definition. In several countries, it was not possible to make a breakdown between expenditure on hospital pharmaceuticals and pharmaceuticals supplied out of hospital with and without a prescription. The limitations of the figures supplied by the different countries of the Community are set out below.

BELGIUM

The statistics available include only the cost of proprietary products and exclude products made by pharmacists. They do not necessarily include all use of proprietary products by hospitals and some products used for veterinary purposes are included. Made up preparations are believed to amount to about ten per cent of the cost of proprietary products. It is not moreover possible to make a division between pharmaceuticals provided by hospitals and those provided outside as the health insurance statistics do not cover all pharmaceutical consumption.

DENMARK

The figures include sales by pharmacies to other pharmacies. Among non-prescription drugs are included about five per cent of sales of pharmacies which go on other items (vitamins, nursing requisites and other items).

IRELAND

As no reliable statistics are available for pharmaceuticals supplied without a prescription and the only figures for prescribed drugs are confined to the population covered by the general medical service scheme and health insurance which had risen to about 85 per cent of the population by 1975, no figures are included in the tables.

FRANCE

The figures exclude the running costs of hospital pharmaceutical departments, but include the cost of the actual pharmaceuticals. Moreover expenditure on bandages dressing etc., is included and this is believed to constitute about five per cent of the total. Reliable information is not available on sales of pharmaceuticals without prescription and this has been estimated 20 % of total sales for patients other than in-patients. The total consumption of pharmaceuticals by in-patients in public and private hospitals has been estimated on the basis of the accounts of these hospitals.

GERMANY

The official statistics do not include any figures for total pharmaceutical consumption. While there are figures for the total sales of pharmacies, a variety of non-pharmaceutical products are sold by them. Estimates of sales of pharmaceutical products in other shops are far from reliable. There are, however, statistics of medicaments, therapeutic products and medical aids

from pharmacies in the compulsory health insurance statistics but no reliable information is available on products bought without a prescription. Information on pharmaceutical consumption in hospitals is available only from 1972 onwards, and it does not include the cost of hospital dispensing departments.

The estimates have been pieced together by attempting to reconcile such sources of information as are available. The trend figures need to be interpreted with particular caution as certain percentage relationships have been assumed to be constant over the period covered by the statistics. No attempt has been made to include the cost of hospital dispensaries.

ITALY

The figures for pharmaceutical consumption in hospitals include the cost of hospital pharmacists and their assistants but not other costs of hospital pharmaceutical departments. Hospital pharmacies are entitled to purchase proprietary products under the law at special discount prices which amounted to at least 50 % from 1974 onwards in the case of the vast majority of products. Similarly discounts are allowed on pharmaceuticals supplied under the health service outside hospital of 17 per cent up to August 1970 and 25 % thereafter. In the first case consumption is shown after discount and in the second case before discount.

LUXEMBOURG

As until 1977 all hospitals purchased their pharmaceutical supplies from retail pharmacists, it is not possible to identify separate consumption by hospitals.

NETHERLANDS

The figures cover only prescription drugs used outside hospital. Reliable figures for drugs used in hospitals or obtained without prescription are not available.

UNITED KINGDOM

The figures cover England and Wales and are for financial years. The figures for private expenditure outside hospital cover 'medicines, lotions, surgical goods, dressings and appliances' and are subject to a sampling error of roughly £ 10 million. The figures for the National Health Service non-hospital consumption include dressings and appliances which amount to about five per cent of the total expenditure. Pharmaceuticals in private hospitals are not included but this sector is very small. The figures for national health service hospitals exclude dressings and appliances, but do not include pharmaceutical department's staff costs and overheads. All private expenditure is classified as not on prescription though a small proportion was prescribed in private practice outside the National Health Service.

Thus the most important points to bear in mind in interpreting the figures are :

1. No figures are available for Ireland.

2. Only the figures for Luxembourg include the whole cost of hospital pharmaceutical departments, though those for Italy include the cost of hospital pharmacists and their assistants.

3. There are no estimates available for non-prescription drugs in the Netherlands. Percentage relationships have been used to estimate the trend of sales of non-prescription drugs for France and Germany. The figures for Denmark and the U.K. (England and Wales) contain some items other than pharmaceuticals.

4. The Belgium figures exclude preparations made up by pharmacists.

The figures for total consumption of pharmaceuticals can be shown including or excluding tax. The tax rate on pharmaceuticals has varied over the period covered by this study in the different countries of the Community. The rates as at 1966 and 1975 are given below. In the case of France and the United Kingdom higher rates of tax were at some time charged between these two years than the figures shown for either year.

	1966	1975
Belgium	6 %	6 %
Denmark	Nil	15 % (9 % from late September)
France	16.08 %	6.54 %
Ireland	Nil	Nil Taken by mouth
		10 % Injections
		20 % Antiseptics
Germany	Nil	11 %
Italy	5.2 %	5.65 %
Luxembourg	Nil	2 % Drugs
		5 % Dressings
Netherlands	0 % Prescription drugs	4 % Prescription drugs
	6 % Over the counter drugs	18 % Over the counter drugs (from 1.10.1976)
U.K.	Nil	8 % Except when supplied by a pharmacist against a doctor's or dentist's prescription.

The estimates of total pharmaceutical consumption including tax are shown in Table 1 as a percentage of gross national product.

There appear to be wide variations in the role of pharmaceutical consuption in the different countries of the Community.

TABLE 1

Estimates of total consumption of pharmaceuticals at current prices (including tax) - E E C 1966-1975

Millions of currency units

	Belgium(1)	Denmark	Germany	France	Italy(2)(3)	Luxembourg(2)	Netherlands (4)	United Kingdom (England and Wales only)
	BFR	DKR	DM	FR	LIT	LFR	HFL	UKL
1966	10 016	498	5 360	8 103	663 592	341	-	236
1967	10 659	582	-	9 082	742 349	380	-	253
1968	12 704	667	6 860	9 780	827 034	340	600	268
1969	14 358	758	-	11 547	890 209	484	-	295
1970	15 809	841	8 500	13 229	1 000 839	523	800	319
1971	17 468	958	-	14 969	1 140 099	592	-	356
1972	18 122	1 101	10 740	16 649	1 288 433	634	1 200	397
1973	22 188	1 157	-	18 444	1 573 282	701	1 300	445
1974	24 770	1 359	13 381	20 743	1 700 643	773	1 700	516
1975	28 152	1 539	14 570	24 618	2 108 500	861	1 900	650
							As percentages of Gross National Product	
1966	1.10	0.59	1.09	1.52	1.72	0.96	-	0.78
1967	1.09	0.63	-	1.58	1.77	1.06	-	0.79
1968	1.21	0.66	1.27	1.55	1.75	1.10	(0.63)	0.78
1969	1.24	0.66	-	1.60	1.71	1.07		0.81
1970	1.22	0.66	1.24	1.64	1.72	0.98	(0.70)	0.79
1971	1.23	0.68	-	1.67	1.80	1.09		0.78
1972	1.15	0.69	1.29	1.65	1.86	1.04	(0.82)	0.77
1973	1.24	0.64	-	1.61	1.91	0.95	(0.77)	0.74
1974	1.18	0.67	1.34	1.57	1.72	0.89	(0.82)	0.72
1975	1.21	0.68	1.40	1.70	1.89	1.03	(0.80)	0.75

(1) Excludes products made up by pharmacists.
(2) Including cost of hospital pharmaceutical departments in whole or part.
(3) Includes only registered medical products in the case of non-prescription medicines.
(4) Only drugs prescribed outside hospital.

In France and Italy, pharmaceutical consuption in 1975 was between 1.5 and 2 % of gross national product, and in Belgium and Germany it was between 1 and 1.5 % of gross national product and just over 1 % in Luxembourg. In Denmark and United Kingdom in the same year, pharmaceutical consuption amounted to 0.66 and 0.75 % of gross national product respectively.

Only in the United Kingdom (England and Wales) was total consuption of pharmaceuticals a slightly lower proportion of gross national product 1975 than in 1966. In Luxembourg no clear trend upward or downward can be seen in the relationship between pharmaceutical consumption and gross national product. In the other countries the figures show a slight if uneven trend towards an increasing proportion of gross national product being devoted to pharmaceutical consumption.

Total pharmaceutical consuption excluding tax is shown in Table 2 as a percentage of national income.

The results are similar to those for Table 1 except that there is no longer an upward trend in the case of France and there is less of an upward trend in the case of Belgium, Denmark and Germany. This was due to the introduction of Value Added Tax in 1968 in the case of Germany.

In Table 3 the estimates of total pharmaceutical consuption (including tax) are shown as a percentage of the estimates of the total current cost of health services (including tax).

The estimate of the current cost of health services used are those presented in the study of the cost of health care (1) and are subject to the important qualifications set out in that study. The most important identified reasons for non-comparability are the following :

1) The figures for Belgium include some capital costs and the figures for the other countries exclude them.

2) The figures for Luxembourg are for health insurance service only.

3) The cost of the depreciation of hospital buildings is included in the figures for France, the Netherlands and partly in those for Belgium, but not in those for the other countries.

4) The figures for Germany are based on imperfect semi-official estimates for the two years 1968 and 1972. The figures for the other years are estimated on the basis of trends in the expenditure of the health insurance schemes.

5) The figures for the Netherlands exclude non-prescription drugs and those for Italy include only registered medical products obtained without prescriptions.

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(1) B. ABEL-SMITH and A.MAYNARD : "The organization, financing and cost of health-care in the European Community".

TABLE 2

Estimates of total consumption of pharmaceuticals (excluding tax) as a percentage of National Income - E E C. 1966-1975

Percentages

	Belgium(1)	Denmark	Germany	France	Italy(2)(3)	Luxembourg(2)	Netherlands (4)	United Kingdom (England and Wales only)
1966	1.31	0.81	-	1.70	2.06	1.21		0.86
1967	1.31	0.82	-	1.75	2.13	1.35		0.87
1968	1.45	0.82	1.48	1.65	2.04	1.41	(0.79)	0.86
1969	1.47	0.80	-	1.70	1.99	1.38		0.89
1970	1.46	0.79	1.45	1.74	2.01	1.25	(0.82)	0.88
1971	1.47	0.82	-	1.77	2.10	1.40		0.87
1972	1.35	0.84	1.51	1.75	2.14	1.35	(0.97)	0.86
1973	1.44	0.77	-	1.75	2.19	1.23	(0.91)	0.80
1974	1.37	0.80	1.57	1.69	2.00	1.13	(0.92)	0.79
1975	1.41	0.84	1.65	1.70	2.15	1.31	(0.97)	0.82

(1) Excluding products made up by pharmacists.
(2) Including cost of hospital pharmaceutical departments in whole or part.
(3) Includes only registered products in the case of non-prescription medicines.
(4) Only drugs prescribed outside hospital.

TABLE 3

Estimates of total consumption of pharmaceuticals (including tax) as a percentage of estimates of the current cost of health services (including tax) - EEC 1966-1975

Percentages

	Belgium(1)	Denmark	Germany	France	Italy(2)(3)	United Kingdom (England and Wales only)
1966	-	15.7	22.8	29.7	53.9	18.0
1967	-	15.8	-	30.0	51.9	17.7
1968	-	15.3	24.1	30.3	52.1	17.6
1969	-	15.0	-	29.5	49.7	17.7
1970	-	14.3	23.9	29.8	44.6	17.1
1971	-	14.2	-	29.5	41.6	17.0
1972	-	13.8	21.3	28.8	39.8	16.9
1973	27.3	12.8	-	27.6	40.5	16.7
1974	23.8	12.1	18.8	26.6	30.2	14.9
1975	19.5	11.1	17.6	25.5	36.0	13.8

(1) Excludes products made up by pharmacists.
(2) Includes cost of hospital pharmaceutical departments in whole or part.
(3) Includes only registered products in the case of non-prescription medicines.

There are remarkably large variations in the role which pharmaceuticals play in total health expenditure in the different countries of the Community. The variations are too large to be wholly explained by the non-comparability of the figures both for pharmaceutical consumption and for the cost of health services. The figures for 1975 show a variation from about 11 % of the cost of health services in Denmark (1974) and about 14 % in the United Kingdom to around 25 % in France to 36 % in Italy. Some of the reasons for the variations are analysed later in this chapter.

In all countries in the Community for which figures are available, there is a clear downward trend in the proportion of total expenditure on health services devoted to pharmaceutical consumption. Over the period 1966 to 1975, the proportion dropped in Italy from nearly 54 % to 36 %. The figures for Belgium show a drop in percentage over the three years 1973 to 1975 from 27.3 % to 19.5 %. The fall in the percentages between 1966 and 1975 was less marked in France (29.7 % to 25.5 %), Germany (22.8 % to 17.6 %), the United Kingdom (from 18 % to 13.8 %) and Denmark (15.7 % to 11.1 %).

Few countries were able to divide pharmaceutical consumption with reasonable reliability into non-prescribed medicines, prescribed medicines in hospital and prescribed medicines given outside hospital. But all estimates given for non-prescribed medicines showed them as a declining share of the total pharmaceutical consumption. For example, the figures for the United Kingdom (excluding tax) indicate a decline from about 31 % of the total in 1966 to about 23 % in 1975. Similarly in Denmark the decline was from about 20 % in 1966 to 14 % in 1975. All the countries with reasonably reliable data showed a rising proportion of total pharmaceutical consumption in hospitals between 1966 and 1975.

In Table 4 total consumption of prescribed medicines (in or out of hospital) is shown as a proportion of the total cost of health services. The trend is downwards for all countries providing date.

TABLE 4

Estimates of total consumption of prescribed pharmaceuticals (including tax) as a percentage of estimates of the current cost of health services (1) (including tax) - E E C 1966-1975

Percentages

	Denmark	Germany	France	Italy(2)(3)	Luxembourg(2)	Netherlands(4)	United Kingdom (England and Wales only)
1966	12.6	14.3	24.3	51.1	39.2	-	12.4
1967	12.9	-	24.5	49.4	39.6	-	12.3
1968	12.8	15.6	24.8	49.7	39.8	-	12.0
1969	12.5	-	24.2	47.4	40.1	-	12.1
1970	12.0	16.0	24.3	42.6	34.7	(11.0)	11.8
1971	12.0	-	24.4	39.9	38.1	-	11.8
1972	11.8	14.9	23.8	37.8	36.6	(11.0)	12.0
1973	10.9	-	22.7	38.6	36.0	(10.6)	11.8
1974	10.4	13.9	21.8	28.9	34.2	(9.9)	10.9
1975	10.6	13.3	21.0	34.5	26.1	(9.7)	10.5

(1) Excludes products made up by pharmacists.
(2) Includes cost of hospital pharmaceutical departments in whole or part.
(3) Includes only registered products in the case of non-prescription medicines.
(4) Excludes drugs prescribed in hospital.

B. THE ANALYSIS OF TRENDS IN THE COST OF PHARMACEUTICAL CONSUMPTION

Pharmaceutical Consumption in constant prices

Special price indices for pharmaceuticals, based upon a 'basket' of a number of products, are maintained in seven countries in the Community. The products included in the index may be changed over the years. Such an index can only give an imperfect indication in the trend of pharmaceutical prices because of the substantial rate of innovation in the pharmaceutical industry. A new product may replace an older product as the most commonly used treatment for a particular condition. This new product may be launched at a substantially higher price than the product it is replacing. This 'replacement effect' is not fully reflected in price indices based on baskets of goods. Changes in volume are due to the combined effect of changes in both quantity and quality.

The seven indexes are briefly described below :

DENMARK

A retail index is available based on 105 products of which 72 were available only on prescription. New drugs are introduced into the index. The underlying weights were last changed in February 1969. The index is of final prices and includes VAT and the pharmacists' margin. For this reason the wholesale price index is used in this study.

GERMANY

The index is based on 33 made up products which were given 88 % of the weight of the index in 1970. The remaining 12 % of the index covered non-pharmaceutical products sold in pharmacies (e.g. cosmetics, dressings and disinfectants). New products have been introduced to the index as old products are no longer sold on the market.

IRELAND

The index is based on 85 items, six of which are available without prescription. New products are introduced to the index as they become extensively used and older products are discarded as their use drops.

FRANCE

The index is based on 400 products of which 300 are reimbursable by health insurance and 100 are products on sale to the public.

ITALY

The index is based on 31 proprietary products some of which were introduced during the ten-year period.

NETHERLANDS

The index included products which cover 80 % of the consumption of prescribed drugs. The index is weighted every year by the sales of each product included (chain weighted).

UNITED KINGDOM

The index is based on wholesale prices,excluding tax,of 200 closely defined pharmaceutical preparations weighted according to sales. The weights are periodically revised. It includes some non-prescription items.

In Table 5 the seven price indices are compared with the retail price indices for the same country.

In Germany and Denmark there has been little difference in the two indices. In the other five countries, the pharmaceutical price index has risen substantially less than the retail price index. The difference is particularly marked for France where pharmaceutical prices rose just over 18 per cent between 1966 and 1975 compared with a rise of nearly 84 per cent in retail prices.

As mentioned earlier, what indices constructed from a basket of products do not record is the replacement effect which is very important in pharmaceuticals and an important reason for rising costs. The quantitative effect of this can be seen by comparing the trend in the average cost of an item in a prescription with the trend in retail prices and the trend in the pharmaceutical price indices described above. In making this comparison it should be borne in mind that one possible reason for a change in the average cost of a prescription item may be a change in the amount prescribed. Comparisons of this kind can be made for three countries as shown below.

Percentage Increase 1966 to 1975

	Retail price index	Pharmaceutical price index	Prescription Item
France	183.7	118.3	164.5
Italy (1976)	233.2	154.2	180.9(1)
United Kingdom	222	161	257 (2)

(1) Under the INAM scheme.
(2) Ingredient cost in England & Wales.

In Table 6 total pharmaceutical expenditure excluding tax is shown in constant prices using the above pharmaceutical price indices even though they are not wholly appropriate for this application.

