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FINNISH HIGH-TECH INDUSTRIES AND EUROPEAN INTEGRATION; SECTORAL STUDY 3: THE PHARMACEUTICAL INDUSTRY

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ABSTRACT: This paper analyzes the Finnish pharmaceutical industry in an international context in relation to the EC integration process and presents future scenarios for the industry.

The moves towards a large single market have stimulated structural changes in the European pharmaceutical industries. Furthermore, the regulatory rules in licensing and registration are being harmonized, new forms of cooperation in R&D are opening up, and the competition is increasing.

The Finnish pharmaceutical industry, in practice, is dominated by two firms. The industry is shifting from a strong reliance on eastern markets to increased emphasis on Western Europe. The market shares of domestic suppliers in Finland are falling as well. The upcoming changes in patent legislation are another factor adding impetus to the strategic shift towards manufacturing own original products. In short the industry is undergoing major structural and strategic changes. The effects of the European integration and future scenarios are presented in the conclusions of the paper.

KEY WORDS: Pharmaceutical industry, EC integration, high technology

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TIIVISTELMÄ: Työn tavoitteena on analysoida Suomen lääketeollisuutta kansainvälisillä markkinoilla varsinkin suhteessa Euroopan yhdentymiskehitykseen ja luonnostella tulevaisuuden skenaarioita tälle teollisuudenalalle.

Euroopan integraatiokehitys on vauhdittanut Euroopan lääketeollisuuden rakenteellista muutosta. Lisäksi lisenssiointia ja rekisteröintiä koskevat säännökset harmonisoituvat Euroopassa, uusia T&K-yhteistyömuotoja avautuu ja kilpailu kovenee.

Suomen lääketeollisuus on keskittynyt käytännössä kahteen yritykseen. Vienti itään on vähentynyt, Länsi-Euroopan vienti on kasvanut ja kotimarkkinoilla suomalaisten markkinaosuus on laskussa. Tulevat patenttilain muutokset vaikuttavat voimakkaasti teollisuuden strategiseen siirtymiseen enenevästi omien alkuperäislääkkeiden tuotantoon. Kokonaisuudessaan teollisuus on merkittävän rakenteellisen ja strategisen muutoksen vaiheessa. EY-integraation vaikutukset ja tulevaisuuden skenaariot on esitetty yhteenvetokappaleessa.

ASIASANAT: lääketeollisuus, EY-integraatio, huipputeknologia

PREFACE

The study on the future outlook of the Finnish high-tech industries in the light of the European Community's internal market program was initiated in late 1988. The project assesses the present position in selected high-tech sectors, especially in relation to the EC, and analyses the future scenarios in relation to the European integration process.

The study is carried out by Teräs-Kari Ltd Consulting with the financial support of the Ministry of Trade and Industry. The study is conducted by Research Economist Severi Keinälä under the supervision of Research Manager Harri Luukkanen.

ETLA, The Research Institute of Finnish Economy is conducting and organizing various studies related to European integration on both the microeconomic and macroeconomic levels. The present study on the pharmaceutical industry supports ETLA's ongoing activities in this field.

Previously published papers on the telecommunications and the data procssing equipment industry were also prepared by Teräs-Kari Ltd Consulting. The final report will be available in the beginning of 1990.

Pentti Vartia
Managing Director
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LIST OF ABBREVIATIONS

CPC	Community Patent Convention
CPMP	Committee for Proprietary Medicinal Products
EFPIA	European Federation of Pharmaceutical Industries' Associations
EPC	European Patent Convention
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
OTC	Over-the-Counter
NCE	New Chemical Entity
PIC	Pharmaceutical Inspection Convention
WHO	World Health Organization

1 Introduction

The pharmaceutical industry is a peculiar one. Drug companies are making enormous R & D investments to produce medicines for people that in most cases do not decide what they buy, and further more, do not pay for them. Doctors prescribe, governments pay, and people take the medicine. Only a minor share of the demand is created by over-the-counter products.

The demand is created by the illnesses and health care needs of the people, but the governments and doctors have a substantial impact on the pharmaceutical industry's structures and pricing. On one hand governments' attempt to curb drug costs, but simultaneously require lengthy and expensive trials to ensure the safety of the products. Some governments allow high domestic price structures to enable the industry to create enough funds for the development of new chemical entities, while others do not support the domestic pharmaceutical industry.

The EC integration process has great potential in altering the existing structures of the European pharmaceutical industry. Some directives are already in effect, but the central issues including the licensing and marketing practices are yet on the table.

The Finnish pharmaceutical industry has been concentrated into fewer units, and reorganization is still taking place within the two large producer groups. This has been partly brought about by the changing patent legislation that forces the Finnish industry to shift its strategies towards its own original products and seek for export markets in the western industrialized nations.

2 Global Industry Background

In the following a broad picture of the industry will be drafted introducing products, the nature of R & D activities, pricing mechanisms, markets, production and producers, and finally, international trade in pharmaceutical products.

2.1 Products

A medicinal product is "any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis of to restoring, correcting, or modifying physiological functions in human beings or in animals is likewise considered a medicinal product."[1]

The Finnish definition also refers to "a preparation or substance that is used internally or externally to cure, mitigate or prevent disease or its symptoms in man or animals", or "to investigate the state of health or to determine the cause of disease in humans or animals", but it does not include the "modifying physiological functions" as in the EC definition.[2]

Medicinal products, drugs, or pharmaceutical products belong to the chemical industry covered by the SITC 54 heading of the OECD that encompasses the entire medicinal section, as well as specific active substances. This study does not penetrate into the subcategory level, but approaches the pharmaceutical industry as a whole.

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1 EC Directive 65/65 (OJ V 22 og 9.2.1965)

2 Kansainvälinen Lääketeollisuuden Suomen Yhdistys.

Pharmaceutical products can be divided into four groups each having distinct features[1] (various other divisions are used as well):

1. breakthrough discoveries
2. innovative imitations
3. improvements, and
4. "me too's"

Breakthrough discoveries form the elite of the patented sector and represent the most advanced high technology sector. A company has developed a new chemical entity (NCE) and is producing it under patent protection, and has possibly sold or swapped production licenses to producers in other markets.

Innovative imitations also belong to the patented sector and contribute to the development of pharmaceuticals sector. The difference from the previous group is that a NCE created belongs to the same category as the preceeding break through innovation.

Improvements are made to differentiate the product from that of competitors by differing dosage forms, effect times, method of administration, package design, and through combining several substances to achieve synergy effects or to reduce adverse effects.

The "me too's" are imitations of existing products that are not protected by patents either geographically or when the patent has expired. This is also called the generic sector, where several producers manufacture similar products at a considerably lower price. Lower prices are largely due to fractional R & D input of the "me too" sector, and also due to the fact that actual production of pharmaceutical goods is relatively inexpensive in relation to the substantial development costs.

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1 Hansén, 1981.

Patented products are mainly "ethical" or prescription drugs, but the generics include both prescription and over-the-counter (OTC) drugs. OTCs are dispensed through pharmacies without a doctor's prescription.

Besides the patented, generic and OTC drugs, pharmaceutical raw materials or active substances are traded across frontiers.

2.2 Research and Development

The pharmaceutical industry depends heavily on R & D activity. It has frequently been stated that "develop or die" applies very strongly to this industry. The formulation of New Chemical Entities (NCE) is a long and expensive process and new drugs are not invented by chance, but after determined and systematic research work. R & D energy is strongly biased towards common illnesses in the developed world where large markets with a strong purchasing power exist. Rare diseases do not provide a sufficient market, and developing countries do not possess the purchasing power to commercially justify the high R & D investment.

The creation of a NCE takes on the average over ten years of work and the costs are estimated to exceed ECU 100 million.[1] This is a considerably long development period and the costs are proportionally very high, especially when the time and money invested does not guarantee successful results nor commercial profitability. On the other hand numerous small companies generate new substances on much lower costs. The costs are influenced by differences in efficiency of the research work, and also the NCEs belonging to innovative imitations category are often much less expensive to develop.

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1 Panorama of EC Industry, 1989.

The high global investments in R & D in the pharmaceutical industry results in the introduction of some 50 (in 1984-88 between 43 and 63) new medicines annually. Although the pharmaceutical industry has developed remedies to fight a large number of illnesses, a huge potential in this field still exists since about 30,000 illnesses have been diagnosed with medical treatment developed for only one-third of them.[1]

High development costs are not only caused by difficulties and complications in drug discovery, but also by the lengthy trials required before releasing a drug for general distribution under a doctor's prescription. The discovery of a NCE represents only 30 percent of R & D costs, while the remaining effort is spent on development and testing.[2]

Drugs are chemicals applied to a human and animal bodies, and to avoid harmful side effects governments require stringent testing procedures. Testing procedures are often carried out in several markets simultaneously. On one hand this is often necessary to satisfy the requirements of health officials, but this also promotes the NCE to the doctors by involving them in the trials. Opinions have been voiced that with this practice at least some of the R & D expenditures should be categorized as marketing expenditure.

The costs of R & D work in the pharmaceutical industry are mainly covered by the industry itself. Previous discoveries presently on the market are generating the large funds required for the development of NCEs. Consequently, one can claim that R & D work depends on the sufficient profit margins of existing products and the protection of intellectual property rights. Presently patent protection is granted for 20 years, but 8 to 12 years of this time is being spent on the R & D process itself. This cuts the effective time for commercial exploitation under patent

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1 Hakkila, 1989.

2 Green, 8.11.1988.

protection roughly in half. Once the patent expires emerging new competition decreases the prices rapidly thus cutting the profit margins needed to finance the ongoing R & D work.

In Europe demands for an extended patent protection have been called for, especially since US and Japanese companies have been granted extended protection periods in their home markets to compensate for the time required to fulfill administrative formalities.[1]

Estimates of R & D expenditures in the industry vary from 10 to over 15 percent. Some leading companies spend up to 20 to 25 percent of their turnover on R & D activities.[2] The estimates of European expenditure on R & D varies between ECU 4 billion[3] and ECU 6 billion as stated in the following table.

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1 Panorama of EC Industry, 1989.

2 EFPIA, Panorama of EC Industry, Hakkila.

3 Panorama of EC Industry, 1989.

Table 1: Pharmaceutical R & D in Europe in 1987

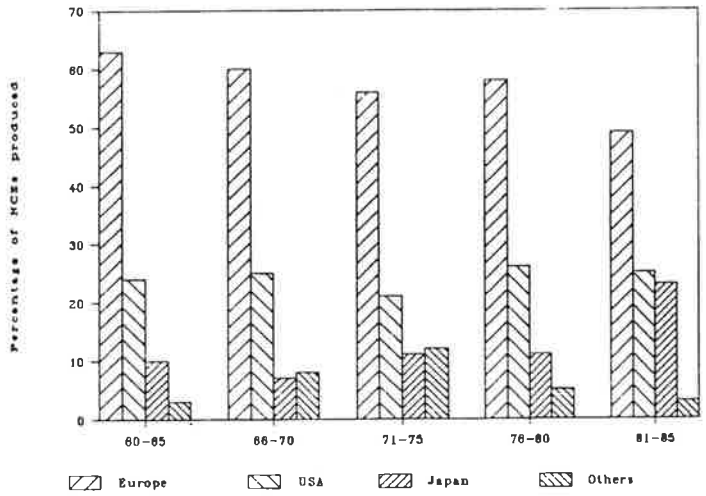
	R & D million ECU
Belgium	116
Denmark	96
France	1,031
Germany	1,301
Greece	..
Ireland	..
Italy	635
Netherlands	135
Portugal	..
Spain	60
United Kingdom	954
EC total	4,328
Austria	..
Finland	41
Norway	31
Sweden	310
Switzerland	1,214
EFTA total	1,596
Europe total	5,924

Source: EFPIA

There are great differences in R & D spending between European nations. The Panorama of EC Industry estimates R & D percentages of turnover to vary between 7.7 and 18 percent in the EC area. The actual funds spent on R & D are high in Germany, France, Italy, and the UK, while Belgium, Denmark, Spain, and the Netherlands represent the lower end of the scale. The Economist Advisory Group, in comparing the R & D spending in the EC as a proportion of the turnover, find the highest ratio in the UK, West Germany, and France, followed by the Netherlands and Belgium, with the middle range being Denmark, Italy, and Ireland, while the R & D activities in Spain, Greece, and Portugal were very low or non-existent (Appendix, Table 2). Of the EFTA countries Switzerland has a very strong R & D input in the pharmaceutical sector.