TABLE 5

Pharmaceutical and Retail Price Indices - E E C 1966-1975

	Germany		Ireland		France		Italy		Netherlands		United Kingdom (England & Wales only)		Denmark	
	R	P	R	P	R	P	R	P	R	P	R	P	R	P
1966	100	100	100		100	100	100	100	-	-	100	100	100	100
1967	100.5	101.0	103.2		102.7	100.1	102.0	100	-	-	102	99	110.8	112
1968	100.5	104.5	108.0	100	107.4	99.4	103.3	104.4	-	-	107	100	117.3	119
1969	101.9	106.6	116.1	101.6	114.3	103.4	106.2	104.4	100	100	113	98	120.3	125
1970	105.4	111.7	125.6	106.2	120.2	105.5	111.6	116.5	103.7	101	120	100	129.5	129
1971	110.6	117.3	136.8	111.7	126.0	105.2	117.2	116.5	111.6	106	132	104	136.2	139
1972	115.9	123.4	148.6	117.0	134.7	106.7	123.8	116.5	120.5	111	141	109	145.0	149
1973	123.3	128.7	165.6	119.8	144.5	106.0	136.6	117.7	130.3	114	154	112	158.5	153
1974	132.8	135.7	193.7	131.3	164.3	111.5	163.1	117.7	143.1	117	179	127	183.8	174
1975	141.1	142.5	234.1	158.9	183.7	118.3	191.2	134.3	157.3	127	222	161	201.9	192

R = Average Retail Price Index.
P = Pharmaceutical Price Index.

TABLE 6

Estimates of total pharmaceutical consumption (1) (excluding tax) at constant prices (2) - E E C 1966-1975

(millions of currency units)

	Denmark	Germany	France	Italy	Netherlands	United Kingdom (England and Wales only)
	DKR	DM	FF	LIT	HFL	UKL
1966	498	6 180.0	6 778.0	629 896		236.0
1967	520		7 591.4	704 854		255.6
1968	561	6 180.0	8 228.5	751 641		268.0
1969	606	-	9 048.6	809 196		301.0
1970	652	7 156.4	10 194.1	815 197	770	319.0
1971	643	-	11 570.0	928 141		342.3
1972	706	8 194.7	12 688.4	1 049 267	1 050	364.2
1973	723	-	14 504.9	1 262 125	1 100	382.1
1974	680	9 270.0	15 508.1	1 364 555	1 240	393.7
1975	700	9 628.4	17 344.9	1 482 445	1 300	391.9
1966	100		100	100		100
1967	104		112.0	111.9		108.3
1968	113	100	118.1	119.3		113.6
1969	122	-	133.5	128.5		127.5
1970	131	115.8	150.4	129.4	100	135.2
1971	129	-	170.7	147.4		145.0
1972	142	132.6	187.2	166.6	(136.5)	154.3
1973	145	-	213.9	200.4	(143.9)	161.9
1974	137	150.0	228.8	216.6	(162.0)	166.8
1975	141	155.8	255.9	235.3	(169.0)	166.1

(1) See notes to Tables 4-6.
(2) Using pharmaceutical Price Indexes.
(3) Only drugs prescribed outside hospital.

TABLE 7

Estimates of total pharmaceutical consumption (1) (excluding tax) per head of total population at current and constant (2) prices - E E C 1966-1975

	Denmark		Germany		France		Italy		Netherlands		United Kingdom (England and Wales only)	
	DKR		DM		FF		LIT		HFL		UKL	
	Current Prices	Constant Prices	Current Prices	Constant Prices	Current Prices	Constant Prices	Current Prices	Constant Prices	Current Prices	Constant Prices	Current Prices	Constant Prices
1966	104	104	-	-	138.2	138.2	12.0	12.0	-	-	4.96	4.96
1967	115	108	-	-	153.7	153.5	13.4	13.4	-	-	5.29	5.34
1968	124	115	103.9	103.9	161.8	160.6	14.8	14.2	(45.3)	-	5.58	5.58
1969	138	124	-	-	186.2	180.1	15.9	15.2	-	-	6.11	6.23
1970	150	132	126.0	117.8	212.3	201.1	17.7	15.2	(58.9)	(58.9)	6.59	6.59
1971	168	130	-	-	237.9	226.1	20.1	17.3	-	-	7.32	7.04
1972	192	141	156.9	132.9	262.3	245.7	22.5	19.3	(86.4)	(78.6)	8.14	7.47
1973	200	144	-	-	295.4	278.6	27.1	22.6	(92.9)	(82.2)	8.75	7.81
1974	234	135	194.2	149.5	329.9	295.7	29.0	24.6	(106.4)	(91.9)	10.21	8.04
1975	268	138	212.5	155.7	389.6	329.2	35.7	26.5	(119.1)	(94.7)	12.89	8.01
1966	100	100	-	-	100	100	100	100	-	-	100	100
1967	110	104	-	-	111.2	111.1	111.3	111.2	-	-	106.7	107.7
1968	119	111	100	100	117.1	116.2	123.2	117.9	(76.9)	-	112.5	112.5
1969	133	119	-	-	134.7	130.3	131.9	126.2	-	-	122.2	125.7
1970	145	127	121.3	113.4	153.6	145.5	147.2	126.2	(100)	(100)	132.9	132.9
1971	162	125	-	-	172.1	163.6	166.7	143.0	-	-	147.6	141.9
1972	184	136	151.0	127.9	189.8	177.8	186.6	160.0	(146.1)	(133.4)	164.1	150.6
1973	193	138	-	-	213.7	201.6	224.8	187.3	(157.7)	(139.6)	176.4	157.5
1974	225	130	186.9	143.9	238.7	214.0	240.8	204.4	(180.6)	(156.0)	205.8	162.1
1975	258	133	204.5	149.9	281.9	328.2	296.3	220.4	(202.2)	(160.8)	259.9	161.4

(1) See notes to Table 4-6.
(2) Using pharmaceutical Price Index.
(3) Only drugs prescribed outside hospital.

TABLE 8

Estimates of Expenditure per head of insured population on pharmaceutical consumption (1) at constant prices (2) (excluding tax) - E E C 1966-1975

	Denmark DKR	Germany DM	Italy LIT	United Kingdom (England and Wales only) UKL
1966	90.4	48.2	9.712	3.41
1967	89.5	53.6	10.877	3.72
1968	91.5	54.8	10.968	3.60
1969	97.2	61.7	10.775	3.89
1970	102.2	64.4	11.052	4.19
1971	106.3	70.6	12.419	4.45
1972	112.5	77.0	14.167	4.80
1973	126.5	85.2	16.087	5.15
1974	117.4	93.7	17.804	5.58
1975	121.0	101.3	19.465	5.83
1966	100	100	100	100
1967	99.0	111.3	112	109.1
1968	101.7	113.6	113	105.6
1969	107.5	128.1	111	114.1
1970	113.1	133.6	114	122.9
1971	117.6	146.4	128	130.5
1972	124.5	159.7	146	140.8
1973	139.7	176.7	174	150.7
1974	129.9	194.5	183	163.6
1975	133.9	210.1	200	171.0

(1) Outside hospital.
(2) Based on Pharmaceutical Price Index.

Between 1966 and 1975, total pharmaceutical consumption rose by about 80 % in Germany (58 % from 1968) and by 67 % in the United Kingdom (England and Wales) and only 41 % in Denmark. The growth in France and Italy was much greater at nearly 156 % and over 135 % respectively. In the case of the Netherlands expenditure on drugs prescribed out of hospital rose by 69 % between 1970 and 1975.

Estimates of pharmaceutical consumption (excluding tax) per head of population in constant and current prices are shown in Table 7. Real expenditure per head more than doubled over the period in both France and Italy. The growth was 61 % in England and Wales and only 33 % in Denmark.

In Table 8 is shown expenditure (excluding tax) per head at constant prices of the population covered by health insurance.

The Extension of Health Insurance

In some countries, the extension of the coverage of health insurance has been a factor leading to an increase in pharmaceutical expenditure over the period. The change is shown in Table 9.

TABLE 9

The Coverage of Health Insurance or Health Services in 1966 & 1975

(includes voluntary members of the main health insurance schemes)

(in % of total population)

	1966	1975
Belgium	75	85
Denmark	90-95	100
Germany	85.6	90
Ireland	39 (1)	85 (1)
France	93.6	98
Italy	85 (2)	94
Luxembourg	100	100
Netherlands	70	70 (3)
United Kingdom	100	100

(1) Coverage varies for different benefits. The figures quoted are for hospital care when coverage is highest.
(2) Only about 3/4 of the insured population were entitled to pharmaceutical benefits.
(3) By 1975 the whole population was covered for long-stay hospital care.

In Italy not only was there an increase in the numbers entitled to pharmaceutical benefits, but another cause of the rise in expenditure was the transfer in 1970 of 6.8 million persons from the reimbursement system to the direct payment system. This group thus added to the number of workers (33 million) already receiving direct benefits.

Variations in Pharmaceutical Consumption by Characteristics of the Population

The change in the demographic composition of the population has been one of the reasons for rising pharmaceutical consumption. There is evidence from a number of countries that consumption per head is substantially higher for the aged than for those below pension age. The proportion of aged has been increasing in all countries of the Community.

In Belgium pharmaceutical expenditure paid for by the health insurance scheme was over three-and-a-half times greater among the aged than among healthy adults of working age in 1975. The consumption rate of invalidity pensioners was similar to that of the aged. In Germany consumption of pharmaceuticals was also over three-and-a-half times greater under the pensioners health insurance scheme than under the general scheme. In England and Wales the difference in consumption between adults under pension age and those of pension age was much less marked - those of pension age cost less than twice the amount of adults under pension age.

In France a Credoc Survey (1) of the consumption of pharmaceuticals by narrow age groups conducted in 1970 showed that the lowest consumption of pharmaceuticals was found in the age group 10-19 where it was 40 % of the average. Consumption in the age group 0-3 was 34 % above the average and consumption rose steadily with age from those aged 10-19 to reach a peak in the age group 70-79 where consumption was 112 % above the average for all age groups.

The same study showed that the consumption of non-prescription drugs increased with the socio-cultural level of the population. In the case of prescribed drugs only small variations were found with socio-professional category, household income and level of educational attainment of the head of household. A markedly lower use of pharmaceuticals was found among farmers and farm workers. A marked variation by family size was also found - the larger the family the smaller the consumption per family member. Moreover the larger the extent of private insurance, the greater the utilisation of prescribed drugs.

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(1) A. A. Mizrahi and S. Sandier, 'Demographical Factors and the Growth of Pharmaceutical Consumption'. Consumption N°1 1974.

Changes in charges or proportion of cost not reimbursed

Also relevant has been the extent to which charges are levied for pharmaceuticals under health insurance schemes. Here there is a wide variation in the different countries of the Community and arrangements have been changed during the period studied here. The systems of charging are described in IIc.

The Consultation Rate and the Prescribing Rate per Consultation

One possible explanation for the very wide differences in the role of pharmaceutical expenditure in total health expenditure among the different countries of the Community may be variations in the extent to which patients consult their doctors and the extent to which consultations result in a prescription of one or more items.

Only a tantalisingly limited amount of information was available on these questions. In Belgium visits and consultations rose from 5.3 to 6.3 per annum per insured person between 1966 and 1975. Under the general INAM scheme in Italy visits per insured person by doctors paid on a fee-for-service basis (who provided services to about a third of those insured under the scheme) rose from 9.2 per annum in 1966 to neraly 11.5 in 1975. In England there are no comprehensive statistics but a national survey suggests a consultation rate of about three-and-a-half per person per year. In Germany the consultation rate was estimated for 1976 as 12 per person per year.

In Eire over 80 % of consultations under the General Medical Service Scheme result in a prescription. Under the 'Régime Général' in France 75 % of consultations resulted in a prescription in 1972.

The average number of prescription items provided per person per year is shown in Table 10.

TABLE 10

Prescription items per person per year

	1966	1970	1973	1974	1975	1976
Belgium	9	-	-	-	9	-
Denmark	-	6.2	-	-	-	6.9
Germany	-	-	11	-	-	-
Ireland (1)	9	-	-	-	10	-
France	-	-	-	-	10.50	-
Italy (2)	13	-	-	-	21	-
Netherlands	-	-	-	4.5	-	-
United Kingdom (England and Wales)	5.7	-	-	-	6.3	-

(1) Under General Medical Service Scheme.
(2) For doctors paid on fee-for-service basis under INAM.

The latest figure for each country is shown in Table 11 with the percentage of the estimated cost of health services devoted to pharmaceutical consumtion from Table 3.

TABLE 11

Doctors per 10.000 population, average prescription items per person per year, and pharmaceutical consumption as a proportion of the cost of health services.

	Doctors per 10,000 population (1) (1975)	Prescription Items Per Person per year under Health Insurance or the Health Service (1975)	Pharmaceutical Consumption as a Percentage of Cost of Health Services (1975)
Netherlands	16.0	4.5 (1974)	9.5 (2)
United Kingdom (England and Wales)	13.1	6.3	13.8
Denmark	16.2(1972)	6.9 (1976)	11.7 (1974)
Belgium (3)	18.9	9	19.5
France (3)	14.7	10.5	25.5
Germany	19.4(1974)	11 (1973)	18.8 (1974)
Italy (3)	19.9(1973)	21 (4)	34.6

(1) Sources - WHO, Annual Statistical Summaries 1965 and 1977.
(2) Only covers prescription drugs outside hospital.
(3) Including doctors practicing dentistry of specialists in odontology.
(4) For doctors paid on fee-for-service basis under INAM.

The very large variations in the average number of prescription items per person per year appear to go a considerable way towards explaining the wide differences in the role of pharmaceutical consumption in the cost of health services in the different countries of the Community. It would be of considerable interest to see how far the differences in the number of prescription items are due to differences in morbidity or differences in the extent to which doctors use pharmaceuticals for particular conditions. There does not appear to be a relationship between the number of doctors per 10,000 population and the rate of prescribing. It is however noticeable that in the three countries with the lowest average number of prescription items per year general practitioners were not paid on a fee-for-service basis under the compulsory health insurance of health service scheme, while in all the countraies with a high average number of prescription items doctors were paid on a fee-for-service basis. This finding warrants further examination. For example, it would be necessary to see how far variations in items prescribed in different countries are affected by what is covered by different health insurance (or service) systems, by the size of available packages, by restrictions on the duration of prescriptions and by the extent to which mixtures of products are available (for example two prescription items may be needed in one country to provide what can be provided in one prescription item in another).

Reasons for the Increase in Cost

The reasons which may explain the changes in cost can be summarised as follows :

i. Increase in the population.

ii. Increase in the coverage of Health Insurance and also, in the case of Italy, a transfer of a section of the population from reimbursed benefit to direct service benefits.

iii. The changing age structure of the population.

iv. Changes in the cost of production and distribution.

v. The replacement of older drugs by more expensive new drugs and their acceptance in social security (in those countries where social security controls what may be accepted).

vi. Changes in the consultation rate.

vii. Changes in the prescription rate per consultation.

viii. Changes in the patterns of disease.

ix. Changes in therapeutics.

x. Increasing sales pressure on doctors by the pharmaceutical industry.

xi. Growing public education, changing attitudes to illness and belief in the therapeutic value of pharmaceuticals which are expected, if not demanded.

In a number of countries attempts have been made to analyse in quantitative form the causes of the increase.

In Luxembourg it is calculated that about 40 % of the increase is due to higher prices including the replacement of old products by new products and about 60 % due to the number of items prescribed.

In Italy the increase in cost is analysed as follows :

Increase in number of prescriptions	31.78 %
Increase in average cost per prescription	32.69 %
Increase in population	3.02 %
Interaction of the above	32.51 %
	100.00 %

In France an analysis for the period 1970 to 1975 in terms of annual growth rates gives the following results :

Expenditure	12.7 %
Population	0.8 %
General Price Index	8.8 %

Expenditure per person at relative prices	2.8 %
Number of consultations	2.9 %
Number of prescriptions per consultation	0 %
Average relative price per package	- 3.0 %

Thus in France the change in the number of consultations played a considerable role over that period.

An analysis for England and Wales produced the following results for the period 1966 to 1975 assuming that each factor operated in isolation :

Rise in total population	+ 3 %
Age structure of the population	+ 2 %
Rise in number of prescription items per person (adjusted for changing age structure)	+ 11 %
Rise in pharmaceutical price index	+ 61 %
Rise in the average cost per prescription (adjusted for the price index and changing age structure of the population)	+ 60 %

The combined effect of the above is to multiply the cost by three. The actual increase in the cost of ingredients was from £ 96 million in 1966 to £ 286 million in 1975 - very nearly a threefold increase in cost.

Forecast

A forecast has been made for France of future pharmaceutical consumption. The forecast is based on the analysis of trends which show :

i. The average number of products prescribed per contact with à doctor (visit or consultation) has been rising by about 1 1/2 % per annum.

ii. There is a greater consumption of drugs the larger the number of visits to patients in their homes.

iii. Specialists and doctors working in hospitals prescribe less than GPs.

The forecasts show that the total volume of pharmaceutical consumption will increase from 9 to 11 % per annum between 1973 and 1980 but the number of items prescribed per consultation will increase at the rate of 5 to 6 % per annum because of a decrease in the number of drugs prescribed per contact with a doctor due to a higher proportion of contacts with specialists rather than GPs. Taking account of the lowering of VAT on drugs, the relative value of drug consumption will increase by between 1.4 % and 2.9 % between 1975 and 1980 which is noticeably less rapid than in the previous period (4.5 % per annum).

A forecast has also been made for England and Wales of the cost of pharmaceuticals obtained with a prescription under the National Health Service. The forecast is based on past trends and indicates a rise in constant prices from £ 420 million in 1976 to £ 523 million in 1980 - an increase of nearly 27 % over this five-year period.

C. FOREIGN TRADE IN PHARMACEUTICALS AND RAW MATERIALS

Three tables (12, 13 and 14) have been drawn up and will be analysed below. First, however, some preliminary remarks are necessary.

The first is that the percentages given - and the trends emerging from them - must be viewed with care and caution. They are rough indicators which are not, in all cases, based on homogeneous data. Thus, production, imports and exports are calculated at different prices (FOB or CIF, for example). Secondly, it has been difficult to break the figures on "pharmaceutical products" down into products for human consumption and other products. Germany, Belgium, Ireland and the United Kingdom explained the reasons for this, but no such information was offered in the confirmation obtained for the Netherlands and Italy.

In Ireland and Denmark the percentages of veterinary products in the total of products consumed are, respectively, according to estimates, 1.8 % and 4.7 %.