When approaching the R & D field from a global perspective European dominance is quite evident. European companies have developed nearly half of the top 50 brand products on the world markets, while the USA and Japan together are responsible for the other half.[1] The USA has had a clear position as second, but it is being challenged by Japan in the 1980's. Japan accounted for 19 out of 56 NCEs introduced in 1987. In the following graph the deterioration of Europe's leading position is clear, while the Japanese share has had a steady upward climb since the 1960's. At the national level the USA is the leading country in new innovations, since Europe is fragmented into 18 nations.

Figure 1: New Molecules and Their Sources
1960 - 1985



Source: Panorama of EC Industry, 1989.

Lately biotechnology has been a much discussed topic in connection with pharmaceutical R & D. The term "describes a range of scientific procedures concerned with altering genetic material in living organisms either to develop new biological entities or make existing natural processes more efficient". Yet there are only about 12 biotechnology-derived drugs for sale. In the USA 81 biotechnology-based drugs and vaccines are in various stages of development, of which 67

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1 EFPIA

are in clinical trials and 14 are awaiting governmental approval to enter the market. The future of biotechnological products is yet extremely unclear since patent protection problems have not been solved.[1]

2.3 Pricing

Pricing systems of pharmaceutical products are strongly influenced by large R & D investments and by the large role of governments' reimbusements of drugs. The pharmaceutical industry is characterized by oligopolistic or even monopolistic market structures that also influence pricing structures.

R & D investments require sufficient profit margins from commercialized drugs to finance the development of new drugs, especially since the industry finances a large majority of the research. This imposes pressure for high prices during the initial years of commercialization when the product is sold under patent protection in order to generate sufficient funds to recover the R & D investment before competition pushes the price down.

In most European nations the government is the main payer of pharmaceuticals. Insurance companies also cover a large share of costs in this field. In the following table the share of state and insurance payments of pharmaceuticals in Europe is presented.

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1 Marsh, 8.11.1988.

Table 2: Payment for Pharmaceuticals by Insurance and State Funding in 1986

	percent
Belgium	52.0
Denmark	53.4
France	65.2
Germany	56.4
Greece	n/a
Ireland	48.0
Italy	64.0
Netherlands	63.5
Portugal	67.2
Spain	66.9
United Kingdom	75.6
Austria	50.4
Finland	61.8
Norway	60.0
Sweden	62.0
Switzerland	52.0

Source: EFPIA

National administrators wish to curb spending on pharmaceuticals as a part of health care costs, but at the same time they are trying to stimulate a healthy domestic pharmaceutical industry. There is a built-in conflict of interest on the government's side in the pharmaceutical industry.

The situation varies greatly even within the EC area. Each country has a different price structure system, the UK being quite particular. The high price countries, namely West Germany and the UK allow drug companies to maintain high prices in order to support expensive R & D inputs, while in low price countries, especially Greece, Portugal, and Italy, the governments place more emphasis on minimizing health care costs instead of supporting the domestic industry. In the low price countries pharmaceutical production is concentrated on OTC and generic products. Consequently, the prices vary greatly in Western Europe. Discrepancies between the countries are more pronounced in the retail prices than in the manufacturers prices. In the

following table the price levels in the EC are being compared.

Table 3: Comparative Price Index for EC Pharmaceuticals in 1988 (EC average = 100)

Country	1) Index of Retail prices	Index of Manuf.prices
Portugal	61	78
France	68	69
Spain	69	73
Greece	71	72
Italy	78	87
Belgium	85	87
UK	110	118
Ireland	128	132
Netherlands	131	129
Denmark	141	122
West Germany	146	133

1) Not weighted, compared with average prices

Source: Scrip/89 7.7.1989 No. 1427 p. 4-7

In the high price countries the system explicitly favors locally-based suppliers. For example, in the UK the domestic firms and companies with large R & D and production investments in Britain are permitted higher prices and higher profits. This provides an incentive for R & D work done in the UK, in effect, a hidden subsidy. The scheme has created a strong pharmaceutical industry in the UK.[1] These indirect subsidies are strictly interpreting against the spirit of the EC regulations.

The pharmaceutical industry tolerates the low price levels in certain countries since the production costs of drugs are relatively low compared to the high initial investment in R & D. The high price sales in domestic markets generate income to recuperate the R & D investment, and additional overheads can be accumulated from sales to lower priced export markets. One could generalize that high price countries have a stronger domestic production, while low

1 Marsh, 15.10.1988.

price countries nations produce generic or out-of-patent products without much R & D effort.

2.4 Markets

The global pharmaceutical market is dominated by the developed countries with a strong purchasing power. Only 25 percent of the world population in developed countries consume 75 percent of the total drug supply according to the World Health Organization (WHO). In the following table the global market shares of the triad are presented.

Table 4: World Pharmaceutical Markets

	Percent
North America	30
West Europe	25
Japan	15
Other	30
Total	100

Source: WHO

The value of the world pharmaceutical markets has been estimated at USD 120 to 135 billion,[1] and the EC market was estimated at ECU 33 billion (USD 37 billion) in 1987.[2] In the following table the US estimates of the world markets are presented. The estimates for 1992 for the triad are USD 53,700 million for Europe, 54,130 for the USA and 37,779 for Japan. The growth is expected to be 7.2 percent in Europe and 10.3 percent in the USA, while growth in Japan is expected to reach 8.3 percent.

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1 various sources

2 Panorama of EC Industry

Table 5: World Market in 1983-87
million USD / percent

		1983	1984	1985	1986	1987
World	USD	85,700	87,100	94,100	110,370	134,400
	%	100	100	100	100	100
Europe	USD	21,300	20,200	22,001	29,800	38,000
	%	25	23	23	27	28
USA	USD	21,266	24,226	26,451	29,238	33,223
	%	25	28	28	26	24
Japan	USD	13,389	13,072	14,038	19,805	25,359
	%	16	15	15	18	19
Other	USD	29,745	29,602	31,610	31,527	37,818
	%	34	34	34	29	29

Source: US estimates / Panorama of EC Industry '89

North America and Japan are large homogeneous markets, while the European market is fragmented into 18 separate markets. In the national markets the prices vary as explained before, but consumption patterns also differ to a significant degree. The differences stem from differences in income, as well as from differences in attitudes towards drugs and in the tradition of medication.

Table 1 in the Appendix presents certain indicators of various domestic markets within the EC area. Clear similarities can be seen between Belgium, France, Italy, and Spain, and on the other hand between Denmark, Ireland, the Netherlands, and the UK. West Germany has similarities with both groups.[1] In the following the consumption per capita is presented for Western Europe.

1 The Cost of Non-Europe

Table 6: Pharmaceutical Consumption Per Capita in 1985

	ECU
Belgium	88
Denmark	67
France	112
Germany	119
Greece	34
Ireland	36
Italy	88
Netherlands	43
Portugal	39
Spain	42
United Kingdom	64
Austria	77
Finland	76
Norway	49
Sweden	75
Switzerland	124
Europe	82

Source: EFPIA

A large majority of the market is dominated by the so-called "ethical" drugs, or prescribed medicines either through retail pharmacies or in hospitals. This segment represented 88 percent of the entire pharmaceutical market in the EC area, while over-the-counter (OTC) drugs accounted for only a 12 percent share of the total market. Details of national differences are presented in Table 1 of the Appendix.

The demand for drugs during the 1980's has risen at a healthy rate, in developed countries at 10 percent annually. Partially this growht is explained by emergence of new expencive drugs, and it should be kept in mind that the rise takes place mainly in monetary terms, not in quantities of medicines consumed. Growth is expected to continue for two reasons. First, new drugs for previously incurable diseases are being invented, i.e. for cancer and aids, and a large market for personality and mental disorder

pharmaceuticals are being opened with advances in brain research.[1]

Secondly, a growing population directly increases the demand, but especially an increasing proportion of elderly people is creating a huge and increasing market for medications to combat many of the diseases that afflict people later in life.

2.5 Production

The production of pharmaceuticals is also dominated by the triad, with Europe holding the leading position. Europe's share of world production (31%) is significantly more pronounced than the market share (25%). In the USA the situation is reverse, the market share (30%) exceeds the production share (22%). Japanese production (17%) is just slightly higher than the market (15%).

Table 7: World Pharmaceutical Production in 1985

	Percent
Europe	31
USA	22
Japan	17
Other	30
Total	100

Source: EFPIA

The USA is the largest pharmaceutical producing country, and even the Japanese production exceeds that of the individual European nations. France, West Germany, the UK, and Italy are responsible for nearly three-fourths of the West European production. All of the EC countries excluding Luxembourg have domestic pharmaceutical production, although

1 Marsh, 8.11.1988.

the share from Greece and Portugal are nominal. Of the small EFTA countries Switzerland stands out as a considerable pharmaceutical producing nation. Swiss industry has largely concentrated on the medical industry and Switzerland earns a large share of its export earnings from this industry. In the following table the European production values and production shares are introduced.

Table 8: Pharmaceutical Production in Europe in 1986

	Production million ECU	%
Belgium	1,077	2.5
Denmark	724	1.7
France	8,824	20.5
Germany	9,573	22.3
Greece	296	0.7
Ireland	1,056	2.5
Italy	6,523	15.2
Netherlands	943	2.2
Portugal	288	0.7
Spain	2,879	6.7
United Kingdom	6,606	15.4
EC total	38,789	90.3
Austria	535	1.2
Finland	358	0.8
Norway	44	0.1
Sweden	613	1.4
Switzerland	2,616	6.1
EFTA total	4,166	9.7
Europe total	42,955	100.0

Source: EFPIA

A total of about 10,000 pharmaceutical companies operate in the world, but the top 100 account for roughly 80 percent of the sales and the top 10 for about 25 percent of the total sales.[1] In Western Europe some 2,100 firms produce pharmaceuticals, out of which some 1,500 are in the EC

1 WHO, Panorama of EC Industry

area, but only about 20 have annual sales exceeding GBP 180 million.[1]

The industry is largely dominated by large companies with the resources to develop NCEs. R & D costs are very high and substantial sales are needed to support the activity. In the EC area there are some 60 firms that have the capacity to develop NCEs. EC-based firms represent slightly over half (33), while the remainder is dominated by US firms (29), and a few Swiss (4) and Swedish (3) production units cover the rest. These large multinational corporations usually have organized the marketing activities on a country-by-country basis, while the production of active ingredients is centralized on a few production units. Following the same model the research work is done centrally, commonly in the country of origin. The conversion of material into dosage forms, as well as the clinical and formulation work is often decentralized.[2]

A large number of smaller companies concentrate mainly on generics or OTC products, or operate domestically with well-established remedies. Their R & D activities are limited, as are the international operations. The relative cheapness of the production of drugs allows a large number of small companies to exploit markets with products of expired patent rights.