Only the French reply gives these percentages at three levels :

Production : 3.70
Exports : 6.90
Imports : 1.00

The third remark concerns Luxembourg, which no longer has a domestic pharmaceutical industry.

TABLE 12

Exports and imports as percentages of national production (NP)

	Year	NP	Exports/NP	Imports/Np	National consumption as percentage of NP
Germany	1974	100	35.22	15.23	80.00
Luxembourg		None			
Belgium	1975	100	43.25	50.41	107.03
France	1975	100	21.84	15.60	93.80
Ireland	1973	100	40.21	32.96	92.70
United Kingdom	1975	100	42.23	13.19	70.82
Netherlands (1)	1973	100	62.60	48.27	84.41
Denmark	1975	100	59.71	34.78	75.08
Italy	1975	100	20.60	19.80	99.20

(1) These figures relate only to pharmaceutical products and not to raw materials.

In all the countries under consideration, except Luxembourg, the pharmaceutical sector - finished products and raw materials - is a sector open to foreign trade, since a fair and sometimes considerable portion is always accounted for by imports and exports. Furthermore, the third column shows the significance of the home market in each country which thus appears to parallel foreign trade.

TABLE 13

Trade with EEC countries as percentage of total trade

	Exports to EEC/ total exports	Imports from EEC/ total imports
Germany	34.44	51.21
Luxembourg	-	90.00
Belgium	62.84	68.52
France	17.55	3.90
Ireland	51.58	84.80
United Kingdom	27.10	49.57
Netherlands	not given	not given
Denmark	29.60	55.00
Italy	30.90	62.70

The percentages refer to the same years as those in table 12.

The volume of trade in pharmaceuticals within the EEC is quite considerable, as will be observed. However, it is hard to attribute this to a single factor. Compliance with EEC Directives by the various countries and the adoption of similar health criteria (safety for use and efficacy) seem to be as important as, if not more important than any specific legislation or customs regulations - as will be seen later under X(A), A*. It is unlikely that any country in the EEC would deny itself the use of a drug of known therapeutic value because of its country of origin.

It might be asked whether the relatively low share of French and British exports consigned to other EEC countries is not a result of the substantial importance of these States' exports to countries previously under their political control. It would, on the other hand, be wrong to ignore the fact that in certain European countries (for example the United Kingdom and Ireland) the exporters are subsidiaries of American companies or are using their patents.

*See Annex.

It would have been desirable to have available information on the respective shares of raw materials and finished products in imports and exports, which would have given an indication as to the value added in each country and the exact nature of the production process. However, all the experts thought the data available to be too fragmentary and untrustworthy for any conclusion to be drawn, at least in a comparative sense. It was, therefore, unanimously agreed not to reproduce them in this summary report.

Finally, in their reports the national experts were asked to indicate, as far as possible, trends in the figures for trade during the past ten years. Only seven countries were able to produce reliable statistics, and the period covered was not always identical; in no case was it greater than five years. The following table sets out the replies.

TABLE 14

	National production	Exports	Imports
Germany (70-74)	+ 58.56 %	+ 58.46 %	+ 75.02 %
Belgium (70-75)	+ 117.35 %	+ 178.04 %	+ 85.50 %
Denmark (70-76)	+ 108.00 %	+ 102.00 %	+ 102.00 %
Italy (70-75)	+ 98.62 %	+ 156.49 %	+ 152.80 %
Netherlands (71-73)	-	+ 34.00 %	+ 34.00 %
France (70-75)	+ 85.66 %	+ 97.58 %	+ 61.79 %
Ireland (70-73)	+ 120.10 %	+ 141.65 %	+ 61.49 %

It is impossible to make any comparisons between countries based on this table. The figures have been expressed at current and not constant prices, i.e. they are inflated by the price rises for drugs during the period.

Thus, it is not surprising to see that these figures for the increase in national production during the review period are higher in France and Italy, where inflation was high, than in Germany and Denmark, where price increases were very limited. It is interesting to note that exports from all the countries, except Germany, increased as much as or more than national production; this fact must be borne in mind when considering whether a price restraint policy has the effect of limiting the pharmaceutical industry's capacity to export. It will be seen later that both France and Italy practice a price restraint policy : despite this, their exports of pharmaceutical products have not been at a disadvantage.

It might also be asked to what extent this increase in trade may result from the partial internationalization of production, with the firms in each country specializing in one of the major categories of pharmaceutical product.

PART II

THE POLICIES

Definition

Pharmaceutical products available in the market can be divided into two categories :

(a) proprietary medicinal products : according to the EEC definition these are medicines prepared in advance, marketed under a special name and packaged in a special presentation;

(b) generic products : these are also medicines prepared in advance and packaged in a special presentation but with no special name, thus differentiating them from the proprietary products.

In both cases the pharmaceutical is characterized by the same composition of active components,but may appear in different pharmaceutical forms (tablets, suppositories, injectable aqueous solutions, etc.).

It is very difficult to ascertain the precise number of medicaments available, especially within the generic category. In the case of proprietary medicinal products, this is easier to establish and the table below, relating to 1974-1975, has been drawn up.

Country	Registered names	Pharmaceutical forms
Germany	-	26 000
Belgium	-	7 300
Denmark	1 698	3 400
France	4 500	11 000
Ireland	5 000	12 000
Italy	8 932	16 150
Luxembourg	5 742	8 654
Netherlands	3 475	-
United Kingdom	-	29 741 (1)

(1) Including 10 439 in the generic category.

A. THE ORGANIZATION OF THE PHARMACEUTICAL MARKET BY THE RELEVANT AUTHORITIES

1. Introduction onto the market

In all countries of the Community there are laws governing the marketing of proprietary pharmaceuticals. Decisions on whether such a product may be marketed are taken in Denmark by the Registration Board responsible to the National Board of Health. In the Netherlands the "College for the judgment of branded or packed pharmaceuticals" is legally charged with this responsibility. In the other countries of the Community it is the Minister responsible for Health who licenses drugs usually acting on the advice of an expert committee.

The criteria applied are quality, safety and efficacy for stated uses. In Denmark, Belgium, Germany and France, licences are given for five years, but can be renewed and usually are renewed without a review. In the other countries, licences continue unless they are revoked. In Denmark, the Law of 1954 applied only to "new chemical substances" but was amended in 1976 to apply to all products. Old (pre-1954) products are currently being reviewed. Similarly, in France the Law of 1967 applies to all products, though the licensing procedure is occasionally simplified for old products. In the other countries of the Community all old products were given licences on request when the Law was introduced. The Law to license the sale of drugs in Italy was consolidated in 1934 and a series of circulars between 1963 and 1973 strengthened the criteria which were applied. In the Netherlands the operative Law dates from 1958. In Belgium the system of authorization was introduced in 1962 and confirmed by a Law of 1964. The German Law was passed in 1971 and amended in 1978. In Luxembourg the Law was passed in May 1956.

In the United Kingdom the Law was passed in 1968 and came into effect in 1971, but it was preceded by a Committee on the Safety of Medicines established by agreement with the pharmaceutical industry from 1964 to review the evidence on new drugs and offer advice on their toxicity. The pharmaceutical industry agreed to submit data on new drugs and accept the committee's advice. In Eire the Law dates from 1974 but was preceded by an agreement with the pharmaceutical industry similar to that in the United Kingdom dating from 1966. Products are reviewed by the National Drugs Advisory Board.

Article 39 of EEC Directive 75/319 requires Member States to review old products within fifteen years from the date of the Directive and make them conform to Community requirements. In Ireland and the United Kingdom, it is hoped to complete the review by 1983.

In 1976 the main Community Directives on pharmaceuticals could be summarized as follows :

Directive 65/65/EEC

This Directive, which relates to proprietary medicinal products :

(i) requires products to be authorized by a competent authority of a Member State before they are marketed;

(ii) lays down the requirements to be satisfied for each product authorized;

(iii) establishes the conditions for suspension and revocation;

(iv) lays down requirements for the labelling of products.

From November 1976, the following Community Directives relating to proprietary medicinal products came into force :

Directive 75/319/EEC

This Directives, which aims to facilitate authorizations to market products in more than one Member State :

(i) establishes a Committee for Proprietary Products to give opinions on whether particular products comply with the requirements of Directive 65/65/EEC;

(ii) lays down procedures to be followed for a product to be authorized for marketing in more than one country;

(iii) requires manufacturers and importers of products to be subject to authorizations and requires such manufacturers and importers to have at their disposal qualified persons with responsibilities to secure and certify that products manufactured or imported meet the quality standards required.

Directive 75/318/EEC

This Directive lays down uniform rules for tests and trials, the compilation of dossiers and the examination of applications for authorizations to market products.

2. Economic Controls

a) Production

The first question was not whether pharmacists had a monopoly in the ownership of pharmaceutical firms, but concerned the control and manufacture of pharmaceuticals. In other words, is a pharmacist required to be responsible for the operations in pharmaceutical production and supervise it from a technical point of view ?

Only Denmark and Ireland reply firmly in the negative; in Germany the negative response was qualified by the information that persons with appropriate university qualifications in other fields are allowed to manage pharmaceutical production. In the Netherlands, where similarly no monopoly exists, the Government requires overall production responsibility to be in the hands of a pharmacist; he can, however, be replaced by a specialized chemist with the approval of the committee. In Italy technical management of pharmaceutical production may be in the hands of pharmacists, graduate chemists, or graduates in chemistry and pharmaceutical technology.

On the other hand, the law requires the presence of a pharmacist in pharmaceutical laboratories in Belgium, Luxembourg and France. In France the law requires that all pharmaceutical undertakings must either be owned by a pharmacist or have a pharmacist on the management board or board of directors (in the case of a company). In both cases the pharmacist is personally responsible for the application of regulations made in the interest of public health; in the case of companies, this is without prejudice to the joint liability of the company.

It appears clearly from the replies that monopoly is rare, and even though the presence of a pharmacist is often required, this is for reasons connected with public health rather than economics.

Since November 1976, the problem has been regulated by Article 21 of Directive 75/319/EEC. According to the Directive pharmaceutical products must be produced under the supervision of a qualified person whose training meets the conditions prescribed in Article 23 of the aforementioned Directive.

It follows that a country can lay down that, on its territory, this person must be a pharmacist where the university studies pursued by such a person meet the conditions prescribed in the aforementioned Directive, but the same country cannot refuse the import of pharmaceutical specialities from countries within the Community where their manufacture and control have been supervised by a non-pharmacist whose studies had likewise met the conditions prescribed in Article 23 of the Directive.

On obstacles to investments by firms with headquarters located outside the EEC the answer from all countries was No. Some countries (Germany, Italy, Ireland) added that such operations must comply with general regulations on the sale or establishment of businesses laid down by national legislation, but this is of course a principle which would be respected everywhere. In Ireland, far from raising obstacles, the authorities actively encourage foreign investment in their country; this applies to the manufacture of pharmaceuticals in the same way as to any other form of enterprise.

b) Imports

In all the countries the same procedure is followed for marketing products of foreign origin as for domestic products. In Germany a licence granted in another country may be recognised as equivalent to a German licence. This

however is only a possibility and not automatically the case; the licence granted in another country will be recognised in Germany only when the controls carried out in the exporting country are similar to those practised in Germany.

France is a special case, in that the conditions imposed for marketing authorization are so strict that they amount to a virtual ban on foreign imports of pharmaceuticals. The latter accounts for only 1 % of the market, are authorised item by item, and are distributed in France solely through the central pharmacy of the Assistance Publique (a legal entity embracing most of the public hospitals in the Paris region). However, imports are expected to expand in the coming years.

For authorised imports the later controls are carried out in conformity with Article 22 of Directive 75/319/EEC.

There are two possibilities :

- importation from another EEC country : each consignment must be accompanied by a certificate of conformity prepared by a qualified person employed by the manufacturer;

- importation from a third country : each consignment imported is subject to full qualitative and quantitative analysis of either the main constituant or constituants, and this must be undertaken by a person recognised as qualified by the legislation of one of the EEC countries.

c) Distribution of products for human application

1. Monopolies

A distinction must be made between monopoly in the ownership of pharmacies and monopoly of the sale, retail or wholesale, of pharmaceuticals.

As far as ownership is concerned, a monopoly exists in three countries only : Luxembourg, Denmark and Germany. Another distinction must be made in the case of Luxembourg; there, pharmacists have a monopoly in pharmacies set up before 1905. Since then, the State has been the titular owner, with the pharmacist merely owning the stock-in-trade and fixtures and fittings.

Although there is no absolute monopoly in France, the great majority of dispensing pharmacies belong to pharmacists, except for those attached to public and private institutions where patients are treated, health insurance funds and the miners' social security fund. No monopoly exists in Ireland or the United Kingdom, but wholesale business can be carried out only by a licenced wholesaler whose facilities and standards are regularly checked by the Department of Health. In Belgium there is no legislation on the ownership of dispensing pharmacies. In Italy, although the great majority of pharmacies do belong to pharmacists (92.50 % in 1975), they do not have a monopoly. Under the law of 8 March 1968, companies are no longer permitted to own a dispensing pharmacy, but public assistance and welfare institutions and cooperatives complying with legislation laid down are still allowed to do so.

The same law authorised the establishment of new communal pharmacies, municipal pharmaceutical undertakings (5.5 %) and hospital "dispensaries" open to the public (1.5 %), which together represent 50 % of all new pharmacies.

As far as the sale of medicines is concerned, certain distinctions must be made. In all countries, only dispensing pharmacies can supply products available only on medical prescription.

For other products, which can be purchased without prescription, the situation varies.

Monopoly of ownership is accompanied in Luxembourg and Denmark by monopoly of sales. The same applies in Germany, except that a few products may be sold other than in pharmacies : "medicines included exclusively for purposes other than the elimination or alleviation of illnesses, pains, bodily injuries or pains arising from illnesses" (Article 44 AMG new version). There is full monopoly regarding the sale of medicines in Italy, France and Belgium, although there is no monopoly of ownership. In all three countries there has to be a pharmacist on the premises, whether the owner or an employee, although an exception is made in Italy for pharmacies set up by decision of the provincial medical officer in zones where no pharmacy existed. These "dispensaries" keep stocks of basic medicine and first-aid material, but usually come under the responsibility of the owner of the nearest pharmacy; when this is not possible the commune, through the local medical officer or another member of the medical profession, acts as manager.

In the same way, a few doctors in France known as "propharmaciens" are allowed to deliver medicines in remote areas far from a pharmacy.

Belgium makes the same concession. In some small hospitals a person other than a pharmacist is allowed to deliver drugs from the hospital supply. In Denmark patients can buy medecines not only from one of the 323 pharmacies belonging to pharmacists but also from other sales points (which are numerous) where the presence of a pharmacist is not compulsory but these sales points are placed under the regional pharmacist. On the other hand, there is no monopoly on sales in the United Kingdom, Ireland and the Netherlands. For example, in the United Kingdom, doctors and dentists can sell or supply medicines, e.g., in rural areas; the same applies to ordinary shops, which can sell certain simple drugs for human or animal application. In Ireland, doctors are not allowed to sell pharmaceutical products but simple drugs such as analgesics may be sold in supermarkets.

The absence of a monopoly does not imply that other sales outlets can sell all pharmaceutical products freely. For drugs which must be sold only under prescription, the presence of a pharmacist is always essential. For off-prescription drugs, where there is no pharmacist, free sale is usually restricted to relatively simple or paramedical products, as in Germany.

A related question was whether pharmacies were allowed to sell products other than medicines, and if so, whether their freedom to do so was total or limited.

An affirmative answer was received from all countries. Many examples were cited : they ranged from articles of hygiene to cosmetics, from thermometers to bandages and plasters, from baby foods to health foods.

This type of sale seems to be quite free from restrictions, except in four cases. In Germany, legislation determines the conditions of sale for products other than medicines (section 12 Apothekenbetriebsordnung). In Italy, pharmacies must have a licence from the commune and be registered at the Chamber of Commerce to sell products other than medicines. This applies to health products for babies or elderly people, as well as to products appearing on a list drawn up in agreement with the trades and professions concerned, under the patronage of the Ministry for Industry and Commerce.

In France, pharmacists can sell only merchandise appearing on a list established by the Minister for Public Health on the recommendation of the national council of the Order of Pharmacists. In Belgium, it is forbidden to sell other items but law allows the sale of accessories, hygienic products and certain dietary foodstuffs.

To give an idea, the French report estimates that these sales of non-pharmaceutical and non-proprietary products account for 14 % of the turnover in pharmacists' shops. In Belgium this percentage is between 4 % and 5 %.

2. Conditions of establishment

The first question was whether there is any control over the number of retail pharmacies and, if so, what criteria are used.

Only the United Kingdom and Ireland have no limit of any kind. Whilst in Germany there is no limit on the number of pharmacies, no licenced pharmacist may own more than one. In the Netherlands there is no legally-imposed limit, but the profession makes its own restrictions : a committee of the Association of Pharmacists regulates the setting-up of pharmacies and in the big towns, this practically amounts to a limit on the ratio.

In all the other countries the number of pharmacies is restricted either by legislation or regulations. The criteria vary, but are essentially based on the population needing to be served, with proportionally fewer pharmacies per segment of the population in the larger towns. Geographical factors may also be involved; distances to be covered, and distances between neighbouring pharmacies, both come into the picture.

Italian regulations on this matter seem to be more "interventionist" than others, the pharmacy being virtually regarded as a public service and benefiting from certain concessions. Provision is made for every commune to keep an up-to-date record, revised every two years, showing the number and location of all pharmacies, the radius which they serve and the zone.

In fact, the ratio between the number of pharmacies and the population served varies considerably. The table below gives the number of stockists per million inhabitants, excluding hospital pharmacies. The ratios obtained vary by a factor of almost 1:8, with Denmark and the Netherlands at one extreme and Belgium at the other, whilst the policy of limiting the number of outlets seems to make little difference, since Ireland and the United Kingdom, in neither of which a limit is imposed, are at widely varying points on the scale.

Denmark	65
Netherlands	66
Luxembourg	191
United Kingdom	200
Germany	220
Italy	243
France	356
Ireland	380
Belgium	527

These figures are averages, and the ratio may vary widely within the same country. This is particularly noticeable in Italy, where the authorities have tried to encourage the setting up of pharmacies in rural and mountainous areas, where per capita income is low and there is not enough incentive to private enterprise. When this happens, the authorities either directly encourage the creation of communal or hospital "dispensaries" or act indirectly in granting subsidies to private pharmacies. Under the present law 50 % of all new pharmacies must be opened by the communes and hospitals.

As far as the opening of non profit-making pharmacies is concerned (hospitals, dispensaries, pharmacies operated by provident funds or the social security authorities), regulations vary from one country to another.

There are no pharmacies run by insurance funds or cooperatives in Luxembourg. In France they can be authorized only by the Minister of Public Health. This amounts in practice to a ban, since no Minister of Public Health has permitted the setting up of a pharmacy of this kind for 30 years. The situation in Italy was frozen in 1968 as regards public assistance and welfare institutions as well as cooperatives : these bodies can continue to run any "dispensaries" which existed when the law was passed, but cannot transfer, set up, or acquire any new ones.

In Germany the authorized health insurance funds are not entitled to set up their own pharmacies. There are two obstacles, one legal and one financial, to the setting up of hospital "dispensaries"; in small hospitals they would not be profitable, whilst the law forbids several hospitals to run a joint pharmacy unless they are owned by the same body.

In Belgium and Ireland, non profit-making organizations and private individuals are treated in the same way when opening a new pharmacy. There is no discrimination. The same is true in the United Kingdom in so far as there is no limitation on the number of pharmacies.

3. Conditions for the acquisition of pharmacies

There are no special regulations governing the transfer of businesses in Ireland, the United Kingdom or Germany.

Such transactions may also be carried out quite freely in Belgium, except as regards one consideration : the maximum price for pharmacist's shops open to the public is set at 150 % of the gross annual profit, averaged out over the preceding five years.

In Luxembourg, as already mentioned, the law makes a distinction between pharmacies opened before 1905 and others. In the former case the business may be transferred; in the latter it cannot, since it belongs to the State.

In France a pharmacy may be acquired in any manner involving valuable consideration (purchase, exchange) or otherwise (gift, legacy, inheritance). The new proprietor does not have to apply for a new licence. He retains the licence issued to the pharmacy when it was first registered or when it was opened. However, the new proprietor must comply with the general rule relating to the acquisition of pharmacies : prior declaration to the prefecture where it is to be registered. Application for registration, made on unstamped paper, is appended to a dossier containing the relevant supporting documents required by the Code of Public Health.

Freedom of transfer is the most restricted in Italy. Communes and hospitals are not allowed to acquire a pharmacy, but may have one allotted to them which has become vacant or was newly created for the purpose. Individual pharmacists can acquire a business only after succeeding in a provincial competition, where both their qualifications and their examination results are considered. The same procedure takes place when a business is ceded through the death of its owner; pharmacies cannot be inherited, even when the heir is qualified. In addition, a pharmacist can sell or otherwise transfer his business only after five years and cannot enter the competition for a new pharmacy for at least ten years from the date of transfer of the old one; however, he is offered one opportunity of acquiring a second pharmacy in the year following the transfer without having to resit the examination (under the law governing trade and commercial activities).

B. PRICING POLICY

1. Production

a) The control of prices

In only two countries, the Netherlands and Germany, do manufacturers appear to have complete freedom in fixing their prices.

In the Netherlands the market and competition offer the only form of restraint. The Dutch report indicates that this pressure has been enough to keep prices at a reasonable level, and in some cases to bring them down.

In Germany the pharmaceutical industry is subject to scrutiny by the antitrust authorities, as it is in every country. The Federal trust office can force a price reduction for a certain product if it can be proved that a dominant position in the market is being exploited (Article 22 of the law against the prevention of unfair competition).

Ireland and Denmark occupy an intermediate position on this question. In Ireland there is no regulation of the prices set by the industry for new products. On the other hand there is a control on raising prices of products already on the market. Authorization for a price rise has to be given by the Ministry of Industry and Commerce's "Price Commission". It is granted only in cases where production or distribution costs have increased.

In Denmark, from 1954 to 1975, the Minister of Health had the right to determine the price of specific drugs. In practice, the right was hardly ever exercised, and registration of drugs proceeded solely on the basis of health considerations.

The "Medicines Act" of 1975 was intended, when it came into force on 1 January 1976, to operate a real price control system. The task was given to the monopolies office (Monopolies Commission Agency or MCA), which was charged with applying the same regulations which were in force for other sectors of industry to the pharmaceutical industry. But owing to the particular position of the pharmaceutical industry, the MCA was requested by Parliament to prepare a special report on the type of control to be used in this sector, for 1 January 1978. In the meantime, the MCA tried to find ways of imposing the general price control regulations - which attempt to sanction any prices considered not "reasonable" - on the pharmaceutical industry. It had little success. In the spring of 1976, the MCA demanded a reduction of 20 % in the price of tranquillizers. In May 1977, the Monopolies Tribunal reversed this decision, on an appeal by the industry.

The most original formula seems to be that implemented in the United Kingdom. Laws exist under which prices could be controlled but in practice they are controlled by the provisions made on agreements. The British Association of the Pharmaceutical Industry and the Ministry of Health have worked out a joint programme on price regulation applicable to all firms supplying drugs under the National Health Service (NHS). Excluding the small firms all companies have to submit for each financial year a breakdown of their sales, costs and capital outlay for the production of drugs. The Department of Health and Social Security then determines whether the company has made a reasonable profit on sales of pharmaceuticals taking into account its capital, research and investment. If the Department considers too much profit has been made it negotiates an overall reduction. The company must then reduce the prices of its specialities in order to achieve the overall reduction requested, but it is usually free to decide which prices should be reduced provided the overall reduction is obtained.

The Department considers that the procedure has kept prices at a reasonable level for the NHS, while ensuring a viable and healthy industry essential to the national economy.

In Belgium, Italy, France and Luxembourg price control in the pharmaceutical sector has been effected by the provisions in the regulations. In Belgium price control has been the responsibility of the Ministry of Economic Affairs : from 1953, the price of new drugs and price increases for existing products were subject to ministerial authorization until 1975; the criteria varied according to whether an equivalent of the drug had been developed abroad or not. When the equivalent of the drug had originated abroad, the price of the product on sale in Belgium, whether imported or manufactured in the country, could not exceed the selling price to the public in its country of origin.

A system along similar lines was applied in Luxembourg.

When the drug had no equivalent abroad, the manufacturer's prime cost was marked up according to a certain profit margin which varied inversely with the cost of raw materials (120, 90 or 60 %). But to encourage Belgian research programmes, these margins were increased to 140, 110 and 80 % for the first five-year period of sales of a new product, provided that it represented a new therapeutic substance and was the result of research carried out in Belgium. The same principles guided the Luxembourg legislation.

In 1975, new legislation was passed. This permits the Minister for Economic Affairs to determine maximum prices for specific drugs, after consultations with "a price commission for specific drugs" (on which consumers, the industry - manufacturers, importers and distributors, - and the various ministries involved, are all represented). The following factors are now taken into account :

- the elements which make up the manufacturer's or importer's price, plus their turnover;

- general economic factors (investment, employment, exports);

- comparative elements : international (with the price level in other countries) or national (with the established price of similar drugs already in use).

The earlier legislation had its positive and negative aspects. Positive - the prices of products already on the market were controlled, at least up until 1973 : negative - there was little incentive for the development of Belgian processes and products, as profits were proportional to manufacturing costs. The system of fixing prices for imported products or for those manufactured in Belgium under license in accordance with prices in their country of origin had the effect of favouring companies in countries where prices were high, or VAT rates were greater than in Belgium. The proof that these pricing arrangements were fairly generous was afforded by the case of medicaments which were eligible for reimbursement by the health services : often, the reimbursement approved by health insurance organizations was such that firms decided to cut their prices voluntarily to levels below those accepted by the Department of Economic Affairs.

The new system set up under the law of 1975 seemed, on the other hand, to be more effective. This was mainly achieved by comparing the price requested by manufacturers either with the price of other identical or similar products, or with the price in all other countries (not only the country of origin), after deduction of VAT.

In Italy changes in legislation were introduced in 1970, but did not come into effect until June 1977. Under the earlier system the Ministry of Health, assisted by a committee of experts, was the competent authority for the fixing of specific drug prices. The method is fairly simple :

- calculation of the manufacturer's prime cost, which includes the cost of medicinal raw materials, material used in production, labour costs (direct and indirect) and running costs;

- multiplication of the prime cost by a coefficient varying between 2.5 and 4, in inverse proportion to the total cost of manufacture. This multiplication produces the margin for covering general and distribution expenses.

The review of registered specific drug prices is the responsibility of an interministerial pricing committee which has exercised its authority on more than one occasion.

Under the new system, the same interministerial pricing committee will be responsible for fixing new prices and revising old ones.

It will be a more complex system, consisting of :

- breakdown between costs of raw materials and materials used in production;

- calculation of conversion costs (cost of labour, industrial value added);

- inclusion of a margin over and above the previous sums, to cover costs of research, advertising, and capital return;

- profit margin plus VAT.

To cushion the abrupt changeover to the new pricing system for specific drugs which are already on the market, upward price adjustments for an 18-month period are limited to 30 % and downward adjustments to 20 %. At the end of this period, the prices calculated on the new basis will be applied without any restrictions.

A percentage breakdown of the selling price to the public, arrived at using the system which has been in force up till now, is as follows :

industrial prime cost	33.33 %
administrative costs	6.60 %
general costs	1.66 %
publicity	3.34 %
commercial expenses	3.34 %
returns and exchanges	1.66 %
samples	7.52 %
manufacturer's profit	6.33 %
distribution costs	36.00 %

The policy has had the effect of holding drug prices down (the average cost has increased much less than the general price index). But a bad result has been the disappearance of some cheap patent medicines of the older type, which nonetheless were of proven therapeutic value, in favour of new products, some of which are merely new presentations of old remedies. It was to ameliorate this awkward situation that a general price rise of 12 % for all products on the market before 28 February 1974 was granted.

When the new law giving authority to the interministerial pricing committee came into effect in 1977, the revision of all existing specific drugs was undertaken in two stages (June and December).

Finally, in France, the price of specific drugs (other than the patent medicines on sale to the general public) is fixed by a "committee for the admission of drugs to the list of products which are reimbursable by the national health services" which was set up in June 1967 in its present form, and which meets in the Ministries of Public Health and Social Security. The same procedure is followed whether the patent drug is a new one or one which has been marketed already at a different price. The committee establishes for each :

- the manufacturer's prime cost : cost of components and packaging materials, labour costs, production and control costs;

- the manufacturer's total cost : the prime cost to which is added commercial, administrative and financial expenses, taxes and research expenses (in France);

- the gross production cost before taxation : the manufacturer's total cost to which is added capital return and profit margin.

However, the price which is set does not depend only on these simple factors. The committee also takes into consideration the cost of treatment by the drugs of similar therapeutic value.

Exactly the same procedure is followed for price revisions of existing drugs. Increases are requested by the manufacturer, and do not generally exceed 30 %. Decreases arise when a new drug which is cheaper, but has the same properties, is introduced. When the basic active component becomes cheaper, there may also be a price decrease. Requests for price decreases are followed by a programme extending the decrease over a period of time, on which the manufacturer is consulted (for example, a programme to lower the price of ampicillins by 30 % is in progress at the present moment, and will be completed by 1 January 1979).

The results of ten years of operating by the committee seem to indicate that it has reintroduced an element of competition, without affecting the consumer, and has set up favourable conditions for a slow increase in prices, and even sometimes price-lowering. The trend in the retail price index when compared with the rise in the cost of medicaments, shows that the latter have risen less than the overall increase for all products.

In short, very great differences exist in the various countries' approach to the question of control of manufacturers' prices for pharmaceutical products. It is interesting to note that the four countries which introduced a system of price control have all had to modify them in the direction of greater control (France in 1967, Italy in 1970, Denmark and Belgium in 1975). The pragmatic approach adopted by the British leaves more flexibility to changing situations.

The various countries' attitude to price control seems to depend on whether the authorities believe in the effectiveness of competition between pharmaceutical manufacturers. In the Netherlands, Ireland and Germany the authorities believe that competition will have a restraining effect on pricing. In the United Kingdom they do not believe that competition has the right effect and the controls are intended to ensure (among other things) that no excess and unjustified profits are made as a result of a monopolistic or semi-monopolistic situation.

In France, Italy, Belgium and Denmark the authorities put no trust in "spontaneous" competition, and try to offset the absence of competition by checking prices in the context of the firm, and also in comparison with national and international prices. This does not exclude the possibility of controlling prices directly. The authorities may decide on a general price freeze, which affects pharmaceutical products like all others, or they may simply freeze the price of pharmaceuticals, or even raise them (as they did in Italy in 1974). But these are generally temporary and short-lived; they mitigate against a true pricing policy, whether it be one of liberalism or containment.

Except in the United Kingdom and Italy, in no country are the pharmaceutical laboratories authorized to return any discount to health insurance organisations (or NHS).

In the United Kingdom firms are asked to pay to the National Health Service part of their profits if they are higher than was expected at the time the prices were fixed to leave only a reasonable profit margin. Between 1966 and 1976 it occured 17 times. Under the new provisions accepted by the industry in 1977, estimated financial results will be prepared at the beginning of each year. Repayments are expected to be fewer in the future but could still happen.

In Italy repayments were made but not by individual firms nor were they related to "excess profit margins". During the years 1955-1970 all pharmaceutical firms have had to give a 12 % discount to health insurance organizations. In October 1970 this was raised to 19 %. The overall nature of this obligation, coupled with the fact that upward price revisions for old products were not permitted, represented a heavy burden for some firms; discounts were not given, in some cases, for months and even years. This system was discontinued by Decree No 187 of 4 May 1977, in application of Law No 395.

On the second point, there are great divergencies. Advantages for dispensing pharmacists, other than price discounts, are proscribed in Belgium. In Denmark they can be given only to hospital "dispensaries". In other countries they are not legally prohibited; they can be made as cash or quantity discounts, which in practice comes to the same thing. In the latter case, extra quantities are supplied free-of-charge. This happens in the Netherlands and Germany. In the Netherlands discounts can only theoretically be given following agreement between the manufacturers' professional organization and dispensaries. However, in practice, manufacturers supply a considerable quantity of free products to hospital dispensaries, dispensing chemists and wholesalers, and to those doctors who are permitted to sell drugs.

Cash discounts, that is a percentage of the selling price, are offered in Ireland, France, United Kingdom, Belgium and Italy. Usually rebates depend on the size of the order, or the speed of payment which can give rise to a discount. Generally speaking, where discounts are allowed there is no regulation governing them, and it is up to the manufacturer to decide what he wants. The only rule in force seems to be one in France concerning rebates to wholesalers. For sales to these, the manufacturer can set up a scale of prices, depending on the wholesalers' overheads. The administration must be informed of these scales, and manufacturers are not allowed to make rebates or offer special conditions other than those specified in the scales.

In principle, manufacturers are not authorized to grant hidden discounts to dispensing pharmacists but it is difficult to control these hidden benefits. In the Netherlands a dispensing chemist may not legally accept any discount from his supplier and if he does so he must pass it on to the customer. But the usual practice is said to be otherwise.

b) Composition of the effective industrial price of pharmaceuticals

Information on this point was found to be unsatisfactory when the comparison was made. The figures quoted were not given on an identical basis and their origin differed. In a number of cases they were provided by the manufacturer's organizations themselves. The financial profitability of this sector that is assessed from the percentage of profit obtained is given below by way of information only and it would be a mistake to draw any comparisons, particularly since in certain countries the profit margins given are the extremes, whereas in others they are an average. Similarly, and for the same reasons, not much importance should be attached to the percentages for advertising and research.

Lastly, the size and number of multinational pharmaceutical companies distorts the figures, since profits may be shown in a given country for tax reasons rather than actual profitability.

An attempt is made to compare the data in the rough table below using the following breakdown :

1. administrative costs
2. manufacture (including transport, raw materials, and general expenses)
3. processing and packaging
4. research and development
5. patents and licenses
6. sales promotion
7. profit

	1	2	3	4	5	6	7	Total
Belgium	----------	50 - 80	----------	15 - 35		2 - 15		100
Denmark	5	----	60 ----------	10	5	10	10	100
Germany	13.4	----	35.9 --------	17	----------	23	10.7	100
France	----	40-55--	7 - 3	8	5	17	4 - 10	100
Italy	5	---------	60 ---------	8	3	20	4	100
Netherlands	----	31 ------	15	18	8	16	12	100
United Kingdom	11.5	----49.2	-------	12.1	1.7	13.7	11.5	100

There is no breakdown for Ireland, and Luxembourg, it may be remembered, has no pharmaceutical industry.

In most countries the figures are for the total activities of pharmaceutical companies, namely all manufactured products, whether sold on the domestic market or exported.

In Denmark and the United Kingdom, however, the figures relate only to the domestic market, and are confined to products on prescription. In the United Kingdom the figures relate to products on prescription provided under the NHS and manufactured by the larger companies. The data were obtained from different sources (the administration in France and the United Kingdom, the pharmaceuticals industry in Belgium, Denmark and Italy).

2. Imports

In Part I-C the size of foreign trade in pharmaceuticals was described. It therefore seemed of interest to find out whether imports were controlled, either on a general basis or according to geographical origin (non-EEC countries or the rest of the world).

No provisions exist in Germany or Denmark or in the Netherlands. In France the question does not arise in the case of specific drugs, since imports are practically non-existent, in view of the strict rules governing marketing of imports. When imports are permitted, their price is controlled by the same regulations which apply to indigenous products.

In Belgium the price of drugs which are imported ready packaged and the price of those which, while having been developed in a foreign country, are manufactured and packaged in Belgium, are both fixed in the same way. There is no difference, therefore, in the regulations. In Luxembourg the same rule applies and the price free of VAT of pre-packed imported drugs must not exceed that - also free of VAT - which is in force in the country of origin, using official exchange rates.

In the United Kingdom prices of imported drugs are subject to the procedure under the joint programme on price regulation in the same ways as products manufactured in the United Kingdom. Transfer prices are checked to ensure that the costs taken into account are reasonable and exclude any distortion which might result from an abnormal increase in transfer prices.