Among the largest pharmaceutical producing companies the US firms are quite dominant. Swiss industry, although smaller, is very visible among the innovative large corporations. Of the EC countries West Germany and the UK are strong, while French firms are less dominant. Research-based companies of Belgium, Denmark, Italy, the Netherlands, Finland, and Sweden have strengths in some areas, but have their limitations of moderate size. Other European producers are

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1 EFPIA; Marsh, 11.10.1988.

2 Economists Advisory Group, 1988

uniformly weak. Few Japanese firms appear on the list of largest corporations, although they mainly supply their domestic markets. In the following table the leading pharmaceutical companies are introduced.

Table 9: Top Pharmaceutical Companies Worldwide

	Sales in 1987 FIM billion*	Market share**
Merck & Co (USA)	17.9	4.7
Hoechst (WG)	13.7	2.8
Ciba-Geigy (CH)	13.4	2.9
Glaxo (UK)	12.4	2.6
AHP (USA)	12.3	2.4
J & J (USA)	11.3	1.8
Takeda (JP)	10.8	2.4
Bayer (WG)	10.8	---
Sandoz (CH)	10.7	2.3
Pfizer (USA)	10.3	2.3
SmithKline (USA)***	10.2	2.1
Lilly (USA)	9.8	2.3
Bristol Myers (USA)	9.4	2.2
Roche (CH)	8.9	---
Schering Plough (USA)	8.3	---
Upjohn (USA)	8.1	---
Squibb (USA)	8.0	---
Sankyo (JP)	7.9	1.6
B Ingelheim (WG)	7.5	1.7
ICI (UK)	7.5	1.8
Rhone Poulenc (FR)	7.4	1.8
Warner Lambert (USA)	7.3	1.0
Beecham (UK)***	7.2	1.4
A Cyanamid (USA)	6.1	1.4
Sterling (USA)	5.8	---
Wellcome (UK)	5.8	1.2
Shionogi (JP)	5.6	1.1
Schering AG (WG)	5.5	---
Fujisawa (JP)	5.3	1.1
Dow (USA)	4.8	1.1

*Uusi Suomi
**BZW Research
***Beecham and SmithKline merged into Smith Kline Beecham in 1989 thus becoming the second largest pharmaceutical company in the world.

Source: Uusi Suomi 8.5.1989 and
Financial Times 13.7.1989

Even the largest pharmaceutical company, Merck of the USA holds only a 4.1 percent market share and it is only two to

three times larger than number 20, ICI, on the table above. At first glance the pharmaceutical market seems quite fragmented with relatively low market shares, but after analyzing the concentration of production within one segment, for example medication for a certain condition, the picture is quite reverse. Within the sub-markets, a leading company commonly holds over 40 percent, and the top four over 80 percent of the market. This degree of concentration allows the companies to gain a dominant position in the market.[1]

The success of large corporations depends largely on the development of NCEs that require huge R & D inputs. Merck's R & D input is USD 650 million annually, and they have succeeded in developing six new drugs that have reached the world's top 50 in commercial drugs.[2] That is twice as many as any other company.

Most firms depend largely on the sales of one successful product. British Glaxo climbed into the top five from the 25th position with one single medicine. Their ulcer remedy, Zantac, became the most sold drug in the world and generates approximately half of Glaxo's FIM 14 billion annual sales. The UK company, ICI, reached the top twenty list with its Beta blocker and increased its market share from 0.5 to 1.4 percent. Another UK company, Wellcome, generates over 20 percent of its FIM 7 billion revenues from one new virus medicine.[3]

A quite general claim is that a pharmaceutical company has to have at least USD 2 billion sales in order to finance the R & D and increasingly expensive marketing of new products, although numerous smaller units are also generating new products. This argument has been boosting the rapid concentration of the industry. During the past year more

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1 OECD, 27.12.1983.

2 Buchan and Marsh, 27.1.1989.

3 Hankkila, 8.5.1989.

mergers and acquisitions have taken place within the pharmaceutical sector than in the past twenty years all together.[1] In the following table the main moves are presented.

Table 10: Mergers and Takeovers in the Drug Industry and Combined Prescription Drug Sales 1988 Est Since 1985

Company	Year	bnUSD
SmithKline/Beecham	1989	5.4
Bristol-Myers/Squibb	1989*	4.1
AHP/A.H.Robins	1989*	3.1
Dow/Marion	1989	1.9
Monsanto/G.D.Searle	1985	1.0
Eastman Kodak/Sterling	1988	0.8
Novo/Nordisk	1989	0.6
Mérieux/Connaught	1989*	0.5

*proposed

Source: BZW Research, The Economist

Of the EFTA nations a few Swiss companies, as well as the relatively large Swedish manufacturers Astra and Pharmacia are considered to be "large enough." The recent (Jan. 1989) merger between Novo Industri and Nordisk Gentofte, both of Denmark, boosted Novo-Nordisk's annual turnover to USD 0.85 billion and brought it to the same category with the Swedish firms. Novo-Nordisk also depends heavily on one product group, namely insulin. The merger joined two firms in good financial health in order to create a company large enough "to be a major player in the increasingly competitive world market."[2]

In Finland a similar trend can be observed in the merging activities of Orion and Farmos, as well as in the Huhtamäki Group's acquisitions.

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1 Midland, Michigan, 22.7.1989.

2 Barnes, Hilary, 13.1.1989.

Although the prevailing opinion is for large units in the pharmaceutical industry, some opposing views are also voiced. British Glaxo, one of the world's most successful drug companies prefer an organic growth strategy. The drug industry is heavily dependent on the successful creation of NCEs, and it is widely accepted that the R & D work is best done on a small scale, not in huge R & D outfits.[1]

In addition to the research (drug discovery), development (testing and approval of drugs) and marketing are the key elements in pharmaceutical industry. The latter two tend to benefit from the economies of scale to larger extent than the research work, and there is no denying the impact of the development and marketing on the success of a drug firm. But still the basis is in drug discovery - research - and some argue that money is better spent on buying people instead of firms.[2]

2.6 Trade

In the triad the export levels vary greatly among the countries. In some European countries exports represent over 40 percent of the total domestic production, while in Japan the figure is a mere 2 percent. European countries export over 15 percent in most cases, and European exports beyond the continent are 16 percent of the total production. The high figure for Europe in the following table is largely due to the small and fragmented markets of the continent compared to the huge domestic markets of the US and Japan.[3]

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1 "Drug companies merge", 5.8.1989.

2 same as above.

3 EFPIA.

Table 11: Pharmaceutical Exports as a Percentage of Total Domestic Production in 1986

	%
Europe	35
USA	10
Japan	2

Source: EFPIA

Japanese firms have been able to grow large in their huge domestic market without considerable export operations. Japanese often prefer to license products to non-Japanese companies rather than market products internationally. The USA has a healthy trade balance, and it has established numerous production units within Europe. Both the US and Japanese companies can benefit from large domestic markets to recover the development costs of new drugs, and liberalization in Europe is expected to increase competition from both directions.

Europe had a ECU 5.2 billion surplus in pharmaceuticals in 1986 with the rest of the world. Total exports outside Europe were ECU 7.0 billion and imports only ECU 1.7 billion. European countries imported from other European nations over ECU 8.5 billion in the same year.[1] European nations were responsible for over two-thirds of the total world pharmaceutical exports.

In the EC the supply of pharmaceuticals is highly internationalized. In the Community indigenous companies supply 43 percent, while in France and West Germany the figure exceeds 50 percent. A further 23 percent are supplied by other EC countries, while the remaining 34 percent comes from firms based outside the Community, mainly in the USA and Switzerland. Foreign companies supply drugs both by trade

1 EFPIA.

and local production, the latter representing about 40 percent.

The EC trade balance in pharmaceuticals has been positive over the 1980's exceeding ECU 3.1 billion in both 1986 and 1987.[1]

Large price differentials demonstrate the lack of free trade in the pharmaceutical industry in Europe. Prices are set on a national basis and are, in some cases, used as an indirect subsidy to the industry. Also lengthy registration procedures restrict the trade. Other barriers such as tariffs and direct import restrictions have been eliminated (soon also in Portugal and Spain), patent protection has been unified, and direct subsidies are significant only in Ireland. Discriminatory registration procedures and price controls are the main trade distorting measures.

Pricing systems and indirect subsidies via pricing have been discussed above. Discriminatory registration processes and delays in registration hinder the trade significantly. The patent protection time is already limited by lengthy development times, and delays in registration rather emphasize this problem. National requirements have converged during past decades, technical standards have only a few differences, and a uniform 120-day decision period has been agreed upon. Although in practice the registration times are considerably longer and methods of evaluation vary. Only France approaches the 120-day limit at times, but West Germany and the UK take approximately two years, and Italy or Spain three or more. The Community average is currently 18-24 months and the tendency is for longer delays.

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1 Panorama of EC Industry

3 Areas of Change in the European Community

Following the EC integration logic in the pharmaceutical industry would require a general harmonization of the widely differing governmental regulations between nations. The areas where widest differences exist are in the pricing and in the licensing of drugs. The Commission's decisions in these fields have a potentially great impact not only on the EC companies, but also on other European, North American and Japanese firms.

The officials of the European Commission have a paradoxical set of problems in their hands. Three separate aims influence the direction of the decisions:

- minimizing the cost of paying for drug purchases,
- maintaining the position of the European R & D based pharmaceutical industry, and
- providing safe drugs with minimal side effects to the general public.

The differences between the member nations in production and price structures are distributed very unevenly and harmonization has relatively a large potential for "side effects". The policies of member countries vary from minimizing the drug prices in countries where the production is minimal or non-existent, to complex systems where indirect subsidies are channeled to the industry by allowing them to maintain high prices.

The issues of technical barriers and border controls are not central in the pharmaceutical industry, rather the work consists of harmonizing the opposing governmental policies.

The opening of the pharmaceutical market is likely to lead to a further consolidation of companies that wish to strengthen product ranges, combine R & D efforts, or to link similar products with more resources for marketing.

Trade, cross-border partnerships, and mergers are expected to increase along with the EC integration process.

3.1 The Commission's Measures

The Commission's measures aim at protecting public health and harmonizing the laws, regulations, and administrative provisions in each member nation. They are aiming at a common market in pharmaceutical products and to supporting the development of the industry.

The EC has issued a series of directives directly on the pharmaceutical industry. Control was initially established in Directive 65/65/EEC, followed by Directive 75/319/EEC which established a Committee on Proprietary Medicinal Products (CPMP) and enabled a company to apply for marketing authorization in several member states simultaneously. Still, in the end, each nation makes the final decision on authorization.

Presently the licensing directives do not cover all medicinal products, but the Commission is aiming to include the yet excluded products by 1992. Proposals have been submitted to include immunological medicines and radiopharmaceuticals.[1] The directive on medicines derived from human blood was concluded (Directive 89/381/EEC).

The Commission has also proposed measures to encourage cooperation in evaluating new products (especially in the biotechnological field) by Directive 87/22/EEC, and provided additional protection for original research work and associated data in Directive 87/21/EEC. Also the pricing directive came into effect in January 1989 in Directive 89/105/EEC.

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1 Single Market Factsheet 6.

The key areas of the pharmaceutical industry licensing and marketing are not yet regulated by new directives, but the issues are being worked on.

3.2 Areas Under Consideration

For pharmaceutical industry the central areas of potential change include regulations on pricing, sales licenses, marketing, industrial property rights, and rules pertaining to production and quality control. The main decisions of the Community effecting the pharmaceutical industry are yet to be taken and the decisions are expected to materialize gradually towards and after the turn of the century.