Italy has adopted a special set of regulations. If there is already an Italian drug on the market which is similar and already registered, then the imported drug will be sold at the same price as the Italien one. If, on the other hand, there is no corresponding Italian drug, the price will be calculated according to the selling price of the drug in its country of origin, increased by the amount of exchange costs, customs duty and freight.

There are no regulations concerning pharmaceutical products that affect those from outside the EEC differently from those of EEC origin. There are differences in customs duty payable on the two categories, but these apply to all products, not merely pharmaceuticals.

Finally, there seems to be no deliberate pricing policy for imported pharmaceutical products. Luxembourg, with no industry of its own, imports patent drugs already packaged. France, because of its regulations, imports hardly any. The other countries import more or less according to the intensity of their own national industry; there does not appear to be any connection between the volume of imports and regulations controlling their price.

3. Distribution

a) Wholesalers

Wholesalers' gross profits, (1) worked out as a percentage of the retail selling price of the drug, all taxes included, are as follows :

Italy	6.4
Ireland	8.69
France	7.12
Denmark	6.4
Belgium	8.35
Netherlands	14
Germany	9
Luxembourg	8.8
United Kingdom	7.4 to 9.2

Only Germany, up until 1977, has not had any legislation regulating wholesalers' profit margins. Since 1978 a bracket of 12-21 % of the manufacturer's selling price has been fixed depending on the price of the product, but these provisions apply only to sales to pharmacists' shops.

In Ireland there is no legislation. Wholesalers' profit margins are fixed through agreements between the trade and the Ministry of Health, but profit margins cannot be changed without authorization from the Price Control Commission.

Likewise, in the United Kingdom, wholesalers' profit margins are not fixed by law. A manufacturer is at liberty to use the services of a wholesaler or not : if he does so he must pay them,which he does by selling the product to the wholesaler at a price between 82.5 % and 86 % of the price at which the wholesaler will on-sell the product to the retailer. The Department of Health does not intervene in this process except in cases where the manufacturer offers wholesalers conditions that are much more profitable than the margin allowed.

The situation seems to be the same in the Netherlands and Denmark. In the former, profit margins are laid down by agreement within the industry, and in the latter, through agreements between manufacturers and wholesalers.

In Italy legislation does not specifically limit wholesalers' profits, but restrictions result from the minimum guaranteed to pharmacists (see b) below), and from agreements made between the interested parties in the industry, and through the Ministry of Health.

(1) Generally, except in the United Kingdom and Ireland, wholesalers sell only to internal markets, their profit margins relate only to these sales.

In Luxembourg, France and Belgium margins are laid down by the Ministry of Economic Affairs. In all three countries a percentage has been laid down, but in Belgium a quantitative platform is also introduced : whatever the price of the product, the wholesaler's profit may not be more than BFR 73 per item.

Profit margins appear to have remained steady between 1965 and 1975, except in two countries where they went down slightly (from 6.95 % to 6.40 % in Italy). Only the Italian report mentions that the particularly low wholesale profit margin in that country, due to the very competitive market in pharmaceuticals, has caused the number of wholesalers to decline during the last ten years.

b) Retailers (pharmacies)

Here again, reports were asked to indicate gross profit margins as a percentage of the retail selling price of the drug, all taxes included.

Italy	24.33
Ireland	33.33
France	33.44
Denmark	32
Belgium	31
Netherlands	26.2-33.4
Germany	34
Luxembourg	33.83
United Kingdom	25

In all countries apart from the Netherlands profit margins are laid down by the authorities. In the Netherlands they are fixed by groups within the industry. In the other countries the permitted margin is determined either by the Ministry of Public Health or by the Ministry concerned with the economy (Price Commission in Ireland).

The systems used are usually complicated. In addition to variations in the basic rate, extra honoraria depending on the requirements of the patient, or special problems connected with the nature or the preparation of the medicine, may also be demanded.

For the basic profit margin allowed on pharmaceutical products, only Italy has fixed a minimum (25 %), but not a maximum. France, Luxembourg, Italy, Belgium and Ireland impose the same profit margin limit on all products irrespective of price. In Belgium, however, there is a double restriction : the margin may not exceed 31 % of the retail price and in absolute value BFR 250. In Germany and the Netherlands there is a decreasing sliding scale. In Germany it ranges from 68-30 % of the cost price, but is no more than hypothetical, as it can be increased by the quantity discounts which wholesalers give, or decreased by the discounts which the pharmacists grant to health insurance funds.

In the Netherlands the percentage profit on the retail price for products which are U.A. (the official price fixed for the health service) ranges from 26.2 to 33.4 %.

In the United Kingdom each pharmacist's profit margin varies depending on trade (speed of turnover, number of specific drugs in stock, depending on the prescription habits of local practitioners and the local sickness ratio). The amount received by the pharmacist for prescriptions dispensed under the NHS is calculated each month on the basis of four factors :

- the wholesale price of medicines and appliances as laid down by the regulations governing the price of pharmaceutical products, less a discount of 0.1 % if the chemist dispenses over 1 500 prescriptions a month, rising to 2.7 % where the number of prescriptions dispensed is over 8 000; this tariff is laid down by the Government after consultation with the representatives of dispensing pharmacists;

- packaging costs at the rate of 2 1/2 pence per prescription;

- an average fee of 24 1/2 pence per prescription that varies with the type of prescription in accordance with the scale fixed for pharmaceutical products, and depending on the service rendered (for exemple, fees for an emergency);

- an allowance equal to 10.5 % of the wholesale price of the drugs and appliances sold before deduction of the above-mentioned discount of 0.1 to 2.7 %.

Under this system, the last two factors represent the pharmacist's gross profit. To arrive at the particular values used, the parties involved, i.e., the Department of Health and Social Security and the professional body of the pharmacists, make regular surveys to establish the real cost of the work performed and the general running costs, as well as a "net profit per prescription", which is negotiable. The process is a contractual arrangement, with provisions for periodical adjustments, so that the objectives of the scheme can be achieved.

Although made-up medicines represent a very small part of the total expenditure on pharmaceuticals in most countries, it is noted that the pharmacist's honorarium for these products is determined in various ways. In Luxembourg and Italy the Ministry of Public Health lays down "preparation fees", which are added to the cost of the raw materials and packaging. In Belgium these same honoraria are fixed by agreement between professional bodies representing the pharmacists and health insurance organizations. In the Netherlands the health insurance organizations fix the sum which shall be reimbursed in the case of made-up medicines. In the United Kingdom preparation fees are fixed by the Government.

To the basic honorarium for making up a prescription various other items are sometimes added. Three systems of remuneration exist in other countries.

The first case concerns extra fees which are not linked to any particular service in the Netherlands, where the health insurance institutions pay the pharmacists a fixed annual amount of HFL 21 000 for the first 5 000 patients, a fixed annual amount per patient (HFL 15.20) and an additional amount of HFL 1.84 per prescription.

In Ireland the system is the same for patients who are not covered by general medical services : in addition to the retail price which includes a margin of 33 1/3 %, chemists receive 50 pence per prescription.

The second case arises if the pharmacist is called on to perform extra work. The most frequent case is the fee for delivering medicines outside normal working hours (after closing time, on Sundays and public holidays); this is paid in Italy, Belgium, France, United Kingdom, Luxembourg, Denmark and Germany. In France and Italy provision is also made for special fees for dispensing dangerous or toxic drugs which have to be entered in special registers.

In the third case, special payment is received by pharmacists on account of the need to provide all areas of a country with pharmacists' facilities. This may be difficult in sparsely populated or poor regions. Two ways exist of providing facilities when the number of patients - and hence the turnover - is small. The authorities may decide either to set a reasonably high profit margin, which will allow a small isolated pharmacy to survive, but which may produce excess profits for one in an urban area with a large or growing clientèle, or they may decide to set the profit margin at a lower level, and grant extra remuneration to assist pharmacies with a small turnover. This system is practised in the United Kingdom. In some cases pharmacists who handle only a limited number of prescriptions, but who are considered to provide a necessary service to the public, receive a special grant each year. In other cases, in Scotland, the rate at which the allowance is calculated, normally 10.5 % of the wholesale price, increases progressively for pharmacies handling less than 1 000 prescriptions per month.

Similar provisions are in force in Italy and Denmark. In Italy the public authorities subsidize rural pharmacists whose turnover is inadequate. At present 2 800 pharmacists are subsidized. The subsidies depend on the number of inhabitants, under 3 000, and the receipts; but the amount of aid granted is not enough to encourage the opening of new pharmacies in the poorest areas. The Danish system is more ingenious since it results in some redistribution between pharmacists. The pharmacists pay an amount between 3 and 9 % of a fixed turnover. When their turnover exceeds the average turnover by a certain percentage they pay 40 % of the difference. On the other hand, some pharmacies with a low turnover receive a subsidy.

Retailers' profit margins laid down by regulations can be cut down if they are required to make repayments to health insurance bodies or the NHS. (Repayment of excess profits by wholesalers is not obligatory in any of the Member States).

The United Kingdom system is based on an attempt to arrive at a balance between payments due and payments made. The public authorities do not regularly review the net profit due per prescription (in other word, remunaration of capital used, which has remained unchanged at 16 % since 1970). They achieve the desired balance by adjusting fees and/or the rate of compensation; net profit is not paid separately but is included in the fees and the compensation.

In other countries the rebate is fixed by regulation. This is the case in Germany and Italy. In the former country the statutory sickness insurance pays the dispensing pharmacist the sale price of the drug after deduction of a 7 % rebate imposed by law (lowered to 5 % since 1978).

In Italy health insurance institutions receive a 16 % refund on galenical preparations for all pharmacists. In addition, only rural subsidized pharmacists must make an additional 5 % discount on specific drugs and 21 % on prepacked natural products.

In France dispensing pharmacists signed an agreement with the national health insurance scheme in 1968 to refund to them 2.5 % of the total of their sales to health insurance patients. The system functioned only for a year and was replaced in July 1970 by one with a lower basic rate. Today all that exists is a convention signed by friendly society dispensaries, guaranteeing a refund of 3 % to the health insurance funds.

The reason for these repayments, however, is not excess profits, since the provisions extend to all pharmacists, whatever their turnover or net income. For example, in Italy, even pharmacies in the country which receive a subsidy are obliged to make these repayments. As prices have been more or less frozen for the past decade, with profits held at a low level, the burden of paying back refunds to the health insurance funds has become heavier.

Under the special system in force in Luxembourg dispensing pharmacists allow a discount of 3.4 % to beneficiaries under the worker's insurance scheme.

To sum up, the structure of dispensing pharmacists' earnings is relatively rigid, being determined either by the percentage of the price of products or an overall contractual remuneration as in the United Kingdom. It is equally rigid over time. The changes made between 1965-1975 were minimal and limited to certain countries (Germany, France, Italy). Consequently they have had little effect on the overall cost of drug consumption. In any case in all countries the system of remuneration means that there is almost no competition as far as the price of pharmaceuticals offered to patients or health insurance organizations is concerned.

4. Taxation

a) National indirect taxation

The figures relating to the tax burden in each country at the beginning and the end of the period 1966-1975 were given on page 8 of Chapter I.

Depending on the country the figure given is either that for tax on turnover or for value added tax. There has recently been a tendancy for there to be a reconciliation between the different national policies. Five countries which formerly did not subject pharmaceutical products to indirect taxation do so today and, in 1975, such taxation existed in all the countries.

Taken overall, taxation levied on pharmaceutical products is relatively small. The only exception used to be France, where until 1 July 1975, the taxation in force amounted to 17.6 % instead of the 6.54 % to which it has since been lowered. It is doubtless owing to the fact that the cost of drug consumption is largely supported by some form of group insurance (health insurance schemes or national health services) that this is so.

b) Local indirect taxation

This is almost non-existent. In France a local tax of 2.75 % on the selling price was in force until 1967, when it was abolished. The only exception seems to be Ireland, where wholesalers are obliged to pay a tax on the increased value of their stocks; curiously, the same rule does not apply to manufacturers themselves.

C. THE REGULATION OF CONSUMPTION

1. The Doctor

In all countries in the Community, the pharmaceuticals which may be paid for in whole or part by health insurance schemes or health services are defined. In Belgium, Denmark, Italy and Luxembourg special, more detailed lists are maintained which specify those products which are covered by health insurance. In Germany a list is being prepared of minor drugs which are generally consumed in cases of light restriction of physical well-being which will not, or only under special conditions, be prescribed under health insurance. In France and the Netherlands a list is maintained of what doctors are recommended to prescribe under health insurance. In Germany a special list is also being prepared taking account of cost and efficacy to guide doctors prescribing under health insurance. The coverage of all these special lists varies considerably in content and presentation.

In seven of the nine countries, action is being taken to influence or regulate the prescribing patterns of doctors in an attempt to contain costs. The two exceptions are Belgium and France. In Belgium no action is taken at all, though strong sanctions including prison sentences can be imposed on doctors who wrongly prescribe narcotic or habit-forming drugs. An administrative medical committee carries out checks on such prescriptions. While no action was being taken in France at the time of the study, a profile of doctors' prescribing patterns is being prepared for the first time. Any sanctions against excessive prescribing would have to be applied by committees representing all parties to health insurance at the local level where payments are made.

In the seven countries where action is taken it forms part of the administration of health insurance (or in the case of the United Kingdom of the National Health Service). In Denmark the health insurance agencies make spot checks on prescriptions. Participating doctors can in theory be fined for excessive or unnecessary prescribing, but fines are, in practice, hardly ever applied. In Ireland the prescribing rates of doctors participating in the General Medical Services covering 37 1/2 per cent of the population are analysed annually, and doctors with high rates of prescribing are interviewed. This procedure is believed to be effective. No legal sanctions backed up this procedure until 1978. In Luxembourg consulting doctors and pharmacists employed by health insurance check payments for prescriptions. The consulting doctor can make a formal protest to any doctor who issued a prescription arguing that it goes beyond the limits of what is necessary and thus breaches the Health Insurance Code. It is also possible for him to report the doctor to a committee set up under the Law by the Minister of Health which can issue warnings with the ultimate sanction of banning the doctor from medical practice.

In the Netherlands the Council of sickness insurance funds employs inspectors who try to persuade doctors to replace expensive medicines by cheaper ones of the same quality. The purpose is to convince doctors to follow the recommendations set out in "Regeling en Klapper". This provides the inspectors with criteria by which to assess unduly expensive prescribing.

In both Germany and the United Kingdom the average prescribing cost of each general practitioner is calculated and compared with that of the average for doctors practicing in the area. In Germany the system also extends to each type of specialist. The doctor who exceeds the average by 20-30 % in Germany is informed of the fact and asked to explain what appears at first sight to be excessive prescribing. The control is operated by the Association of Panel Doctors. If a doctor continues to over-prescribe without a satisfactory explanation he can be fined by the sick board. In the case of persistent infringement his panel licence can be withdrawn.

In England and Wales the control is operated by salaried medical officers (Regional Medical Officers) employed by the Department of Health and Social Security which is responsible for the National Health Service. These doctors visit general practitioners whose prescribing cost per patient on his list is significantly above the average of other doctors in the same area and discuss their prescribing with them and offer advice. They might also take with them detailed analyses of the doctor's prescribing pattern and particular prescriptions written by that doctor which seemed at first sight to require explanation. The Regional Medical Officer reports to the Headquarters of the Department on the advice given to the doctor. If, in a subsequent analysis of the doctor's prescribing, it appears that the advice has not been taken this can lead to the opinion of the Local Medical Committee being sought. These Committees, elected by all the general practitioners in the area, can recommend that a proportion of the doctor's remuneration is withheld. It has not, however, been necessary to take a case to the Local Medical Committee during the past four years. The Regional Medical Officer himself is not involved in any disciplinary procedures; his role is to act as adviser to the doctor in many fields including prescribing.

In Italy what a doctor can prescribe under the health insurance schemes is laid down in the Health Care Handbook which contains a list of proprietary medicines compiled and brought up to date periodically (new products being added and obsolete entries eliminated) by the Ministry of Health, through an appropriate committee. The rules for the use of the Health Care Handbook and the agreements between the insurers and the various health authorities also determine the quantities which may be prescribed and dispensed. Doctors and pharmacists are bound to apply these provisions; any prescriptions which do not conform are dispensed entirely at the patient's expense.

The various Italian health insurance bodies, until they are replaced by the National Health Service, as provided for under the health service reform measures (already partially in force in respect of hospital treatment), exercise control over doctors' activities through their local offices by checking prescriptions, bills and visits to patients. Those doctors whose performance is open to criticism are called in to be interviewed (summoned by letter) and finally, in cases where these efforts prove useless, referred to appropriate committees. The INAM, for example, has a committee in every

province, chaired by the president of the Medical Association and made up of six doctors representing the Ministries of Labour and of Health, the INAM, the employers, the workers and the medical profession. At INAM's request, the Commission examines the case referred to it and can take the following steps : discharge, formal warning, suspension from practice for up to two years or permanently. The steps taken concern only the relations between the doctor and INAM and in no case affect the former's private practice, since steps concerning the latter can be taken by only the Council of the Medical Association. The doctor can appeal against the Provincial Committee's decision to an appropriate Central Committee.

Sales Promotion

a) Written Matter Sent to Doctors

In France and the Netherlands all advertising material sent to doctors has to be approved in advance. In France drug advertising is controlled by the "Commission for the control of pharmaceutical advertising". The Commission ensures that any advertising will neither endanger nor put at risk public health, that it is honest, truthful and susceptible of proof and that possible undesirable effects are included. Advertising certificates are issued for a period of five years. In the Netherlands an office indirectly under the control of government (KOAGG) approves all advertisements before publication.

In Ireland sales promotion conditions are imposed as part of the licensing of products by the Department of Health acting on the advice of the National Drugs Advisory Board. When it is considered that a risk is being created by the manner of promoting a product already on the market, the National Drugs Advisory Board takes the matter up with the industry and generally achieves its objective. In addition, the industry operates a voluntary code of marketing practice. A special committee set up by the industry with a legally qualified chairman, who is also a pharmacist, adjudicates on complaints that the code has been broken. The Committee has a consultant medical adviser to assist in such assessments.