3.2.1 Pricing

The EC Commission has recognized the effects of disparities in the national pricing systems on the trade. A directive on pricing was concluded in January 1989. This directive makes the pricing mechanisms more transparent, reduce price barriers to trade, and consequently, stimulate competition, while at the same time taking into account the industry's needs in innovative activities.[1]

The differences in pricing in the EC member countries vary greatly. Although the price differences are expected to diminish along with the moves towards a single market, the Commission is not at the moment striving for uniform pricing mechanisms across the EC area.

The reduction of price differences is most likely to benefit not only the large EC producers, but also other European, North American, and Japanese multinationals that operate in the EC markets. This places an additional complication for

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1 Single Market Factsheet 6

the Commission to consider, since this could weaken the overall EC pharmaceutical industry's relative position.

A general belief supports the theory that large multinationals would benefit most from the reduction of trade barriers, but a recent study by Shearson Lehman Hutton (Pharmaceuticals in Europe) provides contradictory evidence. They see the large producers relying strongly on the high price markets to be the losers, while the companies concentrating on low-priced markets and generic products are expected to reap the benefits of price harmonization. The argument is based on the estimate that the markets would shrink up to 10 percent along with the lower price levels, and that the big companies with sales distributed widely across Europe would lose their competitive edge to companies that already function with low price strategies. The companies worst affected would be those with the highest concentration of sales to high price markets.[1]

3.2.2 Registration and Licensing

All medicinal products need to be registered prior to obtaining a sales licence. The Commission's aim is to formulate a uniform EC registration procedure, but this has proven to be a very difficult task. Consequently, the national systems have been supplemented by two different EC registration methods, namely the Multi-State Application Procedure of 1985 (or Committee for Proprietary Medicinal Products, CPMP) and the EEC Consertation Procedure of 1987.

The CPMP system is a voluntary method. After one nation has accepted the registration application, the authorities send the results to corresponding bodies in other countries where the same application is pending. Based on the reciprocal acceptance of one others' results the registration

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1 Marsh, 14.2.1989.

should be accepted in several countries with a single application and a single approval. In practice the CPMP documentation is very demanding, but still various authorities have been reluctant and often requiring additional country specific clarifications.[1]

The EEC Concertation Procedure concerns high technology and biotechnology products. According to the procedure the applicant first submits the documentation to all national bodies and the CPMP committee simultaneously. If the CPMP committee accepts the application, and the member countries should register the product in question within 30 days.

These two methods have not received a wide acceptance. Only 100 to 200 applications have been submitted to the CPMP committee on Multi-State Application Procedure, and less than 100 on the EEC Consertation Procedure. The large majority of applications are still submitted directly to the national bodies.

Presently the Commission is formulating the "Community Authorization Procedure" for veterinary products to arrive at a centralized EC wide system that overrides the national bodies. The aim is to extend this system also to human products by the end of the century.[2]

3.2.3 Marketing

Regulations on marketing practices are expected to evolve into formal proposals by the end of 1989. It is expected that the medicinal products would be subject to EC marketing rules by 1992. Three options are yet being considered for permission to market products in various national markets:

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1 Kavetvuo, 1989.

2 Kavetvuo, 1989.

mutual recognition of national decisions, a centralized Community system, or an intermediate approach.[1]

3.2.4 Industrial Property Rights

The European Patent Convention (EPC) has already been applied since 1978 aiming at a pan-European patent convention. The significant issue for the pharmaceutical industry in the EPC is the prerequisite of a product patent system for joining the convention. Also EC membership requires the application of a product patent. Spain and Portugal have until 1992 to switch to a product patent.

Also the Commission Patent Convention (CPC) has been prepared, but the implementation is still waiting for some member countries. The main difference between EPC and CPC is that the CPC overrides national legislation while the EPC does not.

Besides the patent convention an EC directive on trademarks is being prepared to harmonize national regulations.[2]

3.2.5 Production and Quality Control

When a pharmaceutical product is being initially exported to the EC area it must be re-analyzed. This creates a major technical barrier to trade against non-EC producers. PIC Convention (Pharmaceutical Inspection Convention) has constructed a system of reciprocal acceptance of the analysis. The PIC includes in addition to the EFTA countries some EC nations (Denmark, Ireland, Portugal, the UK and West Germany). The EC rules override the PIC Convention, and the EFTA countries are required to have the products

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1 Single Market Factsheet 6.

2 Kavetvuo, 1989.

re-analyzed even when exporting to PIC countries within the EC area. Presently the EC is preparing a similar community wide convention aiming at a pan-European harmonized system also in this field.

The Commission has also prepared new guidelines for Good Manufacturing Practice (GMP) and is preparing Good Laboratory Practice (GLP). In practice these guidelines become rules for factories marketing to the EC area.[1]

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1 Kavetvuo, 1989.

4 Finnish Pharmaceutical Industry

The Finnish pharmaceutical industry is presently going through a strategic change from the previous emphasis on parallel and licensed products to a future stronger reliance on self developed products as a source for export earnings. Simultaneously the industry is undergoing a major structural change after a strong concentration wave among the pharmaceutical producers.

In this chapter the products, R & D, producers, domestic markets and foreign trade will be introduced. Also the strengths and weaknesses of the industry will be analyzed, and the opportunities and threats of EC integration will be drafted.

4.1 Products and R & D

Finnish production has been fully relying on generic, licensed and parallel products up to the early 1980's when its first own original products were introduced. The situation has been possible due to the prevailing patent legislation which differs compared to most other Western industrialized nations.

The industry has been, and still is, operating under a patent legislation that does not allow for products to be patented, only the production processes have been able to seek for industrial rights protection. Most industrialized Western nations have applied the product patent system, with the exception of Norway, Spain, and Portugal. Developing and Socialist countries do not provide product patents for pharmaceuticals.

Differing patent legislation has allowed Finnish producers to exploit the situation and develop parallel processes to produce drugs originally developed abroad. The system has

not stimulated domestic R & D work since it has allowed for the production of parallel products for domestic markets as well as for export markets that do not acknowledge the product patent, namely Socialistic and developing countries.

Presently production is largely based on generic or out of patent products, parallel products and licence production. Only a small portion of production is based on industry's own original products, also called innovative improvements or imitations. No breakthrough discoveries have been developed by the Finnish industry.

No reliable estimates of production shares between "me too's", parallel products, licenced products and original products are available, but making an educated guess based on various sources (desk research, interviews, discussions) the following estimate of production shares was constructed.

Table 12: Rough Estimate of Finnish Production Categories

Product Category	Percent
Me too's and Parallel products	50-60
Licenced products	20-30
Own original products	10-20
Total	100

It has been argued that the absence of a product patent has granted the Finnish pharmaceutical industry an advantage in licensing negotiations due to the possibility of developing parallel products. Consequently the share of licenced products is quite significant.

The Finnish industry is facing new challenges since Finland has decided to join the product patent also for medicinal products in 1995. From 1983 the R & D investments have been intensified and the industry has already created seven new

innovations. Some of these can be classified as new chemical entities (NCE), while others are improvements either in new uses of the drug or in better absorbin qualities with less side effects. NCEs inclued Domosedan, Dormitor, Fareston and Antisedan, but none of them are break through innovations. Already in 1978 original contraceptive devices were developed. Finnish innovations are presented in the following table.

Table 13: Original Finnish Pharmaceutical Innovations

Brand name	INN-name	Use	Company
Domosedan	detomidiini	sedation and analgesia of large animals	Farmos
Normosang	hemiarginaatti	care of porfyria blood disease	Leiras
Bonefos	klodronaatti	supportive cancer treatment	Leiras
Domitor	medetomidiini	sedation and analgesia of small animals	Farmos
Erasis	erytromysiini-asistraatti	bacterial infections	Orion
Fareston	toremifeeni	breast cancer	Farmos
Antisedan	deksmedetomi-diini	binging animals around after sedation	Farmos

Source: The Pharmaceutical Information Centre

Although Finnish R & D activities in drug research are young and relatively small compared to Sweden or Denmark, the operations are being rapidly intensified. In 1988 R & D spending exceeded FIM 200 million, representing 22.5 percent of the chemical industry's total R & D spending. The R & D share of the turnover grew from 9.4 percent in 1981 to 13.3 percent in 1987 (Chemical Industry Federation figures for 1987 12.63 percent, and for 1988 10.03 percent).

Research and development work is largely done internally within the firms, and only slightly below eight percent of this was financed by external sources (TEKES and SITRA). R & D work is also being carried out in the universities and university hospitals. This cooperation is seen as a very important link by the industry representatives. The work conducted in universities does not show up in figures, but it can be assumed that through this channel significant support is funneled from the government to the industry.

The pharmaceutical industry employs half of the R & D doctorates in the chemical industry, and 25 percent of the total R & D personnel. Within the pharmaceutical industry 19 percent of labor is involved in R & D.[1]

In the following table R & D percentages of the turnover of the Finnish pharmaceutical industry exhibit a clear increase from the 1970's to 1980's, but the growth is not dramatic. Previously relatively high R & D expenditures were directed towards developing parallel products and processes for existing medications, while during the 1980's the emphasis has been shifted towards creating original drugs.

Table 14: R & D Expenditure of Turnover of Finnish Pharmaceutical Industry

Year	R & D %
1971	9.9
1973	---
1975	---
1977	7.7
1979	8.5
1981	9.4
1983	12.8
1985	11.4
1987	13.3

Source: Central Statistical Office

1 Chemical Industry Federation and the Pharmaceutical Information Centre.

The upcoming changes in patent legislation have intensified the R & D work in Finland. Companies have to develop their own original products to be able to compete in the post-1995 more competitive markets. Also government authorities have recognized the increased need for R & D finance by channeling FIM 40 million to pharmaceutical R & D via TEKES. The industry is adding another FIM 10 million for the eleven research projects to be conducted over the next five years.

Besides developing original products Finnish R & D is further developing existing medications by making the dosage of the drugs simpler and by increasing the absorbing qualities of the active ingredients.

The concentration of the Finnish pharmaceutical industry has a positive effect on the R & D resources, thus stimulating the development of NCEs. In addition, the firms are concentrating on separate areas of development to avoid unnecessary overlapping in research.

4.2 Production

Both production strategies and structures have been changing rapidly over the past years. As described above, the emphasis has been switching from the present parallel production towards the creation of its own original products in the future. Simultaneously the industry has collected the forces into a few more concentrated units resulting in two relatively large corporations, but still allowing for the existence of another two very small producers.

The move to R & D based strategies has been taken relatively late compared to Sweden and Denmark. The leading pharmaceutical producers in industrialized countries rely on their own NCEs and support much narrower product lines compared to Finnish firms. Orion, the largest Finnish

producer is the "world's largest pharmaceutical company" if measured by the product range.[1] The future of the Finnish producers depends on their ability to develop original pharmaceutical products for the post-1995 era when the product patent laws will be applied also in Finland.

It is difficult to quantify the effects of the differing industrial rights protection for the Finnish industry, but the largest drug importer, Glaxco of the UK, claims that it is losing FIM 20 million annually due to the copying activities of Finnish producers.[2] The bottom line is that the adaptation of the product patent system will intensify the competition and make licensing negotiations less favorable for Finnish producers.

Between 1978 and 1982 Finnish production under licenses decreased from 17.2 to 12.7 percent[3], but according to a more recent study approximately 30 percent of Finnish production was based on foreign production licenses in 1985. The industry is estimating that licence protection will remain very central through the 1990's, decreasing only along with the domestic development of NCEs.[4]

Production structures have concentrated basically on two large units during the mergers and acquisitions of the past few years. In the beginning of 1988 two of the three main drug producers, Orion and Farmos, merged under the Orion Group. This acquisitions made the Orion group the largest pharmaceutical producer of Finland. The Huhtamäki Group has collected all pharmaceutical units under the Leiras factory. In the restructuring of the industry Leiras acquired Medica, Rohto and Star becoming larger than Farmos as seen in table

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1 Kartila, 23.3.1989.

2 Mård, 20.4.1989.

3 Elinkeinohallitus, 1983, s.21.

4 Lääkepatenttityöryhmä, 1987, s.29.

15. In 1985 the Association of Finnish Pharmaceutical Industry had 12 members, but by 1989 the number had decreased to four.

During 1988 the Finnish Pharmaceutical industry went through a comprehensive product rationalization programme. Over 200 similar preparations were removed from the market and an agreement was reached on each company concentrating on certain therapeutic areas to increase the international competitiveness of the Finnish industry.

Orion Pharmaceutica is strengthening its position in the field of anti-arrhytmics, neuroleptics, enternal nutrition, penicillin drugs, as well as certain OTC preparations. Farmos is concentrating on anticancer agents, epilepsy, and also on infusion and irrigation solutions. Both discontinued some product categories where overlapping existed. The product rationalization strengthened Leiras' position in infusion liquids, contraceptive and gynecological preparations, eye and ear drugs, as well as drugs against infectious diseases.

The invoicing of the Finnish pharmaceutical industry was nearly FIM 1.9 billion in 1988, 7.7 percent higher than during the previous year. Domestic demand consumed FIM 1.3 billion, and FIM 0.6 billion was exported.

The largest pharmaceutical group was the Orion Corporation consisting of Orion Pharmaceutica and Farmos. Huhtamäki Group's Leiras was slightly over half of the Orion group. Pharmacal and Terpia were small suppliers operating in domestic markets. In the following table the invoicing of Finnish firms is presented.

Table 15: Invoicing of Finnish Pharmaceutical Firms
FIM million

Firm	1987	1988	Change %
Orion Group	1,094.8	1,198.2	+ 9.4
Orion Phar.	687.4	754.3	+ 9.7
Farmos	407.3	443.9	+ 9.0
Huhtamäki Oy Leiras	650.6	680.8	+ 4.6
Pharmacal	16.2	17.8	+10.1
Terpia	1.0	0.7	-32.9
Total	1,762.6	1,897.6	+ 7.7

Source: The Association of Finnish Pharmaceutical Industry

4.2.1 Orion Pharmaceutica[1]

Orion Pharmaceutica has its division head office in Espoo. Production facilities consist of four factories in Finland (Espoo, Kuopio, Seinäjoki, and Kemijärvi) as well as in Vedaek in Denmark. The decision to construct a second production unit in Denmark has been made. Construction will be initiated in 1989 and completed by the fall of 1990. In addition, Hiven Oy has production in Paimio, and Fermion produces pharmaceutical raw materials in Espoo and Hanko. Sales subsidiaries have been established in Sweden, Denmark, West Germany, and two in Switzerland.

Orion Pharmaceutica's net sales grew by 7.6 percent from FIM 727.7 million in 1987 to FIM 782.9 million in 1988 (a slight difference from the table above). A total of 35.9 percent of this was contributed by exports and foreign subsidiaries. This was 15.9 percent above the previous year. Exports to the Soviet Union dropped sharply during the previous year, but remained at the same level in 1988.

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1 Based mainly on the Annual Report.

An upswing in the exports to western markets was experienced and this trend is expected to continue.

The first Orion's innovation was Erasis and the development of the pediatric dosage of Erasis has reached the pilot production phase. The innovation bases on existing molecyle, but the absorbing qualities have been improved and side effects decreased. A new molecule for the treatment of Parkinson's disease is reaching its final stages of phase I clinical studies and phase II is scheduled for the fall of 1989. Another research area includes cardiac failure studies, and the development project on nucleic acid identification methods yielded the first product that can be utilized to identify and type the human papilloma virus. The R & D spending in 1988 was 10.2 percent of net sales of pharmaceutical preparations.

Exports consisted of products developed by Orion including patented Divina and Orion's original Guarem, as well as generic products Verpamil, Alsucral, Pratsiol, and Cardil. Licenced products Deprakine and Aciloc are strengthening their position in Danish markets. The majority of Orion Pharmaceutica exports consist of generic "me too" products (50-55%), largely of licenced products (30%), and to a lesser degree of it's own original products (15-20%). Orion's patented products represent only a minor share of exports.

Exports of raw materials by Fermion faced very strong price competition in world markets. The main export markets were in West Germany, the USA and Japan.

4.2.2 Farmos[1]

The Farmos pharmaceutical division consists of two drug factories: Lääkefarmos and Medipolar with a joint research

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1 Based mainly on the Annual Report.

center and a chemistry plant. In addition, two subsidiaries, Suomen Rohdos Oy and Finndrug Oy, belong to the division. Foreign sales are assisted by the international division's matrix organization. Farmos Group Ab, Cutrin Ab, and Item Development Ab in Sweden, Farmos A/S in Denmark and Farmos Inc. in the USA are the extensions abroad.

The pharmaceutical division's total net sales rose 7.5 percent to FIM 416 million. The foreign net sales reached FIM 145.5 million, 10.1 percent above the previous year's level. The exports consisted mainly of pharmaceutical preparations (FIM 83.5 million), but also a large share was contributed by raw materials (FIM 43 million). The raw materials stayed at the level of the previous year, but the pharmaceutical preparations exports expanded 21.7 percent.

Farmos initiated the work on its own original drugs in the 1970's with the result of its present four own NCEs. They have two products in clinical testing for human medication, and the work on animal drugs continues. They have concentrated their R & D work on cancer medicines and alfareceptor, but other fields are being considered. They also have researcher exchange with research institutes and medical firms in the USA.[1]

The first original drug intended for humans, Fareston, was granted a sales licence in Finland at the end of 1988, and phase III clinical studies have been reached in Scandinavia and in the USA, and phase II in other markets.

The original veterinary drug, Domosedan, was granted a sales licence in France and Canada. Domitor obtained additional licenses in Norway and in the UK; consequently, it is now on markets in all of Scandinavia. Licence applications for their original drug, Atipamezole, (used to bring around animals after Domitor treatment) was filed in

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1 Farmoksen tavoitteena....., 16.11.1988.

Finland, Sweden, Norway and Denmark. The new development project on desmedetomidine for use as a preanesthetic proceeded well in Finland.

The world markets for veterinary drugs represent approximately 5 percent of the human medicine markets, and the development costs are roughly half of the human drugs due to lower competition in smaller markets. The markets are presently approximately FIM 60 million in Finland and are expected to grow to FIM 100 million within a few years.[1]

Important areas for the division include anticancer drugs, neurological drugs and infusion and irrigation solutions.

At the end of 1988 an agreement was signed between Farmos and a large Italian counterpart on the development and production of their original product at the Farmos Chemistry plant.

The largest share of Farmos' pharmaceutical specialities exports consist of licenced products (80 percent). The own original products form a minor part of the exports. The most important export products were Antepsin (a gastric ulcer drug), Eldepryl (Parkinson's disease), Nitrong (angina pectoris), Frusene (a diuretic), and the own veterinary drugs Domosedan, Dormitor, and Broilact.

4.2.3 Leiras[2]

Leiras forms the core of the pharmaceutical division of the Huhtamäki Group. Medica was added to it in 1985, and two other plants, Star and Rohto, in 1987. The production units are located in Turku, Vantaa, Tampere, and Tammisaari, and research centers exist in Turku, Tampere, and Helsinki.

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1 Farmokselta kolmas....., 30.6.1989.

2 Based mainly on the Annual Report.

Leiras has foreign sales units in Sweden, Denmark, the United States, and Singapore.

In 1988 Leiras' turnover reached FIM 577.7 million, which was 12.7 percent above the previous year according to the annual report information. According to the Association of Finnish Pharmaceutical Industry the invoicing in 1988 was FIM 680.8 million and the growth from 1987 4.6 percent.

The production consists mainly of pharmaceutical preparations (60%), but also pharmaceutical chemicals (20%) and contraceptives (20%) contribute a significant share of the sales.

The most important product groups include family planning products, drugs for the supportive treatment of cancer and ophthalmological drugs, drugs for heart and respiratory diseases and infusion solutions.

The most innovative products include Bonefos (supportive cancer treatment), Oftan series (ophthalmological drugs), and Normosang (for porphyria). Original products also include the contraceptives Nova-T and Norplant. Applications for certification were filed in several countries for Bonefos original preparation. This was the first time the material was prepared in accordance with the new EC directives. Agreements were signed with three major drug companies for worldwide marketing of Bonefos.

Research at Leiras focuses on ophthalmology (Oftan range), supportive treatment of cancer (Bonefos and antibiotics), and contraception (follow-up and development for Norplant). These will constitute Leiras's international areas of focus. In addition, in the drug technology sector, efforts will be directed towards innovative medical dosing methods. Leiras's R & D spending reached FIM 71.5 million, representing 12.4 percent of its turnover.

The latest achievement of research on inhalation technology at Leiras is a new type of inhalation chamber, Rondo. It is compact and provides improved bioavailability of drugs as compared to other inhalation chambers.

Leiras initiated in cooperation with Swedish Pharmacia AB a joint research project to develop hybrid antibiotics as a part of the EUREKA programme. This basic research project aims at developing new molecules of the anthracycline group for the treatment of cancer.

Leiras has a long tradition in marketing cooperation with West German Schering AG for some 30 years, and also with French Rhone Ploulenc. In addition they have a minority share of a small British firm.

The share of exports in invoicing is 30 percent, totaling FIM 185.5 million. Exports rose 19.3 percent compared to the previous year. The main export products are contraceptives, ophthalmological and anticancer preparations. Demand for the Norplant contraceptive implants exceeded production capacity. Exports to the Soviet Union remained at the previous level. Growth appeared in Western Europe (ophthalmological drugs) and in the Far East (contraceptive preparations). Leiras's own sales subsidiaries were established in Sweden and in the US. The export distribution is presented in the following table.

Table 16: Leiras Exports

Area	Percent
CMEA (Europe)	40
EC	25
Asia	15
America	10
EFTA	5
Others	5
Total	100

Source: Huhtamäki

Leiras' own original products represent a minority share, purchased licenses play a considerable role, but generic and especially branded generic products carry the majority of the volume.

Leiras's know-how is being utilized in building a factory producing contraceptive intrauterine devices in India, and similar projects are under way in China and Vietnam, as well as in the Soviet Union on a joint venture basis.

4.3 Domestic Market

By 1988 the domestic demand had reached FIM 2,440 million, of which 52.1 percent (FIM 1,271m) was satisfied by domestic suppliers, and 47.9 percent (FIM 1,170m) by imports. The market share of domestic producers has been declining during the 1980's, roughly two percentage points annually since 1985.

Table 17: Sales of Pharmaceutical Specialties in Finland 1970 - 1988

Year	Domestic Sales of Fin. Prod.		Imports		Total
	mFim	%	mFim	%	mFim
1970	129.6	54.1	110.1	45.9	239.7
1975	318.7	52.8	262.2	47.2	580.9
1980	593.7	57.8	433.4	42.2	1,027.1
1985	1,041.4	57.3	777.1	42.7	1,818.5
1986	1,095.2	55.5	878.4	44.5	1,973.6
1987	1,177.8	54.0	1,003.1	46.0	2,180.9
1988	1,270.6	52.1	1,169.7	47.9	2,440.3

Source: The Association of Finnish Pharmaceutical Industry

Imports are relatively low compared to other small European nations. In Sweden imports represented 59 percent in 1988, and corresponding figures for Norway and Denmark were 77 and 68 percent.[1] Swiss imports were nearly 80 percent.[2] In Norway the domestic pharmaceutical industry is quite small, but other countries mentioned have a strong domestic pharmaceutical industry, definitely so compared to Finland.