In Italy the "labels" (and accompanying illustrated brochures) of proprietary medicines have to be approved by the Ministry of Health at time of registration of when subsequent amendments make this necessary. All data sheets, leaflets, advertisements and particulars given to representatives have to be consistent with what has been approved - particularly directions for use, warnings and contra-indications. Graphic designs which are irrelevant, not of a scientific nature, or which can give a false impression of the medicine are not permitted.

In Belgium regulations specify that all advertising material or technical and scientific information relating to a particular product must be honest, truthful and susceptible to proof. It must be strictly consistent with the details submitted at the time of applying for registration of the product.

Technical information and advertising material intended for the medical profession and pharmacists must include all the particulars contained in the instructions for use : the brand name, the common name, the name and address of the commercial agent, the ingredients, forms of packaging available, dose and method of administration, therapeutic indications, contra-indications and side effects as established at the time of registration and, if necessary, an endorsement required by the public health department. However, this obligation does not apply to reminder advertising in which the brand name is mentioned.

In Denmark the Law requires all advertisements to be sober and factual and not to give an exaggerated, incomplete, misleading or deceptive picture of the medical product. Advertisements sent to doctors are submitted to spot checks. In dubious cases the industry's own ethical advertising board or the Health Department can be consulted and will intervene of its own accord.

In Germany a law passed in 1965 specifies that misleading advertising and vague references to reports, testimonials and scientific publications are prohibited. An amended law coming into effect from 1978 requires advertising material or advertisements in medical journals to contain the following information : the name and place of business of the firm, the name of the product, the composition including active ingredients, its field of application, contra-indications, side effects and particular warning signs. No public agency continuously monitors the observance of the law but legal proceedings are taken when complaints of a breach of the law are made. The Industry has, however, to prevent advertisements which give prominence to the positive features of a product and much less prominence to contra-indications and side-effects. Information on the price is required to be included in advertisements.

In Luxembourg, regulations published in 1975 specify that advertisements must contain the name and the address of the manufacturer or product licence-holder, the name of the product and its active components, principal therapeutic indications, contra-indications and side-effects, dose and method of administration. Abbreviated advertisements are, however, permitted containing only the name of the product and the name and address of the manufacturer or licence-holder.

In the United Kingdom the Medicines Act 1968 forbids advertisements to describe falsely a product or be likely to mislead as to its nature, quality, uses or effects. It is also an offence to recommend the product for uses other than those stated on the product licence and advertisements have to be consistent with the particulars on the product licence.

Regulations, which came into effect in 1978, specify that certain advertisements must contain specific information on active ingredients, indications for use, dosage, major side effects, precautions, contra-indications and cost. They also specify the prominence to be given to certain parts of the information, prohibit misleading graphs and tables and prohibit the misuse of words like "safe". Further controls on advertising practice are implemented by a Code of Practice operated by the industry. The Code of Practice is administered by a Committee, which includes independent members. All advertisements have to be certified as satisfactory by at least one doctor nominated by the manufacturing company. The industry

has established machinery to monitor advertisements as they appear to ensure compliance. The Code of Practice committee has agreed to ensure that any advertisement complained of by the Department of Health and Social Security will be withdrawn pending an investigation by the Committee.

b) Restrictions on Representatives who visit doctors

Only in Germany and the United Kingdom are there laws governing the representatives of firms. The new law in Germany coming into effect in 1978 specifies that representatives must have particular specialist knowledge. They can be prosecuted under the law following a complaint but no monitoring of their activities is planned. Beyond this, there is no restriction on what they can say to doctors. In Ireland the activities of representatives are governed by the Industry's voluntary code of practice. In the Netherlands doctors tend to limit the number of visits from representatives. In Italy there is a ministerial circular recommending the qualifications which medical representatives should possess, how many of them there should be and how often they should visit doctors. In the United Kingdom false and misleading representations and oral recommendations of a product for uses other than those stated on the licence are forbidden. When a sales representative visits a doctor and initiates discussion of a product, he places a copy of the data sheet for that product (approved by the licensing authority) before the doctor. The Code of Practice of the Industry requires representatives to be thoroughly trained and maintain a high standard of ethical conduct.

c) Restrictions on Hospitality provided to doctors

In Belgium and the Netherlands there are no restrictions. In Denmark, Germany, Ireland and the United Kingdom hospitality is restricted by the Code of Practice laid down by the Industry or by agreement among firms. In Germany the guidelines laid down by the Industry specify that expenditure on an individual participant should not exceed DM 30-40. In Ireland and the United Kingdom the voluntary code states that hospitality must be modest in nature and cost. In the United Kingdom an agreement reached with the Industry in 1977 specifies that hospitality can be allowed only as a charge on the Health Service under the PPRS (1) when given at medical symposia, and even then must not exceed what a doctor would normally buy for himself. In Luxembourg the law forbids firms to give or offer doctors "any material benefits". In France there is a ban on any individual gift in cash or kind being given to members of the medical profession. In Italy doctors are forbidden to accept any payment in kind from pharmaceutical firms. This does not rule out hospitality at medical symposia.

(1) Pharmaceutical Price Regulation Scheme.

d) Restrictions on Samples

In Belgium, Germany, France and Luxembourg there are legal provisions specifying that samples can be sent to doctors only if they request them. There are similar provisions under the voluntary codes of the Industry in Ireland and the United Kingdom. In Belgium medical samples are not allowed to exceed 4 % of the turnover of that product from the end of the first year of its registration. In Germany records have to be kept of samples which are sent and the Industry has undertaken to send no more than six of the smallest packs of each product per written request. In France no samples can be sent after the product has been on the market for two years. In the United Kingdom samples, apart from those given for recognition purposes, can be supplied only at the written request of a doctor and the cost of samples other that for recognition purposes is not allowed as a charge on the Health Services under the PPRS.

In Denmark only one sample can be sent to any doctor and this has to be in the smallest package, and it can be sent only during the first year after the product has been put on the market. In the Netherlands, samples can be sent only on the introduction of a new product and cannot exceed the amount needed to treat three patients.

e) The Quantity of Sales Promotion

In France and Belgium the amount and proportion of expenditure on sales promotion is examined as part of the process of regulating prices. In the United Kingdom the Government has recently announced that it will allow as a cost in regulating profits only 10 % of turnover spent on total sales promotion from the year 1979. The reduction is being phased and as the first stage a reduction of 2 % of turnover was made in 1977. Any expenditure above the prescribed limit would have to come out of profits. There are no restrictions on the quantity of sales promotion expenditure in the other countries in the Community. In Italy the new method of fixing prices for proprietary medicines is intended to curtail expenditure on sales promotion activities and the distribution of samples.

2. The Pharmacist

In Ireland and France pharmacists can supply only up to one month's supply of a pharmaceutical prescribed under health insurance. In Italy the amount which the pharmacist may dispense, to which the doctor must conform when prescribing, is limited to two packages (containers) of the same proprietary product or alternatively two products in individual packages, except for antibiotics and serums which may be dispensed in sufficient quantity for two days of treatment on a single prescription. Galenic products and first-aid supplies may also be included in the same prescription within predetermined limits. In Germany and the Netherlands the pharmacist has to dispense the smallest packed quantity when no indication is on the prescription. There are no limits in the other countries of the Community. The renewal of prescriptions is allowed when the doctor has authorised it in Belgium, France and Luxembourg. In Belgium one prescription cannot exceed two months', and in France six months' supply. In Luxembourg a patient has to have a copy

of the prescription certified by the Health Insurance Organisation before the pharmacist is authorised to renew it.

In Germany a pharmacist is expected to substitute the cheapest generic product when a doctor has not specified a particular manufacturer. In the other countries of the Community the pharmacist has to dispense precisely the product which the doctor has prescribed (in the case of the Netherlands the product has to be in the "Regeling en Klapper").

3. The Patient

Maximum and minimum prices

There are maximum prices which retail pharmacists can charge patients in all countries in the Community, except the United Kingdom (for products not provided under the National Health Service). These are also the minimum prices in Denmark, Germany, France, Luxembourg and Italy. In the other countries the pharmacist is free to charge less. In Belgium discounts are limited to 10 % of the published price (or on what remains to be paid by the insured person) and can be claimed only at the end of the year.

Charges and cost sharing

Only in the Netherlands are pharmaceuticals free of charge to all patients covered by health insurance. In Ireland free pharmaceuticals are provided to the limited number of patients covered by the General Medical Service Scheme : middle income group patients can claim a refund for any expenditure on pharmaceuticals in excess of £ 6.50 per month.

In Italy there is at present no system under which the insured person shares the cost, but for a number of the proprietary products listed in the Health Care Handbook, the insured is nevertheless required to make a contribution. Proprietary products not provided free of charge represented 7.09 % of the total number in 1976, or 1.50 % of the total amount invoiced. A more general system of charging is to be introduced, granting exemption for pensioners and other categories.

Charges are flat rate in Belgium and the United Kingdom. In Belgium (from mid-January 1977) a charge of BFR 35 is made for generic preparations and BFR 70 for proprietary preparations. These charges apply to the smallest pack size. However, Invalidity and Retirement Pensioners, and Orphans and Widows earning less than a stated amount are not charged for generic preparation and pay only BFR 40 for proprietary preparations. In cases of chronic diseases the charge is limited to BFR 40.

In the United Kingdom, apart from contraceptives which are provided free of charge under the National Health Service, the flat rate charge is 20 pence - unchanged since 1971. Exempt from these charges are :

1. Children under the age of 16.

2. Expectant mothers or others with a child under the age of 1 year.

3. Women aged 60 or over and men aged 65 or over.

4. Persons with a specified medical condition requiring continuous medication.

5. Persons exempt as requiring prescriptions for disablement arising out of war or service in the Armed Forces.

6. Persons and their dependants on Supplementary Benefit (public assistance), Family Income Supplement, or assessed as too poor to be able to pay.

On top of this "prepayment certificates" can be purchased for £ 2 covering a period of 6 months or for £ 3.50 covering a period of 12 months.

In Denmark there are three rates of charge : 25 %, 50 % or 100 % according to the therapeutic significance of the drug and to some extent the price. Persons with low incomes in relation to the cost of the drug are exempt from the charges. In Germany, up to July 1977, the charge was 20 % of the cost of a prescription up to a maximum charge of DM 2.50. Children whose parents are insured and pensioners were exempt from charges. From July 1977 the charge is DM 1 for each prescribed drug : only children are exempt. Some medicines (e.g. laxatives and cough remedies) will not be paid for by the sick funds in future. In France the normal charge is 30 % of the cost. But from December 1977 a charge of 60 % has been introduced for certain "comfort" pharmaceuticals such as laxatives. For some particularly costly preparations only 10 % of the cost has to be paid. No charges are made for preparations needed to treat chronic diseases or illnesses arising from work. War veterans and certain other categories are exempt from charges. In Luxembourg the patient has to pay 15 % of the cost, but some pharmaceuticals are exempt.

Insurance against charges

No country forbids insurance against charges for prescriptions. Only in France is insurance of this kind common.

Direct payment or reimbursement

In France and Luxembourg (except for manual workers) the insured person has to pay the whole cost of the prescription and then claim back the share covered by health insurance. In the other countries (and in the case of manual workers in Luxembourg), the health insurance scheme pays the pharmacist direct. In the case of Ireland this applies only to those covered by the General Medical Services Scheme.

D. EFFECTS OF THE POLICIES ADOPTED

1. Economic effects

a) External trade

It is obvious that in a country where there are no price controls or where controls are of minor importance, exports and imports will develop freely, and will be affected only by the policy followed in other countries. This is the case in Germany, Denmark, and Ireland, as well as in Luxembourg, where of course there is no national pharmaceutical industry.

Where legislation affecting the prices of indigenous pharmaceuticals exists, two opposing forces may be at work. Firstly, a moderate internal price structure will encourage the penetration of external markets, especially if competition exists between several exporting countries. Secondly, this same price structure will lead to lower profit margins for sales made within the country which will in turn be a disadvantage, since laboratories will not be able to allocate enough to research and development, and hence will not be able to develop the right commercial policy for breaking into external markets. When prices are too low on the home market, in other words, the effect will be felt in the export market. Obviously this is the view taken by the pharmaceutical industry. Another argument bears out the same hypothesis : when the importing country fixes the price of admission or reimbursement by reference to the price in the country of origin, low internal prices will mean that insufficient returns are made on products exported. The reports on Belgium, France, Ireland, Italy and the United Kingdom all made this point; the Franch report, however, added that despite the restrictions on price increases the share of exports in overall pharmaceutical production in France in recent years has been increasing. In the Netherlands, export prices are usually below those for the domestic market; they do not contain an element for amortization, as do prices for products sold in the country.

The British report stressed the fact that the strategy of the multinationals will be influenced by any price restriction in force in a particular country when they are considering whether to install production facilities there. If regulations are too restrictive, they will be disinclined to invest there for fear of the price structure leading to too low a platform for export prices.

Their strategy may also be influenced by any regulations in force for health insurance repayments. When such regulations have the effect of almost totally prohibiting the import of patented drugs, firms wishing to enter the market in that country have no alternative but to install laboratories there. This occurs to a notable extent in France.

As a general rule, health regulations intended to ensure the safety and effectiveness of drugs seem to have little effect on imports or exports in a particular country. Italy and the United Kingdom mention exceptions. In Italy health regulations tend to favour the importation of drugs which have already been registered in another country; this prior registration exempts importers from having to submit drugs to the tests of the health authorities. New Italian drugs or Italian equivalents to drugs already registered elsewhere would both have to be subjected to such tests for safety. From the opposite point of view, the British report suggests that internationally accepted criteria for safety and effectiveness tend to increase exports. Many importing countries require certification that the product has passed the health regulations in its country of origin.

b) Pharmacists' incomes

For the period 1965-1975, a comparison of the income of dispensing pharmacists with the average per capita income for all classes, and with the income of similar professional classes, particularly those treating the sick (doctors, dentists, etc.) is, indeed, very difficult to establish.

Replies were sketchy for the most part. In most countries available statistics were not adequate, and accurate conclusions cannot be drawn. The British report for instance stated that the only figures available were those drawn from NHS files, so that the overall figure for dispensing pharmacists' income is unknown and cannot be compared with that of other classes.

The Danish report noted that the equalization fund referred to under II B above was designed to eliminate too sharp a difference between pharmacists' income as a result of differences in their turnover. If the aim was that a pharmacist's average income should be equivalent to that of a senior civil servent it would not seem to have been achieved, particularly in recent years.

Only Belgium and France attempt any scientific evaluation, but even this was based on sample surveys. In Belgium an unpublished study conducted by the National Statistical Institute on the basis of income tax returns for 1966-1972 produced the following figures for the percentage increase in income :

overall	+ 59.97 %
blue collar workers	+ 62.75 %
doctors	+ 86.40 %
dentists	+ 26.93 %
pharmacists	+ 52.97 %

This shows that pharmacists' incomes have increased a little less than those of the population as a whole, and much less than those of doctors. In absolute terms, in 1972 dispensing pharmacists' incomes were roughly five times those of the population as a whole and 20 % less than those of independant doctors.

In France studies were carried out by CREDOC, an independent research organization, for the period 1965-1975. The first finding was that for 1975, in absolute terms, a pharmacist's average income was 10 % lower than that of independent doctors, 20 % higher than that of upper management (engineers), and more than seven times greater than the per capita income of the population as a whole. The trend in income over the period 1965-1975 has followed an irregular curve. Between 1965 and 1970, the increase in pharmacists' average incomes at relative prices was more than that of the average per capita income, but between 1970 and 1975 they grew less rapidly (average annual growth rate 1.60 % against 4.30 % for the second period). It seems then that there has been a slight falling-off in pharmacist's incomes recently, but the range was still wide in 1975.

For the other countries, reports were based on impressions rather than accurate statistics. In Germany and Denmark pharmacists' average incomes have probably increased less rapidly than those of the population as a whole or those of other similar professions. The German report notes however that the large number of new pharmacies which have opened indicates that expected incomes from this profession are still considered to be more than commensurate with the training required, despite the trend mentioned above. In Ireland, where about one million extra people were covered by some form of social security in 1972, the number of customers in pharmacies increased by about 50 % at that time. Since then however, pharmacists' incomes have kept in step with incomes of other classes. Although in Italy the average income of a pharmacist has also grown less slowly than that of actual incomes, this depends on the location of the pharmacy. Luxembourg notes that the average income of pharmacists is higher than that of the population as a whole and comparable with the income of doctors and similar professions; the report gave no indication of trends in these various incomes over the last decade.

The only exception to this general tendency is in the Netherlands, where surveys indicate that pharmacists' incomes have grown much more rapidly than incomes in the population as a whole, except for the last two years.

c) Employment

As regards the relationship between general employment policy and the pharmaceutical regulations connected with production and consumption, replies were extremely varied. Employment statistics for the pharmaceutical sector (laboratories, wholesalers, pharmacists' shops) show that different trends occur in each area. At the industrial level, increased production has been accompanied by an increase in the number of people employed except where concentration has occured (that is disappearance of small labour-intensive units in favour of large mechanized or automatically controlled production units, which are more profitable). Also, the increase in imports of patented drugs, that is finished products, has the effect of cutting down the number of people employed in domestic production. In the United Kingdom, however, the number of people employed between 1963 and 1975 has risen from 61 300 to 74 800.

TOTAL NUMBER OF PERSONS WORKING IN THE PHARMACEUTICAL INDUSTRY - NACE 257

	B	DK	D	F	IRL	I	L	NL	UK	TOTAL EEC
1973	9.276	5.409	85.500	77.329	-	64.787	-	12.199	67.100	321.600
1974	9.587	5.660	85.500	65.111	-	66.522	-	11.548	68.900	312.828
1975	9.716	5.723	85.621	65.976	-	66.827	-	11.000	71.372	316.235
1976(1)				55.338(2)						
1977(1)	14.600	6.625			8.000	± 60.000(3)	-	13.000		
1978(1)			90.000				-		74.000	

(1) IERAM 1978 (European Institute for medical research and health economy).

(2) Not including sales representatives of whom there are approximately 8 to 9,000.

(3) These figures have not yet been confirmed.

The narrowing of profit margins has had an effect, notably, on employment in the wholesale sector in some countries. It has brought about concentration and modernization, with a consequent reduction in the number of people employed. In other countries, mainly in Germany and Italy, the number of people employed in pharmaceutical wholesaling has increased probably because turnover has increased at each wholesaler.