Over half of the domestic market is dominated by the Orion Group and Huhtamäki Oy. Two other Finnish producers, Pharmacal and Terpia, are quite insignificant. The gross sales of pharmaceutical specialties in 1988 were over FIM 820 million for the Orion Group (Lääketehdas Orion FIM 528m, Farmos FIM 292m) and FIM 432 million for Huhtamäki Oy.

The largest importer was Glaxo with slightly over FIM 100 million, followed by Suomen Astra, Panfarma, Sandoz, Suomen MSD with between FIM 50 to 100 million. Importers are more numerous than domestic suppliers, and none have reached a 5 percent market share. In the following table the market shares of Finnish producers are presented.

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1 The Pharmaceutical Information Centre.

2 Kartila, 23.3.1989.

Table 18: Market Shares in Finland / Percent

Firm	1987	1988
Orion Group	34.2	33.6
Orion Pharmaceutica	21.7	21.6
Farmos	12.5	12.0
Huhtamäki Oy Leiras	19.1	17.7
Pharmacal	0.7	0.7
Terpia	0.0	0.0
Total Domestic	54.0	52.1
Total Import	46.0	47.9
Total	100.0	100.0

Source: The Association of Finnish Pharmaceutical Industry

Furthermore, the distribution of drugs in Finland is dominated by a few wholesalers (in 1988 Lääketukku Oy 1/3, Oy Tamro Ab 1/3, and Oriola Oy 1/3 market shares). At the end of 1988 Tamro Oy acquired Lääketukku Oy further concentrating the distribution channels. The distribution follows a so-called "single channel" system, where each producer and importer has concentrated the distribution to a single wholesaler. This diminishes competition and forces the pharmaceutical outlets to maintain relationships with all wholesalers to provide an adequate product range for their customers.[1]

The situation of oligopolistic supply and concentrated distribution is not very favorable in creating healthy competition and can thus have a significant impact on the prices. The pricing in the domestic markets is controlled by the public authorities.

1 Elinkeinohallitus, 1983.

4.4 Foreign Trade

The Finnish trade balance in 1988 in pharmaceutical products was strongly negative, imports of all pharmaceutical products reached FIM 1,170 million, exports being FIM 554 million. Pharmaceutical specialties were imported for FIM 922 million and exported for FIM 354 million during the same year.

Practically all imports originate from the EC and EFTA areas (70.4 and 27.2% respectively), and only a very small slice (2.3%) from other areas. The main importers were the UK, West Germany, Denmark, Switzerland, and Sweden.

Exports grew rapidly during the 1970's and early 1980's, but have remained at FIM 500 to 550 million since. The growth was largely contributed by the trade with COMECON countries that do not apply the product patent system. The growth of exports to COMECON countries expanded until 1985, but has since declined. The weight of the EC area has nearly reached that of the COMECON, and Western Europe, as a whole, has become the largest export area.

The relatively low representation of western markets in pharmaceutical exports is caused by the lack of original products. The parallel product would in most cases face problems with industrial rights on the western markets, where product patents prevail. In Socialistic countries such difficulties are non-existent. According to the industry's own estimates half of the COMECON exports exploit the differing patent legislation.[1]

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1 Lääkepatenttityöryhmä, 1987, s.26.

Table 19: Export of Finnish Pharmaceutical Industry in 1970 - 1988

	1970	1975	1980	1985	1986	1987	1988
Total exports FIM million	10.6	43.1	203.4	542.4	522.3	499.2	554.3
Distribution, %							
EFTA	26.4	12.2	8.3	8.8	7.7	9.5	9.4
EC	12.3	32.9	16.5	18.6	29.2	28.2	28.2
COMECON	8.3	16.0	49.4	52.7	37.4	34.0	31.7
Others	53.0	38.9	25.8	19.9	25.7	28.3	30.7
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Source: The Association of Finnish Pharmaceutical Industry

The share of exports of the total production was a modest two percent in the early 1970's, but the figure started to climb in the mid-70's reaching 9.1 percent in 1979, 16.6 percent in 1980, and 25.0 percent in 1981.[1] In 1985 the figure had reached 32.3 percent declining to 29.2 by 1988.[2]

Over 60 percent of exports is contributed to by the pharmaceutical specialties that represent the major share of the production. Bulk pharmaceutical chemicals are mainly produced for the export markets (97.6% exported). They represent only ten percent of production, but over 35 percent of the exports.

1 Elinkeinohallitus, 1983, s.5.

2 The Association of Finnish Pharmaceutical Industry

Table 20: Pharmaceutical Exports

FIM million	1987	1988	Change %	Share of Gross Invoicing % 1987	1988
Pharmaceutical Specialties	293.0	348.5	+ 18.9	19.9	21.5
Bulk Pharmaceutical Chemicals	187.0	195.5	+ 4.5	97.6	97.6
Others	19.2	10.3	- 46.1	19.1	13.2
Total	499.2	554.3	+ 11.0	28.3	29.2

Source: The Association of Finnish Pharmaceutical Industry

Pharmaceutical specialties are mainly exported to COMECON countries, as well as to Western Europe. Exports to the USA and Japan consist almost entirely of bulk pharmaceutical chemicals, and a large share of EC exports belong to this category as well.

Table 21: Export Distribution of Finnish Pharmaceutical Industry in 1988 / Percent

	All Exports	Pharmaceutical Specialties	Others
EFTA	9.4	12.9	3.5
EC	28.2	25.4	32.8
COMECON	31.7	41.7	14.7
USA	5.8	0.1	15.4
Japan	2.2	---	5,4
Others	23.7	19.9	28.2
Total	100.0	100.0	100.0

Source: The Association of Finnish Pharmaceutical Industry

The Soviet Union is by far the largest national export market for Finnish producers. The lack of product patent in both countries has most likely influenced this development. Also, West Germany reaches a double-digit export share,

other exports being fragmented to numerous countries at moderate levels.

Table 22: Export of Finnish Pharmaceuticals in 1988 by Countries

Country	Exports FIM million	Share %
Soviet Union	123.4	22.3
West Germany	56.9	10.3
Denmark	35.0	6.3
UK	33.1	5.9
USA	31.9	5.8
Sweden	27.8	5.0
Indonesia	19.9	3.6
DDR	19.1	3.4
Canada	17.7	3.2
France	13.9	2.5
Norway	12.0	2.2
Japan	12.0	2.2
Switzerland	10.1	1.8
Poland	9.8	1.8
China	7.6	1.4

Source: The Association of Finnish Pharmaceutical Industry

The exports are quite evenly divided between the three main firms, Lääketehdas Orion, Farmos, and Leiras, with practically no exports from the two other small companies.

Table 23: Export of Finnish Pharmaceuticals in 1988 by Companies / FIM million

Firm	All Exports	Change %	Share %	Medicines	Others
Orion Group	352.81	+ 8.5	63.6	192.91	159.91
Orion Phar.	211.47	+ 6.0	38.1	95.70	115.78
Farmos	141.34	+12.7	25.5	97.21	44.13
Huhtamäki Oy Leiras	201.49	+15.7	36.3	155.59	45.90
Pharmacal	0.02	+100.0	0.0	0.02	--
Terpia	--	--	--	--	--
Total	554.32	+11.0	100.0	348.514	205.81

Source: The Association of Finnish Pharmaceutical Industry

The working group from the Ministry of Trade and Industry (Kauppa- ja teollisuusministeriön lääkepatenttityöryhmä) concluded that the Finnish pharmaceutical industry should rely increasingly upon the export markets outside COMECON, with specialized product catagories, to ensure competitiveness. The domestic markets are limited in size and the R & D investments required huge; consequently, after the new patent legislation will be enforced, the export of one's own NCEs is an essential element of survival of the Finnish pharmaceutical industry.

4.5 Strengths and Weaknesses of Finnish Producers

The evaluation of strengths and weaknesses of the Finnish pharmaceutical industry is based on the preceding desk research and the interviews with the industry representatives. Strengths and weaknesses were identified at various levels from national to industry and company specific features. In the following table the view of the interviewees are presented.

Table 24: Strengths and Weaknesses of Finnish Pharmaceutical Industry

Strengths:	Weaknesses:

- being a Finnish firm
  - recognized as a high quality country (production, clinical testing)
  - excellent infrastructure
  - above average domestic price level
  - domestic consumption per capita relatively high
- relatively high R&D effort
- ability to create own products
- good cooperation with Finnish universities
- production facilities
- production of both raw materials and medicines
- few good own products
- restructured domestic production => size near critical mass
- middle sized companies, small enough to react fast
- new strategy of few own products
- high market shares in few narrow segments(!?)*
- good contact network
- sales network in Nordic area
- eastern trade has provided "base"
- strategic alliances
- young, motivated, educated staff
- early (?!)* initiation of international trade
	- lack of own units outside Nordic area (and USA)
	- still at early stages of internationalization
	- lack of traditions in international trade
	- small domestic market
	- resource problems in R&D and marketing
	- relatively small R&D effort
	- production not highly automated
	- high cost structure (wide product spread)
	- lack of "world class" researchers
	- strategy change process at the moment (from many domestic to few international products)
	- documentation of many products incomplete and outdated
	- conservative older academic staff

* by author
Source: Interviews

Being a Finnish firm has both its strengths and weaknesses. A strength can be found in the high standard of living that generates relatively high consumption levels, in an excellent infrastructure for the industry, and in the reputation of Finland as a high quality country both in production and reliability of clinical testing results. Finland also has an above average price level of pharmaceuticals in a European

context. This allows the industry to generate income for the costly R & D work.

On the other hand the small domestic market is a limiting factor compared to most competitors. This weakness is acknowledged and the effects of it are known in all industrial sectors. Other typically Finnish weaknesses include the cultural distance, lack of traditions in international trade, and the yet early stages of internationalization. Geographical distance does not play a role in the pharmaceutical industry.

The Finnish pharmaceutical industry is a relatively young operator in western markets, and especially the exports of pharmaceutical preparations to western markets have only recently started to expand. On one hand the eastern markets, mainly the Soviet Union, has provided a "base" for larger production volumes, an extended "colonial" market, but on the other hand it has created a relatively high dependency on a single export market. A high dependency on a domestic market and a single large export market has made the industry more vulnerable than it would be if the exports were distributed on wider base.

Since the internationalization of the Finnish pharmaceutical industry has taken place relatively late, the documentation, required for registration, of earlier products is quite incomplete and outdated. Updating the documents is a question of resources. On the other hand the Finnish industry now can shift directly to new EC standards in documentation.

The products naturally form the backbone of strengths and weaknesses in all industries, but especially in the pharmaceutical sector. "Develop or die" is often heard in connection with this sector. The highest profits are generated by patented own original products, and many leading firms rely largely on only one or a few products. Finnish firms have for a long time been operating under the

protection of differing patent legislation, and generating profits from sales to countries without a product patent. Now the situation is changing and the strategies along with it.

The strategic change from a domestic full service house to an international supplier of pharmaceutical preparations for narrow segments is strengthening the product pallet of Finnish firms. Although it was mentioned that the process of changing one's strategy requires considerable organizational energy at the present moment; consequently, being at the present a weakness, it is a strive for future improvements. The strategic changes have brought about the restructuring of the industry that has brought the firms closer to the critical mass and strengthened their position to generate new original products.

Concentration of the industry has increased the unit sizes and the R & D resources. The firms have a relatively high R & D effort that is large enough to generate original products. The resources and strategies of R & D are quite similar to the electronics industry. The percentage shares of R & D are relatively high even in international comparison, but the cumulative volume of R & D is still modest.

The volume of R & D does not allow for extensive basic research that would generate fundamental breakthrough discoveries. It is sufficiently large enough that the researchers have facilities to further develop the findings of basic research carried out internationally, to generate original products, or new chemical entities that are based on existing chemical substances.