As far as chemists' shops are concerned, pricing regulations have had little direct effect. An overall increase in consumption has led to slightly more employment, but not necessarily amongst wage-earners. In Belgium for instance the opening of a large number of new pharmacies has lead to an increase in the number of self-employed chemist-owners, with a corresponding decrease in the number of paid employees.

d) Tax revenue

There is an even greater dearth of statistics in this area. For indirect taxation, if the rate and the base remain unchanged, the amount of tax produced is a direct function of the amount of turnover.

For direct taxation on the other hand, we can only make certain suppositions. In Germany it seems that high profits are made all along the line, with resulting high tax revenue. The situation is reported to be quite different in the Netherlands and the United Kingdom. In the former, pharmaceutical regulations encourage concentration in the industry. This results in reduced tax revenue. On the other hand, there is the question as to whether concentration does not usually lead to greater productivity, a decrease in the prime manufacturing cost, and hence greater profits, which will in turn bring in more revenue from direct taxation based on them. In the wholesale sector, on the other hand, the two factors of relatively narrow profit margins and increased running costs (mainly due to larger stocks) are causing profits to be smaller with consequent reduction in direct tax revenue.

In the United Kingdom the price regulation system has the effect of restricting the increase in the value of sales, and consequently of the network of dispensing pharmacists. This in turn leads to a lower yield from income tax although, given the percentages in question, reductions in the yield are small. The same applies to the pharmaceutical industry, at least as regards the share of production which is not exported. But it is difficult to determine the precise effect of price regulation on profit. The rate of return on pharmaceutical sales in the United Kingdom between 1955 and 1975 has fallen drom 31 % to 15.4 %, in other words, today it is the same as for large United Kingdom companies in general.

The United Kingdom report indicates that "the sale of medicaments does not result in tax revenue". In reality, the situation is probably not so cut and dried, since pharmacists, like all other United Kingdom subjects, pay income tax on their earnings, which will be related directly to the volume of business which they handle, most of it sales of pharmaceutical products.

Although it was not mentioned in any report, it is assumed that no direct tax revenue results from the activities of public health organizations (municipalities in Italy), or private non-profit making ones (friendly societies in France, cooperatives in Italy), which are owners of pharmacies.

e) Role of foreign ownership

It is difficult to estimate if national pharmaceutical regulations are liable to influence the importance (as a percentage) of enterprises directly or indirectly controlled from abroad, on the national markets. Answers to this question were extremely vague. In two countries, however, (Italy and France) such effects certainly seem significant.

In France it has already been mentioned that foreign imports are virtually prohibited and thus foreign investments in or acquisition of firms in France has resulted. In 1975, there were 88 firms under foreign control (affiliates or majority shareholdings) representing 43.6 % of the turnover in pharmaceuticals, and employing 37.9 % of all labour in the industry.

In Italy the virtual freezing of profit margins combined with obligatory refunds to social security organizations has dealt harshly with firms operating largely on Italian soil. The situation, combined with low Italian labour costs and generous ceilings for the prices of imported drugs not having Italian equivalents has encouraged foreign investment in the peninsula and importation of foreign patent drugs by the national industry, to the detriment of the production of drugs which have been developed in Italy.

In the United Kingdom, on the other hand, the growing share of foreign-owned firms seems to be due less to the effects of regulations than to other specific factors such as language, access to markets, the cost of hiring, and the quality of technical staff and the reputation of the medical profession. Pharmaceutical regulations seem to have affected the ratio of imports to total sales of pharmaceuticals rather than the proportion of sales realized by firms under foreign control, whether they are situated in Britain or not.

No report was able to give statistics showing whether foreign capital invested in the pharmaceutical industry in their country came from inside or outside the EEC, for the period of the last ten years. The reports for Italy, the United Kingdom and France did give the following figures. In the case of Italy the situation relates to 1974.

	Number of firms	% of national market
ITALY		
EEC		
Belgium	2	0.4
France	10	4.5
Germany	15	12.1
Netherlands	3	1.2
United Kingdom	5	5.3
TOTAL	35	23.5
Non-EEC		
Australia	1	0.1
Austria	1	0.1
Portugal	1	0.7
Switzerland	7	10.1
United States	29	19
TOTAL	39	30.0

In the case of the United Kingdom a similar table relating to 1975 gives the following :

	Number of firms	% of national market
UNITED KINGDOM		
EEC		
France	3	5.6
Germany	5	8.2
Netherlands	3	2.5
TOTAL	11	16.3
(Other : under 1 %)		
Non-EEC		
Sweden	2	1.1
Switzerland	4	12.2
United States	24	36.5
TOTAL	30	49.8

In Italy and the United Kingdom over half the national market has been cornered by foreign-owned firms.

In France the data are for 1976 and relate to firms with a majority of foreign-owned capital and foreign branches.

	Number of firms	% of national market
FRANCE		
EEC		
Germany	22	12.8
Netherlands	7	2.1
United Kingdom	14	3.8
TOTAL	43	18.7
Non-EEC		
Switzerland	7	7.5
United States	32	17.6
Other	8	1.6
TOTAL	47	26.7

2. Effects on health

a) Freedom of prescription

In all countries the influence of the freedom of prescription on the status of health of the whole population has been recognized as very complex. The question may be examined both theoretically and practically.

Theoretically speaking, freedom in prescribing without any controls carries in itself certain risks, both to health, and of an economic and social nature. In Belgium, the problem is most acute for medication which is complicated to use (specialized knowledge needed by the doctor, special equipment) or for drugs which have a low efficacy/safety rate (wide-spectrum antibiotics, some anti-cancer drugs). The same point was mentioned in the Luxembourg report. The complexity of certain medicaments, especially the possibility of side-effects, was such that the risk of making them available to all general practitioners perhaps outweighed their value. In one particular case, the risks appeared to be so great that the drug was withdrawn from the market by the manufacturer, despite its undeniable efficacy. A better solution than withdrawing it entirely might have been to restrict its use to specialists or to GP's working in hospitals, or to both.

As both the British and Italian reports made clear, clinical freedom imposes grave responsabilities on the medical profession. Not all eventualities may have been foreseen before releasing the drug on the market : some drugs may have very rare side-effects which did not come up during tests; in combination with other medication, interactions which were not foreseen during tests may occur. Some patients may exhibit hypersensitivity beyond what could have been foreseen.

Further, doctors are often unaware of what medication has been prescribed for their patients previously by other doctors.

There are two possible approaches. The first tends to confine freedom of prescription as much as possible. This policy is followed in Denmark where the number of specific drugs marketed is limited to 1 200 approximately, and by subjecting prescriptions to very strict rules. Without going into detail we will mention that medicines are broken down into four categories according to risk (depending on toxicity and dependence). In the case of category A, (such as morphine and equivalent drugs), a prescription is noted on special numbered forms issued by the Ministry of Health, a copy of which is sent to the Ministry of Health and put into the computer. For the others, no copy is sent to the Ministry but depending on the risk, dispensing is restricted (one time; renewal is possible within one year; purchase without prescription). Certain particularly toxic medicines can be prescribed only by hospitals. The increased security has forced some drug addicts who previously obtained supplies by putting pressure on their doctors to have recourse to illegal sources.

The second approach is not to restrict freedom of prescription but to work on practitioners by providing more information or by carrying out subsequent checks.

In the first place then the doctor's professional conscience must be appealed to. In the United Kingdom and Ireland doctors are invited, but not legally bound, to notify any secondary reaction to the Committee for Drug Safety. In Ireland a Council of the Medical Register shortly to be set up under the Ministry of Health will be empowered to prohibit doctors from prescribing products which may be habit-forming if it has been proved that these drugs were prescribed without grounds or in excessive amounts. Also in Ireland, committees have already been set up in hospitals to assess the efficacy of some drugs in a hospital environment. In France there is a pharmaco-vigilance service under the central pharmaceutical department of the Ministry of Health to which doctors can notify drugs which produce certain ractions that were not foreseen during the trial period. In Belgium a similar system has just been instituted.

In Italy health insurance organizations attempt through their drug list ("prontuario") to limit the use of or eliminate entirely drugs whose usage is complicated. Preliminary consultations take place in special or hospital centres, "which is a means not of restricting the freedom of the GP, but of rationalizing action in the therapeutic area".

But as far as doctors themselves are concerned, the best course is to keep up to date with new scientific information after their studies, and even later on to take refresher courses.

Even so, negligence on the part of the medical profession can bring about sanctions. In the United Kingdom, for example, these sanctions can amount to disciplinary measures by the national health service or may fall under the civil code. But the small number of actions which are brought under these two sets of provisions seems to indicate that the consequences of clinical freedom for the health of the British patient are not particularly harmful.

The Luxembourg report put the responsibility for safeguarding the general interest fairly and squarely on those who demand the right to clinical freedom, since it is a responsibility that springs directly from that privilege. When this responsibility is too great - for example for drugs which are especially difficult to prescribe - then it is quite understandable that legislation must intervene to limit that freedom in such cases.

In the German report stress was laid on information and direct action by the public authorities and it contained various proposals that would limit the risks to the patient but would not curb clinical freedom. The risks could be reduced by a standard information system on secondary effects that would function rapidly and immediately transmit warnings to all doctors. It would also seem necessary to subject the content of prescriptions to some control. It would be advisable to withdraw from the market preparations that can have no healing effect (medication which combines different active substances).

In the last analysis, even when a prescription is presented, it is up to the dispensing chemist, who has a moral if not legal responsibility, to notify anything abnormal.

b) Freedom to buy drugs without prescription

In general it is recognized that self-medication is liable to induce dangers which require considerable caution. Only the Belgian report seems to indicate that the freedom which the public has to purchase drugs without prescription does not pose major problems that could be solved by prohibiting sales without prescription. Regulations ensure that drugs shall be delivered only by people holding professional qualifications, bound by their professional obligations and code of ethics. Furthermore, the number of drugs which may be delivered without prescription is fairly limited. In Denmark threats to health are known to exist, but are seen as being minor ones.

In Italy, Ireland, the United Kingdom and Luxembourg, on the other hand, the problem is seen as more serious. Certain products on free sale can be dangerous in some circumstances, though harmless if taken in moderation. The British report cites the example of certain analgesics such as aspirin and Paracetamol. "When taken in large doses, whether intentionally or not, these medicaments present a health hazard. Aspirin and Paracetamol occupy

the fifth and sixth places respectively on the list of drugs whose intentional use necessitates hospitalization. Junior aspirin tablets, also on free sale, constitute one of the main causes of hospitalization due to unintentional overdose."

Dangers arise not only from single massive doses, but from repeated use leading to dependence. This can occur with antihistamine preparations or those containing small amounts of opium. For products which are on sale only in pharmacies (even though a prescription is not required) the pharmacist can ensure a degree of control and give advice to the user. But the British report went on to state that it is no easier for the pharmacist than for the doctor to foresee all possible interactions which may occur, and finally, refusal to sell on the part of one pharmacist may only lead to the person obtaining the drug from another.

The German report also pointed out that unrestricted self-medication can have no good effects on public health. There are three problems :

- the danger of addiction which is not confined to toxic drugs;

- the widespread belief in the unlimited possibilities of pharmaco-therapy that is deliberately reinforced by advertising on the part of the supplier;

- the risk that very serious illnesses will not be spotted and no treatment given for a long time.

The report concludes that self-medication should be allowed only within certain limits, for example, innocuous medicines for coughs and headaches.

The problem can be solved to some extent by limiting the number of products which can be sold off prescription, according to the therapeutic category into which they fall. Recent trends in Italy have been towards limiting the number of certain categories of drugs. The patient is protected against himself and against a certain type of popular pseudo-scientific journalism, which he may not evaluate correctly. But this type of policy is hard to carry through in a single country. The Luxembourg report pointed out that, even within the EEC, legislation varied from one country to another.

For national legislation in this area to be effective, legislation in neighbouring - and especially bordering - countries must be, if not the same, at least very close; unless it is, someone from the country with the stricter laws will not have to traval far to obtain the drug which he whishes to misuse : this would multiply the protection afforded by placing the drug under surveillance in the first country.

Secondly, to place a product - on health grounds - in the category of those which cannot be procured without a medical prescription may have serious economic consequences for manufacturers. According to the Luxembourg report, it has the effect of reducing by one third the distribution of a product that was previously freely obtainable. In such a case the authorities may have to decide between conflicting health and economic considerations.

Thirdly, as regards social security cover, a major infringement of patients' rights to purchase products without prescription may entail additional expenditure for sickness insurance organizations due to the fact that the patient would be obliged to consult the doctor each time.

On this point a solution was found under the partial agreement of the Council of Europe on which the nine EEC countries are represented. The resolution could perhaps be worded in more restrictive terms.

The essential problem here is the level of education in matters of health among the general public. In Ireland awareness of this problem has lead to the setting-up of a bureau of health education, in conjunction with members of the medical and pharmaceutical professions. Its aim is to try and reduce the demand for and use of products of no value. Perhaps the measures to be taken depend on the extent to which the risks are understood. In Britain it is thought that "given the quantity of pharmaceutical products sold off prescription and the inevitable occurrence of certain side-effects, the problem does not have to be regarded too seriously." In Ireland on the other hand the development of self-medication "is leading to a considerable amount of sickness and in some cases to death", as well as to a large number of cases of hospitalization mainly through "prolonged ingestion of some analgesics, antibiotics and hypnotics".

SUMMARY AND CONCLUSIONS

Although the data collected for the countries of the Community were not complete or exactly comparable, the following points emerge from the statistical analysis :

1. In all countries of the Community the cost of pharmaceutical consumption has been increasing in absolute terms over the period 1966 to 1975. (This was believed to be the case in Ireland, even though figures were not available).

2. As a proportion of national income, pharmaceutical consumption (including tax) has been rising slightly in most countries over this period, has changed little in others and fallen slightly in one country (the United Kingdom).

3. In all countries for which information was available, pharmaceutical consumption appears to be falling as a percentage of total current expenditure on health services. But this has occurred over a period during which there has been a substantial growth of expenditure on hospital and specialist services.

4. In countries which maintain price indexes for pharmaceuticals based on baskets of products, prices of pharmaceuticals have risen less than retail prices. (This is not the case in Germany but the index contains few items and has not been recently revised). Thus the increase in consumption is not due simply to increases in the prices of existing products : the volume of consumption has increased and, in addition, old products have been replaced by new products which are generally more expensive. In some countries the extension of health insurance to cover a wider section of the population may have contributed to greater consumption. In many, but not all, countries the number of prescription items provided per person has been increasing.

5. There are substantial variations between countries in the role of pharmaceutical consumption both in relation to the total cost of health services and in relation to national income.

a) As a proportion of the current cost of health services it amounted in 1975 to over a third in Italy, about a quarter in France and less than a fifth in the other countries for which data were available. The lowest percentages were in the United Kingdom (under 14 %) and Denmark (under 11 % in 1975).

b) As a percentage of national income the variation in 1975 was from over 2 % in Italy to under 1 % in Denmark and the United Kingdom.

6. Wide variations in the average number of prescription items provided per person per year - from 4 1/2 in the Netherlands (1974) to 21 in Italy (1975 under INAM scheme by doctors paid by fee-for-service) - appear to go a considerable way towards explaining differences in the relative cost between countries. The number of prescription items per person per year was found to be lower in the three countries where general practitioners were not paid on a fee-for-service basis than in the four other countries (for which data were available) where doctors were paid on a fee-for-service basis.

The analysis of the policies pursued by the Member States and the effects of these policies cannot lead to positive conclusions relating to the influence which these policies have on the costs of pharmaceutical consumption in each of the States.

This would require a much more detailed study as well as better factual information than was at the experts' disposal.

Nevertheless, it is evident that in the pharmaceutical sector two different preoccupations inspire the measures which have been taken and these may be both complementary and contradictory.

A. HEALTH PROBLEMS

These intervene at several levels :

- not everything can be put on the market : every country has procedures (authorization, approval...) which aim to ensure that the quality, the effectiveness and the safety of a product are maintained for its prescribed uses. (Directive 65/65/EEC of January 1965) (1);

- a watch must be kept for side effects which become apparent only with use and appropriate action taken where necessary;

- the different sectors of the pharmaceutical field cannot be left in the hands of just anybody. Whether it be manufacture, prescription, or distribution, all these specialities are normally in the hands of persons who have pursued studies that were often specialized, of a lengthy duration and enabling them - in principle - to assume a certain degree of responsibility. Certain exceptions exist in the distribution sector in some countries and for certain medicines which are less dangerous than others;

- not everyone can be left to prescribe just anything : for certain medicines, prescriptions are registered. This enables public authorities to collect data and also to intervene in individual cases where necessary;

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(1) Completed with the addition of Directives 75/318 and 75/319 which came into effect in November 1976.

- the patient cannot be left to buy everything freely; in general, countries limit self-medication to a greater or lesser extent;

- free competition cannot exist between prices at the retailer level, so that the patient does not encounter any danger;

- finally, excessive geographical limitations should not be allowed to remain so that each citizen has access to pharmaceutical products.

With respect to the above, two observations can be made :

In the first instance, all of these points also have economic implications, as we shall see later. Both preoccupations can come into play at the same time.

It must also be noted that on all these points national opinions can differ appreciably. There is the risk that the transparent nature of frontiers will deprive national legislation of its role of protector in the field of public health if the legislation of the bordering country is less stringent. It would therefore seem particularly desirable to pursue the task of harmonization at Community level.

B. THE ECONOMIC IMPLICATIONS FOR THE COMMUNITY AT LARGE

The burden of cost of pharmaceutical consumption in each country presents a problem as far as concerns that part of the cost which is borne by the community at large.

An examination of the policies which have been pursued during the ten year-period (1966-1975) demonstrates that countries have tried to intervene in controlling both of the factors which constitute cost, i.e. price and volume.

1. The action taken with regard to prices

In no country are the prices of pharmaceutical products totally free at any of the levels where they arise. Naturally, the price control framework varies according to the country.

The price control framework - in most countries at least - comes into play at the production level :

- by means of price limits which are either based on the price of the product when it leaves the factory or on the presentation size of the products;

- or by means of an *a posteriori* control on profits;

- or by limiting certain components of the retail price, such as the distribution of samples or the percentage spent on publicity.