Many Finnish original products belong to the "innovative imitations" category. As in electronics industries, the Finnish industry is utilizing the results of international basic innovations, applying their expertise in a narrow segment, and generating improved products for international

markets. This new approach has a great potential of strengthening the competitive position of Finnish firms, but the industry is still at the early stages of applying the approach.

Some seven new innovations have been generated during this decade, but will this generate sufficient income for further R & D in the increasingly competitive international and domestic markets? The companies still carry wide product ranges and high cost structures, although few original products generated have strengthened their position.

The limited R & D resources are being supported by additional governmental funding via TEKES, but it seems that competitors even in large nations receive relatively higher support from public sources in form of direct subsidies or pricing mechanisms. The universities and university hospitals play a significant role in supplementing the limited R & D resources, and the industry representatives feel that the good relationship with the academic institutions strengthens their position.

Another common claim is the smallness of Finnish firms. Even after the concentration of Finnish pharmaceutical industry the firms remain in the small and medium sized category. As in other sectors pharmaceutical firms see strengths in the reaction speed and flexibility of the smaller firms, but do not touch upon the weaknesses of smaller economies of scale. Still, big is not always the only good solution. The pharmaceutical industry relies very strongly on R & D, testing and marketing. These three areas demand a majority of resources and attention. R & D work often benefits from smaller scale operations, provided that sufficient facilities and personnel is available. The economies of scale bring limited advantages in production, but more so in the testing and marketing phases of a new product. The latter two areas are weaknesses of the medium-sized Finnish pharmaceutical industry.

Production-related strengths include high level facilities measured by international standards, as well as production of both the raw materials and pharmaceutical preparations. Yet the production is not very highly automated. This applies especially to generic and branded generic products in relation to the competitors.

The main industry specific weakness brought up was the lack of companies' units and sales organizations outside Nordic markets. Some outlets exist in the USA, but effectively Scandinavia is the sole market where a sufficient network exists. The lack of a sales network globally is a weakness, and the existence of it in the Nordic market is a strength.

The relative smallness of the units causes not only limited R & D resources, but also limited marketing resources. The solutions for weaknesses in R & D and marketing resources are partially sought from the same source. Concentrating on narrow segments and approaching niche markets allows an improved utilization of limited resources both in R & D and marketing. This has resulted in gaining relatively high market shares in a few niches.

Global marketing is combating the lack of sales network by forming strategic alliances and cooperating with other pharmaceutical companies to gain access to their networks. The existing connections are seen as a strength compensating for the weakness in non-existent sales network of individual companies outside the Nordic markets.

The strength in personnel lies in young, highly educated and motivated, increasingly international staff. The older academic staff is to some degree reluctant to accept change, conservative. Although the R & D staff is well-educated and relatively large, the Finnish pharmaceutical R & D community is short of top specialists. The "world class" researchers

could improve the product range and quality, and the ability to produce innovations in domestic centers.

Overall the weaknesses of the Finnish pharmaceutical industry stem from a small domestic market, medium sized units, shortness of international experience and lack of strategic alliances, limited resources in R & D, and especially a non-existent sales network and inadequacy of international marketing resources.

The position is being strengthened by industry concentration and the strategic move to international niche marketing, directing limited R & D resources to a few products to gain a competitive edge, and to approach the world market through the existing networks of other drug companies. The prevailing strengths can be identified in flexible organizations, quality staff, good Nordic networks, and above all, in the individual companies' already existing original products.

4.6 Opportunities and Threats of EC Integration

Considerable changes in the European economic structures naturally have an impact on the Finnish pharmaceutical industry that is expanding its operations especially to the EC area. The pharmaceutical industry has already been very international for quite some time, and now Finnish firms are joining the highly competitive international markets. All of the interviewed persons saw the integration process more as an opportunity, even though the benefits from the opening opportunities will require an increased workload and the changes will not arrive without potential threats. The initial threats and difficulties seem to be overridden by the long term opportunities.

As presented in the following table, the industry representatives considered the integration process to be significant, although not very significant. They saw the

effects of it to be equally important for the firms they represent and to the entire pharmaceutical industry, but less significant than for the Finnish economy as a whole.

Table 25: Significance of EC Integration for Pharmaceutical Industry
Answers to question "How significant is the EC integration process for your firm/unit, for the industry you represent (pharmaceutical industry), and for the Finnish economy as a whole?"

	Firm/Unit	Pharmaceutical Industry	Finnish Economy
Not significant	-	-	-
Slightly significant	1	1	-
Significant	1	1	1
Quite Significant	1	1	1
Very Significant	-	-	1

Effects of the EC integration process are considered to significantly influence the Finnish pharmaceutical industry. What are the significant changes, and what kind of opportunities and threats will they impose on the industry? In the following table the views of the industry representatives are presented.

Table 26: Opportunities and Threats of EC Integration

Opportunities:	Threats:
- sales licenses across Europe by single documentation - mobility of professionals - students gaining better access to EC universities - R & D cooperation - strategic alliances - branded generic products entering the EC market - patent union - Finland's relationship to the EC	- falling price levels - increased competition in domestic markets especially in OTC market - product patent related issues - no real threats

The most visible immediate effect of EC integration is the unified EC registration of pharmaceutical products. Gaining a sales licence in a single country requires various testing procedures that are both time consuming and costly. A unified EC procedure complicates and makes the process more bureaucratic, as well as more costly if a licence is applied for only one country. Considerable savings in time and costs are achieved since one documentation covers most of the West European nations. This expedites the penetration of the entire European market. The benefit is equal for all firms. For Finnish firms this is especially relevant since they are actively increasing their presence in EC markets.

The developments in the single market of pharmaceutical products are yet to be clarified, but the general belief is that Europe will move towards a single market. Huge differences in prices and pricing structures are the largest area of concern. Falling price levels are a potential threat also to Finnish suppliers, since this would cut profits, and consequently the available R & D resources. The threat is even greater for a larger firm having their main markets in high price countries. The changes are expected to take place over long period of time. Lower price levels and increased competition requires higher efficiency.

Competition is not expected to increase only in the EC markets, but also in the domestic market. The Finnish market has been protected by the differing patent legislation. Already imports are gaining a larger share of the market, and this is expected to escalate by 1995 when the new patent laws take effect. The competition is expected to hit especially hard the OTC and generics sectors in Finland. Nevertheless, Finnish firms have similar opportunities when entering the EC market with its own generic, or better yet, branded generic products.

Product patent changes are said to be separate from the EC integration process, but quite clearly they are related in

the overall economic structural developments of Europe. Product patent issues have been discussed in more detail earlier in this study. The European patent union allows for similar benefits or opportunities as does the unified sales licence regulations.

Other freedoms seem to open additional opportunities. Freedom of labor movements is seen as a potential channel to acquire high quality researchers to work for Finnish industry. On the other hand, first the Finnish firms must be quite a bit more attractive than the company the person is presently employed at in order to persuade the person to move to Finland. Also the free flow of professionals can as well be from Finland and not to Finland.

The movement of students across the frontiers would improve the possibilities for specialization, especially in the fields that the Finnish universities can not offer the top support. This is seen as long term opportunity for educating the coming generations of valuable R & D personnel.

In the R & D sector different pan-European and EC projects as well as direct cooperation with other European firms are seen as potential opportunities. The single market also provides better possibilities for entering into strategic alliances in various niche markets on a European wide scale.

The EC integration brings some changes quite rapidly (type EC sales licence), while others take longer time to actualize (price harmonization). The degree and extent of changes is yet unknown, but it is clear that changes are taking place. Changes require reactions from the firms, that is very rapid reactions. Finland's position being at the edge of the EC brings the changes to Finland with a time lag, and this is seen as a beneficial position by some industry representatives. The time lag allows for a better preparation for the changes, although the reaction time must still be

fast. This argument speaks in favor of the present Finnish policy towards EC integration.

Opportunities are seen mainly in the concrete regulatory changes that ease the entry into the large EC market, while the threats are considered to materialize in a longer term in the structural changes of the pharmaceutical industry.

5 Conclusions

In estimating the effects of EC integration on the Finnish pharmaceutical industry, certain background knowledge is essential for understanding the competitive structures of European (and to some extent global) markets, as well as the nature and size of the Finnish pharmaceutical industry in an international context. This has been roughly drafted in the preceding chapters.

Following this, one needs to identify and evaluate the significance of the EC market for the pharmaceutical industry both as an **export market** as well as a **source of cooperation partners**. Finally the **effects of EC integration** on the Finnish pharmaceutical industry need to be discussed. The purpose of this chapter is to address these questions.

5.1 Significance of the EC for the Finnish Pharmaceutical Industry

The significance of the EC area as an export market for the Finnish pharmaceutical industry has been increasing over the past years. The industry started to internationalize in the 1970's mainly towards eastern markets, but eastern trade has been declining in importance since the mid-1980's, while the EC's share has climbed from a short 20 percent in 1985 to a short 30 percent in 1988. This trend is expected to continue increasing the significance of the EC area making it the largest export market for Finnish producers.

In EFTA and COMECON countries the pharmaceutical specialties play a larger role than bulk pharmaceutical chemicals. The latter group is far more emphasized in the trade with the USA and Japan. In EC trade the difference is not as dramatic as in other markets, although the bulk pharmaceutical chemicals do play a larger role. Growth in EC trade is

expected to be found especially in an increase of pharmaceutical specialties.

Although the exports to the EC area have reached considerable levels, the Finnish industry has not established very strong presence in these markets. Traditionally, the Nordic markets have been emphasized; consequently, the majority of subsidiaries within the EC have been established in Denmark. Orion has a production unit in Vedaek, and construction of a second unit has been decided upon. Also Farmos and Leiras have sales units in Denmark. Outside Denmark there is only one additional unit within the EC area, namely Orion's West German unit. Leiras has also a minority share of a small British company.

Besides the direct extensions of Finnish firms within the EC area, several ties to the area are formed in marketing and distributor agreements, as well as in R & D cooperation and licensing.

The marketing network outside the Nordic area was identified as a weakness of the Finnish pharmaceutical industry. This naturally requires other arrangements for the distribution of products. Leiras has long experience in marketing cooperation with Shering AG (West Germany) and Rhone au Poulenc (France). Only these two specific examples were identified, but it was repeatedly noted that marketing cooperation with European firms was extensive and significant.

Despite the few own units and marketing alliances, the majority of trade is conducted under agent agreements.

Other important linkage to the EC area is in R & D cooperation. Farmos has entered in R & D cooperation with a large Italian counterpart and Leiras is participating in a pan-European research project EUREKA jointly with Swedish Pharmacia AB. The R & D cooperation with other European

firms is expected to expand. Finnish firms are rapidly developing their expertise in certain narrow segments and gaining industrial property rights for their own original products. This increased stock of knowledge will increase their bargaining chip supply in negotiating for cooperation in R & D.

The clinical testing phase in product development requires large inputs and efforts, and in this field the Finnish firms are also cooperating with the EC firms. Occasional manufacturing cooperation was identified, but this form of cooperation was seen as fractional.

The EC area's importance is emphasized in the amount of production licence agreements between Finnish and Community firms. The majority of production licenses are sold from the Community to Finland. This issue has been dealt with more extensively in previous parts in connection with the product patent question. The importance of the EC as a supplier of production licenses will diminish since the product patent will be applied also in Finland, and direct exports to Finland will become more feasible.

On the other hand the yet small amount of production licenses sold to the EC area has the potential of becoming a more extensively used tool along with the further development of original Finnish drugs with an industrial rights protection. This is a parallel development with increased bargaining power in R & D cooperation discussed above.

So far this chapter has discussed the significance of the EC area as an export market or as a source of cooperation partners. The EC firms are exporting significant quantities of raw material and pharmaceutical specialties into Finland. Of the Finnish imports, the EC area is by far the most important, over 70 percent. During recent years the share of imports in the domestic demand has been increasing by two percentage points annually, mainly from the EC area. The

competition in domestic markets is constantly facing increasing pressures from the Community countries. For domestic producers this means decreased domestic market shares; consequently, increased importance of exports as income generator.

Although the Finnish pharmaceutical industry is still at its infancy or barely past it in Western Europe, the significance of the EC area can no longer be neglected. The area plays a large role in present operations, and increasingly so in the future. Leiras has announced it is in the process of establishing marketing units in the EC area, and others are at least keeping their eyes open. Some industry representatives openly admitted that they are actively looking for suitable acquisitions in the Community area. Similarly companies are seeking for new strategic alliances and looking into possibilities of strengthening present linkages by expanding into new areas of cooperation.

5.2 Effects of EC Integration on the Finnish Pharmaceutical Industry

More correctly this chapter should be named "Effects of the European Integration Process on the Finnish Pharmaceutical Industry" since EC integration is a too limited approach, especially in the pharmaceutical sector. The changes taking place in the fundamental issues of industrial rights protection are strictly speaking not included into the EC integration, although they are strongly connected.

The most significant change is the switchover to the product patent system in 1995 also in Finland. Also the last EC member countries are taking the same move in 1992, harmonizing the base for patent protection in entire Western Europe. Along with the EC integration process this fundamentally changes the structures of the domestic pharmaceutical industry, as well as the approach to the

export markets. Furthermore, the strategies of Finnish producers have already taken a dramatic move from being a domestic full-service house to international operator approaching narrow and well defined market niches.

The ongoing changes are shifting the emphasis from a high dependency on domestic markets to the increasing importance of export markets, mainly in Western Europe. The strategic importance of domestic markets is diminishing along with increasing imports and expanding operations in foreign markets.

Initially this increases the awareness in international thinking and emphasizes the importance of international operations. The Finnish pharmaceutical industry can no longer operate in a semi-closed environment protected by differing patent legislation and other non-tariff measures. This is a truism, but an essential element of the European integration development.

What does this international awareness and shift of emphasis mean for Finnish industry? It implies structural changes and industry concentration that has already taken place. It forces the organizations to adapt all functions to new requirements.

Starting from production, the Commission has prepared guidelines from the Good Manufacturing Practice (GMP) and is preparing the Good Laboratory Practice (GLP) that will become essentially rules for firms marketing to the EC area as described in chapter three. Indirectly but effectively these guidelines extend their effect in the peripheral corner of Europe as well.

Similarly the harmonizing regulations in the EC area in the fields of patent applications, registration procedure, sales license applications and marketing practices carry the effects to the Finnish pharmaceutical industry. These

issues have been introduced in chapter three. In effect the standards of products and various procedures are no longer set in only in domestic or Nordic context, but are influenced strongly by a pan-European system.

Adapting the pan-European regulations initially in preparing the export products, and ultimately in all pharmaceutical production and marketing activities require additional efforts. Documentation is becoming more complex, bureaucracy is increasing, and the work load and price in getting a product to the market is growing heavier. On the other hand with this initially higher effort a far larger European wide market will be accessible instead of the limited domestic and eastern markets. Finnish industry has already completed the first EC documentation sales licence application.

In short the large markets are becoming more accessible with higher initial effort, but lower overall efforts. On the other side of the coin is the increased competition.

Competition in the domestic market has already been mentioned. In addition to the falling domestic market shares Finnish producers will not have as favorable a position in production licence negotiations as they have had previously when Finland did not apply the product patent system. This will further weaken the position of the local firms in the domestic market.

Increased competition will in effect bring falling price levels, although this development is not seen to be dramatic, and will possibly take place towards and even after the turn of the century. Prices of pharmaceutical products are tied into social systems of the nations, and differences remain great, as does the resistance to change. In Finland the changes are not expected to be rapid, but the evaluating base for pharmaceutical product prices is expanding from the Nordic approach to cover Western Europe. The Finnish

pharmaceutical industry's first experiences of tighter pricing have been encountered in Denmark, where production had to be tuned to be more efficient to remain competitive.

To remain competitive the industry had to place increased attention to developing original products for niche markets. This has placed additional demands on R & D spending and personnel. European integration has a great potential not only in increasing competition, but also in opening new opportunities in resources for the development of new products and easier access to narrow niches. The large European market provides sufficient size for niche strategy of Finnish firms both from NCEs and branded generic product.

The integration process has not only geared the industry's attention to develop new products, but also the public support for these activities has increased. Further more the possibilities for mobility of university students widens the educational resources and access of Finnish students to benefit from the European specialists. This has a long term effect of potentially improving the quality of the research staff and maybe even producing internationally acknowledged specialists in certain fields. Also the opening possibilities in free movement of professionals can provide additional researchers for the Finnish industry, while at the same time increasing the threat of a brain drain in the other direction. Overall the possibilities for domestic R & D work are improving in financial and personnel aspects.

Despite the fact that EC or pan-European programmes specially designed to promote R & D in the pharmaceutical sector were not identified, European integration improves the possibilities for R & D cooperation within Europe. Finnish firms are actively seeking both acquisitions, as well as strategic alliances in Europe. This essentially includes the R & D element. Also the first EUREKA project has been initiated in the pharmaceutical sector. Movement

towards the single market activates the European industry in seeking out partners that could supplement each other.

In comparison with the leading European nations Finnish public support for the pharmaceutical industry is quite moderate. The basis for cooperation with others is in the firm's own resources. One has to have something to offer. To make Finnish firms more attractive as cooperating partners public funds allocated to support domestic R & D work or larger research programmes would be well invested.

Success in developing one's own original products is a prerequisite for future profitability of the Finnish pharmaceutical industry. Already the industry has some seven new innovations, although their share of total production is still quite modest. The shift to a higher reliance on original products is very slow, as development and marketing of NCEs in general. Parallel products, generics and branded generics, and the modified products will remain as the main cash cows well into the 1990's. A move to higher shares of original products even at its best will be slow.

In developing new drugs clinical testing will be increasingly done abroad both for smoother registration procedures, and for pre-marketing of the product in European markets. Also the marketing of new products requires new structures. Swapping licenses is one alternative, where Finnish firm gains the rights to produce and market certain product in the Nordic area in return for allowing the counterpart to reap some benefits from the commercialization of new Finnish products in other markets. Also direct sales of production licenses to large firms with extensive sales networks is an alternative.

In addition to licensing arrangements strategic alliances could be formulated to find channels for new Finnish products to the international markets. These cooperation arrangements seem most likely, since Finnish producers are lacking

international sales networks outside the Nordic area. Parallel to the various cooperation forms the producers are seeking out acquisitions and establishing subsidiaries to strengthen the international networks. The purpose of expaning international linkages is primarily to create marketing channels, secondarily to support R & D and clinical testing activities, and only minimally to expand production geographically.

Finnish pharmaceutical producers possess fairly good sales networks in a Nordic context, as well as an attractive research portfolio in addition to a few patented products. As such the package could be well-fitted into a larger multinational consortium. Tendencies for merger and acquisition activities have escalated rapidly in recent years. Speculating the takeover of Finnish pharmaceutical industry by foreign firms is one alternative that must be considered when analyzing the potential effects of EC integration, although this outcome seems quite unlikely.

Admittedly the firms are attractive, but they are at the moment in good financial heath. Furthermore the firms are strong only in very fractional markets in the corner of Europe. The market potential is quite small in volume from the viewpoint of large multinationals. Also the firms are small enough not to cause market disturbances that would stimulate defensive moves. Also the stock of Orion Group is well protected against takeovers, and Leiras is a very successful unit within the Huhtamäki concern and not likely to be the first unit to be sold out.

5.3 End Notes

In conclusion the changes that the European integration process is bringing about are taking place gradually. The most important changes are taking place in the regulatory environment, and in the indirect effects of strategic and

structural changes of the industry. The harmonization of regulations will increase the workload, but at the same time allow access to the entire European market. Strategic changes towards own original products improve the possibilities in benefiting from niche markets and increases possibilities for swapping production licenses. This requires strong R & D inputs, and possibly increased cooperation with other European firms. Structural changes have taken place domestically, and the future is likely to bring acquisitions, own subsidiaries and strategic alliances in a European scope. These visions are drafting the most favorable developments.

On the other hand the increasing competition in Western Europe and in domestic markets, combined with falling price levels have the dpotential of lowering the profitability of Finnish firms. Ultimately this could result in a shortage of R & D funds and an inability to generate sufficient stock of own original products that are the essential element of the new strategic approach. The R & D resources both in financial and personnel areas are the backbone of the industry.

The Finnish pharmaceutical industry is in the process of changing its strategies. The slow pace of changes would allow the industry to adapt. This was the primary signal from the industry representatives to the national public authorities.

Also the communication between the industry representatives and public authorities could improve the understanding of the needs and motivations of both parties in adapting to the changing environment. This would require additional effort from both sides. In Sweden the communication takes place in direct contacts, working groups involving both parties in assessing change, and in short seminars addressing central issues.

The bottom line still remains at the resources for R & D. Educational exchange, attracting foreign specialists,

preventing a "brain drain" in the freer movement of professional, and finally the various methods of increasing the financing of pharmaceutical R & D - these factors determine to large extent the success of the Finnish pharmaceutical industry in integrating Europe.

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APPENDIX

Table 1: Pharmaceutical Consumption Within the EC in 1984

	Total sales (1) (million ECU)	Sales per capita (ECU)	as % of GDP %	as % of health care cost (2) %	By type of outlet 1. %	2. (3) %	3. %	Average Price (4) (UK= 100)
Belgium	880	90	0.81	8.6	12	76	12	103
Denmark	337	74	0.50	7.0	15	70	15	154
France	5600	102	0.81	8.8	9	78	13	76
W.Germany	7660	125	0.89	11.0	16	66	18	164
Greece	449	45	0.95	20.2	<-83->		17	73
Ireland	160	46	0.67	8.8	5	80	15	115
Italy	4440	78	0.91	12.4	8	79	13	57
Netherlands	660	46	0.38	4.1	<--- n/a--->			145
Portugal	350	35	1.08	18.9	<-93->		7	low
Spain	1830	48	0.81	12.1	<-88->		12	low
UK	3510	62	0.59	9.6	20	67	13	100
TOTAL	25750		0.78	9.5	12	74	14	91
Finland(5)	335	71	0.51					>aver.

(1) at manufacturers' prices
(2) 1983
(3) 1. OTC, 2. through retail pharmacies including dispensing doctors, 3. through hospitals
(4) using the 1983 indices of the EC statistical office
(5) Lääketeollisuusyhdistys (ECU 1 = FIM 4.7)

Source: Economists Advisory Group, Burstall M.L. & Reuben B.G., 1988.

Table 2: Pharmaceutical Production in EC in 1984

	Number of Producers	Production million ECU	%	R & D Expenditure % of Sales
Belgium	80	1290	3.3	10
Denmark	39	870	2.2	7
France	331	8530	21.7	13
W.Germany	308	10140	25.8	14
Greece	90	405	1.0	<1
Ireland	153	1040	2.6	5
Italy	356	6300	16.0	6
Netherlands	47	1050	2.7	11
Portugal	96	410	1.0	<1
Spain	370	2570	6.5	2
UK	333	6700	17.0	14
Total	2212	39305	100.0	11
Finland(1)	12	305	0.8	12

(1) Lääketeollisuusyhdistys (ECU 1 = FIM 4.7)

Source: Economists Advisory Group, Burstall M.L. & Reuben B.G., 1988.

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