Price control can also intervene at different stages in the commercialization of the product.

In principle, if the public authorities do not object to price competition at the production stage, provision for such competition does not exist in all countries at the wholesale level (particularly where a single, compulsory profit margin is applicable to all) and is virtually non-existent at the retail level, where all are subjected to a single, compulsory profit margin for all products or all homogeneous groups of products.

Along the same lines, some countries have limited the possibilities for creating new pharmacies in such a way as to ensure sufficient income for the pharmacy taking into account the applicable profit margin for distribution.

But even in those countries where price control operates, price levels are never fixed with the sole objective of limiting public expenditure and social security expenditure in the pharmaceutical field. It is a sufficiently important economic sector affecting enough employed persons for the social (employment and income) and political (pressure groups) consequences not to be lost from view. Likewise, both these preoccupations can be brought into play together.

The decisions which are taken generally take acount of the other factors which can have a contradictory effect on price levels and either provoke price increases or limit such increases. The main factors to be considered are :

- the balance of payments with the outside world :
  - . the function of the relationship between export prices and internal market prices
  - . on account of the income obtained through taxation derived from export profits
  - . on account of the tendency to favour or disfavour the implantation of foreign firms
  - . on account of the income and expenditure arising from the exploitation of patents or licences;
- the vitality of national research ("independence" with regard to foreign suppliers);
- the contribution which the pharmaceutical profession as a whole brings to the growth of the gross national product and national income;
- employment problems;
- investment development on national territory.

2. The action taken with regard to prescriptions

a) Regulating consumption to the needs of patients

Whilst most countries have taken measures in this field (limiting the duration of treatment or the availability of repeat prescriptions), the problem has not been satisfactorily resolved. Numerous medicines are prescribed and are either never used - which constitutes a waste - or are later used in self-medication, or are thrown away, which causes health problems. Any solution which is proposed limiting prescriptions, is seen as an infringement of the liberties of the individual and in addition raises highly sensitive control problems which are felt to be a further infrigement. Consequently this problem is as much a political one as a technical one.

b) The choice of medicines prescribed

In the main, public authorities can intervene :

- either by producing a limited list of products that will be reimbursed or taken in charge;

- or by taking sanctions against practitioners who prescribe expensive medicines which are not therapeutically indispensable : in most of the nine countries a system of checking prescriptions is already being operated.

3. Action taken to change attitudes

a) Indirect action

Everything which increases the charges borne by the insured person (the existence of a contribution, the cost of this contribution, the necessity of having to advance the full amount) is undertaken in every country (with the exception of the Netherlands) with a view to restraining the patient's tendency to increase consumption. The individual reports do not quantify the real consequences of this increase and it is impossible to know if, in taking such a decision, the public authorities have modified the attitudes of the insured person.

Those measures which have been judged by the national rapporteurs to be the most effective are those which aim to modify, in the long term, the attitudes of those concerned making them aware of the economic and health problems which are raised.

b) Direct action

- with doctors

  . outside the care system (training, publicity);

  . within the care system (reducing "pressure" from the patient by abolishing the system of separate payments for each intervention);

- with patients

  . (health education, control and sanctions).

It would seem that relatively little has so far been done in this field and that any action that was undertaken would produce positive results, both at the health and the economic levels.

STUDY OF
PHARMACEUTICAL CONSUMPTION
IN MEMBER STATES

QUESTIONNAIRE

(Third Complete version - March 1977)

I. TREND OF PHARMACEUTICAL CONSUMPTION

(Please follow definition provided. If data is not available which conforms to this definition, provide available data on a different definition and please explain definition used).

Final Consumption in current Prices. Currency Unit ... (Million, Billion, etc.)

Year	1 Pharmaceuticals Purchased without Prescriptions		2 Pharmaceuticals Obtained with a Prescription		3		4 Total Consumption		5 Cost of Pharmaceuticals to Health Insurance (1)	
			Pharmacies,etc.		Hospitals (2)					
	Inc. Tax (a)	Exc. Tax (b)	Inc.Tax (a)	Exc.Tax (b)	Inc.Tax (a)	Exc.Tax (b)	Inc.Tax (a)	Exc.Tax (b)	Inc. Tax (a)	Exc. Tax (b)
1966										
1967										
1968										
1969										
1970										
1971										
1972										
1973										
1974										
1975										
1976 Est.										
1977 Proj.										
1978 Proj.										
1979 Proj.										
1980 Proj.										

(1) If possible, specify if pharmaceutical consumption arising from accidents of work and occupational diseases is included in these figures. If possible, give available data for these two items. If necessary, specify the cost of prescribed pharmaceuticals paid by the patient himself.

(2) Give, if possible, the available data and any explanation of their content and their accuracy.

DEFINITIONS :

Pharmaceuticals	: Exclude Veterinary Products. Include material for Injection.
Tax	: VAT and Local Sales Tax.
Obtained without prescription	: Pharmaceuticals actually obtained without a prescription even though a prescription could have been obtained; whether purchased in Pharmacy or other shop (e.g. supermarket). Enter total receipts for these purchases including or excluding Tax.
Obtained with a prescription	: Enter all obtained with a prescription even though some could have been purchased without a prescription.
Pharmacies etc.	: Enter total receipts for Pharmaceutical sales even if some part paid by patient or health insurance or health service. Include any honoraria or fees paid to the pharmacist. 'Etc.' is intended to include other sales outlets where prescribed pharmaceuticals might be purchased (e.g. pharmacies forming part of department stores and supermarkets or in some cases "propharmacists".
Hospital	: Enter total cost of hospital Pharmaceutical Department (Staff Costs and Overheads as well as supplies) supplying both in-patients and out-patients.
Health Insurance	: Voluntary and Compulsory. Includes a Health Service.

II. NATIONAL BACKGROUND DATA

Current Prices. Currency Unit ... (millions, billions, etc.).

Year	6 Total Cost of Health Services			7 Mid-Year Population		National Accounts		Price Indexes	
	Pharmaceuticals	Total		Total	Covered by Health Insur.	GNP	NI	General retail	Pharmaceuticals
		Inc.Tax (a)	Exc.Tax (b)	(a)	(b)	(a)	(b)	(a)	(b)
1966									
1967									
1968									
1969									
1970									
1971									
1972									
1973									
1974									
1975									
1976 Est.									
1977 Proj.									
1978 Proj.									
1979 Proj.									
1980 Proj.									

Definitions :

Cost of Health Services : Running Costs only (Excluding Capital and Depreciation).
Total cost whether paid for by Government, Health Insurance, Charity or the Patient.

Health Insurance : Voluntary and Compulsory. Includes a Health Service.

GNP : Gross National Product.

NI : National Income.

Price Index (es) : Explain in a brief note how index is constructed.

III. FOREIGN TRADE OF PHARMACEUTICALS

5Enter Totals where breakdown not available).

For 1975 or last available Year. Specify Year ... (If possible give figures for 1970).

Home Production			Total
Raw materials Final Products			
Exports (free on board)	to EEC	to non-EEC countries	
Raw materials Final products			
Total Exports			
Imports (cost insurance freight)	from EEC	from non-EEC countries	
Raw materials Final products			
Total Imports			
Net home consumption (factory prices)			

Definitions :

Raw materials and final products :

Give, if possible, an estimate of quantities for human consumption.

Final products :

Pharmaceutical products ready to use.

IV. A. What do you considerer to be the main reasons for the change in Consumption indicated in Table 1 above ?

B. Is it possible to indicate quantitatively what proportion of the change in Consumption was due to specific factors ? Give information where available, as, for instance, any modification concerning scope of social security, demographic changes, new regulations.

V. PHARMACEUTICAL CONSUMPTION BY HEALTH INSURANCE (VOLUNTARY AND COMPULSORY) OR HEALTH SERVICES

Prescriptions provided outside Hospital Only

Year	Percentage of population covered	Proportion of consultations (or visits) leading to one or more prescriptions	Average number of prescription forms for person covered	Average number of prescription items per prescription form	Proportion of expenditure paid by health insurance % (outside hospitals)
1966					
1967					
1968					
1969					
1970					
1971					
1972					
1973					
1974					
1975					

Add any comments to explain the trends indicated above.

VI.A. GIVE, WHERE POSSIBLE, FOR LAST AVAILABLE YEAR, BREAKDOWN OF VALUE AND NUMBER OF MEDICINES PRESCRIBED ISSUED UNDER COMPULSORY AND VOLUNTARY HEALTH INSURANCE (OR HEALTH SERVICE), BY :

a) Age Groups (1) and Number of Persons covered in those age groups.

b) Social Classes and Number of Persons covered in those social classes.

c) Family Size and Number of Families covered by size.

d) Therapeutic Category (2).

B. LIST THE TEN PRODUCTS WITH THE LARGEST SALES IN VALUE UNDER HEALTH INSURANCE (COMPULSARY AND VOLUNTARY) OR HEALTH SERVICE IN THE LAST YEAR WHERE FIGURES ARE AVAILABLE.

C. TOTAL NUMBER OF PHARMACEUTICAL PRESENTATIONS AVAILABLE ON THE MARKET. TOTAL NUMBER OF PHARMACEUTICAL PRESENTATIONS THAT COULD BE PAID BY HEALTH INSURANCE.

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(1) For instance : from 0 to 5 years; from 6 to 20 years; from 21 to 60 years; more than 60 years.

(2) Mr ROBERT prepared a list of 18 therapeutic categories (antibiotics, sedatives, barbiturates, etc.).
It is possible to give a percentage of consumption for each category.

PART TWO - POLICIES OF THE MEMBER STATES

(Where applicable answer questions in terms of the experience of the period 1966-1975. Point out any modification observed during this period or any draft legal modification).

VII. ADMINISTRATION BY PUBLIC AUTHORITY OF THE MARKETING OF PHARMACEUTICALS

A. Regulation of sales

a) General National Regulation

1) What Organization is empowered to decide what pharmaceuticals can legally be marketed ?

2) What criteria are used (e.g. safety, efficacy, quality) and have these criteria been changed in the review period ?

3) In which year was the present system of regulation using present criteria introduced ?

4) Was it applied only to new products ? If so, are there plans to apply the system to old products ?

5) Follow-up given to the three EEC Directives.

b) Regulation of Sales or Purchases by Health Insurance Organisations (or Health Service)

1) Is there a restricted list of pharmaceuticals which will be paid for (in whole or part) by health insurance for use outside hospital ?

IF SO :

2) What criteria are used to decide what products are admitted to the list ? Do they include :

i) Medical Criteria ?
ii) Economic Criteria (Price) ?

3) What criteria are used to remove a product from the list ?
Do they include :

i) Quantity Sold ?
ii) Excessive Price
iii) Failure to make adequate provision for research
iv) Implications for International Trade

- licence sales
- imports and exports.

B. Economic controls

a) Production

1) Do pharmacists have a monopoly of production in the pharmaceutical industry ?

2) Are there obstacles to the establishment of firms which are under the financial control of firms with headquarters located outside the EEC ?

b) Are there national provisions laid down to control importation ?

c) Distribution

1) Elements of Monopoly :

i) Have pharmacists the monopoly of ownership ?

ii) Have pharmacists a monopoly of the retail and wholesale sale of pharmaceuticals ?

iii) Is it total or is it shared by doctors and any others ? Specify.

iv) Can certain or all pharmaceuticals be sold by shops not controlled by pharmacists providing they employ a pharmacist ? Specify whether all or some pharmaceuticals.

v) Can a shop which sells pharmaceuticals sell other products ? If so, what products ?

2) Conditions of Establishment :

i) Is there control over the number of shops or outlets of retail pharmacists ?

ii) If so, what criteria are used to control this limitation (excluding the setting-up of non-profit-making pharmacies) ?

iii) How many shops or outlets were there per million population (excluding hospital pharmacies) at last year when figures available ? Specify. What has been the trend over the review period ?

iv) Exceptions for non-profit-making pharmacies (e.g. hospitals, dispensaries owned by sickness funds, mutual societies) ? Specify.

3) Regulations for the purchase of goodwill :

i) profit-making ownership (appropriation)

ii) non-profit-making ownership :
- hospital pharmacies,
- mutual societies,
- others.

VIII. PRICES

A. Production

a) Are the prices set by the industry regulated ?

IF SO :

1) By what agency ?

2) Using what criteria ?

3) What is, if it exists, the permitted percentage in the breakdown of the prices ?

4) If there is a revision of the prices, what rules govern the revision ?

5) What are the general effects of the system of price regulation (e.g. increasing or reducing prices) ?

6) During the review period has there been one or more price freeze which has been applied to pharmaceuticals ? Specify.

7) During the review period have there been provisions under which firms could be required to pay back excessive profits to health insurance organisations (or the health service) and if so has use been made of these provisions ?

8) Is it allowed for a firm to give a quantitative discount to retail pharmacies ?

b) What percentage of the receipts of the pharmaceutical industry goes on the following :

1) Administrative costs.

2) Manufacture (including transport and the cost of imported raw materials) and packaging.

3) Research and Development.

4) Patents and Licences.

5) Sales Promotion.

6) Profit.

(If a breakdown of receipts is not available in this form give whatever breakdown is available).

B. Importation

a) Are there special regulations to set up prices of imported pharmaceuticals ?

IF SO :

b) Are there special discrepancies for non EEC countries ?

c) What about the setting up of prices for such products ?

d) General considerations on importation policy (distinguish clearly, if possible, pharmaceuticals imported after packaging and raw materials imported before packaging in the consumer country).

C. Distribution

a) Wholesale

1) What is the average margin in the wholesale price ?

2) Is there regulation of wholesale margins ?

IF SO :

3) By what agency ?

4) With what effects ?

b) Retail

1) What is the average margin in the retail price ?

2) Is there regulation of retail margins ?

IF SO :

i) By what agency ?

ii) Explain current regulation.

iii) With what effects ?

3) Are there any special honoraria paid to pharmacists ? Specify.

4) Are 'hidden' advantages provided by manufacturers ? Specify.

5) During the review period have there been provisions under which wholesalers could be required to repay excessive profits to health insurance organisations (or NHS) and if so has use been made of these provisions ?

D. Taxation

a) Are national indirect taxes (e.g. VAT) levied on all or some pharmaceuticals ? If so, at what rate or rates ?

b) Are there local indirect taxes levied on all or some pharmaceuticals ? If so, at what rate or rates ?

IX. REGULATION OF CONSUMPTION

A. The doctor

Is action taken to regulate or inspect what the doctor prescribes ?

IF SO :

1) Who does the regulation or inspection ?

2) How does it operate ?

3) Are there sanctions ? If so, what ? By whom ?

B. Sales promôtion

a) Is there control of the quality of sales promotion material :

   1) Sent to doctors ?

   2) In advertisements in journals ?

      IF SO :

   3) Who operates it ?

   4) How does it operate ?

b) Is there any restriction on the activities of representatives of firms who visit doctors ? If so, specify the control and how it is policed.

c) Is there any restriction on hospitality provided to doctors by firms ? If so, specify.

d) Is there any restriction on the sending of samples of products to doctors ? If so, specify.

e) Is there any control of the quantity of sales promotion activity undertaken by firms ? (for instance provisions for limiting the number of samples).

C. The pharmacist

a) Is there any restriction on the quantity, the duration or the renewing of a prescription which a pharmacist may dispense under health insurance (or the NHS) ?

b) Is the pharmacist expected, required, or allowed to dispense cheaper substitutes for what the doctor prescribes in any cases ? If so, specify.

D. The patient

a) Financial

1) Is there legal provision to control the prices charged to the public by retail pharmacies ? If so, specify.

2) Explain the charges (flat rate or percentage) falling on the patient under health insurance (or the NHS). Are there variations by type of product ?

3) Is it forbidden for the patient to take out private insurance against that part of the cost of pharmaceuticals which the patient is expected to pay under health insurance (or the NHS) ?

4) i) Does health insurance (or the NHS) pay the retail pharmacists directly for all or part of the cost of pharmaceuticals ?
If so, specify.
If not
ii) Is it forbidden to do so ?

b) Quantitative

Are there principles to take into account or lay down to limit the number or type of products which can be obtained without prescription ?
If so, specify.

X. THE EFFECTS OF REGULATION

A. Economic effects

a) Exports and Imports

1) Does the regulation of prices have effects on exports and imports ? If so, specify.

2) Do regulations of health insurance have effects on exports and imports ? If so, specify.

3) Do regulations of safety and efficacy have effects on exports and imports ? If so, specify.

b) Pharmacists' Incomes

1) Has the average income per capita of retail pharmacists increased more or less than average incomes over the review period ?

2) Have the pharmacists' earnings per capita increased more or less than earnings of similar liberal occupational activities (for example, doctors, architects, etc.).

c) Employment

What effects does the regulation of pharmaceuticals have on employment :

1) In manufacturing ?

2) In wholesale distribution ?

3) In retail distribution ?

Please specify what the national trends relating to employment policy are and try to discern what the relationship is between these policies and pharmaceutical production and consumtion (1).

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(1) Give also statistical figures on :
- i) number of laboratories
- ii) personnel of laboratories
- iii) number of wholesalers
- iv) personnel of wholesale distribution
- v) number of pharmacies
- vi) personnel of pharmacies
- vii) trends in consumption between 1970 and 1975.

d) Tax Revenue

What effects does regulation have on tax revenue :

1) From industry ?

2) From distribution ?

e) Role of Foreign Ownership and Control

1) How does regulation affect the proportion of sales (1) in your country from foreign-controlled firms ?

2) How does regulation affect the proportion of sales (1) in your country from nationally controlled firms ?

3) What proportion of capital employed over the review period has been financed by :

i) Other countries in the EEC ?
ii) Other countries outside the EEC ?

B. Effects on health

a) Does clinical freedom have adverse health consequences ? How serious is this problem ?

b) Does the right of the public to purchase pharmaceuticals without prescription have adverse health consequences ? How serious is this problem ?

XI. CONCLUSIONS (ad libitum)

(1) Sales of final products and raw materials.

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- **Trends in expenditure**
- **Main measures taken and underlying objectives of public intervention in this field**

by B. ABEL-SMITH, Professor of Social Administration
London School of Economics and Political Science
P. GRANDJEAT, Conseiller Référendaire à la Cour des Comptes, Paris

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