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A Status Paper on the Pharmaceutical Industry in France

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Abstract

This paper attempts to provide a comprehensive view of the status of the Pharmaceutical industry in France. As a background to the discussion, the paper first elaborates on the demographic features of France and its influence on health expenses. It then describes the drugs circuit and features of the drugs consumption, followed by a discussion on the main characteristics, the regulatory aspects, R&D intensity and innovation potential as exist in the French pharmaceutical industry. The French government spends nearly 10 per cent of its GDP on health. Out of the total health expenditure, 20 per cent is spent on drugs which is higher than the OECD countries like the US, UK, Germany and Japan. The pharmaceutical industry in France is the third largest in Europe and adopted product patents even before the TRIPS agreement. Strict regulatory measures govern the pharmaceutical industry in France. The branded drugs are costlier compared to the generics. In order to control costs and promote generic drugs in the prescription, the government has introduced several regulatory measures, which even other OECD countries have not fully implemented yet. Interestingly, of the total turnover of the pharma industry, turnover from the domestic sales has been declining while the exports turnover has been increasing. The balance of trade in pharmaceuticals has been positive. The French have also been filing large number of patents next to the US and also rank higher in terms of the number of patents granted. In order to compensate the firms for the loss of time in the patent application process, the government grants another five-year term of exclusivity for companies satisfying certain criteria. Though this could delay the entry of generics, yet for pharma companies it provides an extended period of monopoly power over the product. The industry has also responded by investing in R&D to improve further.

JEL Classification : I11, I18L65, H51

Key words : French pharmaceutical industry, Drug consumption, regulation, Research and Development

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Contents

List of Tables

List of Figures

Abbreviations

ACOSS	Agence Centrale Des Organismes De Securite Sociale
AFSSAPS	Agence Francaise de Securite Sanitaire des Produits de Sante
CNAM	Conservatoire National des Arts et Métiers
EPO	European Patent Office
GMPs	Good Manufacturing Practices
INN	International Non-proprietary Name
INPI	Institut National De La Proriete Industrelle
LEEM	Les Enterprises de Medicament
NCE	New Chemical Entities
OECD	Organization for Economic Co-operation and Development
SPC	Supplementary Protection Certificate
TRIPS	Trade Related Intellectual Property Rights
WIPO	World Intellectual Property Organization

A Status Paper on the Pharmaceutical Industry in France

N. Lalitha and Samira Guennif*

1. Introduction

In developed countries where health care occupies substantial share of the government budget, growth of pharmaceutical industry or its specific segments depend on government policies. Factors such as changing demographic features have their impact on the health/drug expenditures via the reimbursement policies and health reforms particularly in curtailing the expenditures and thereby on the pharmaceutical industry. This paper provides a detailed account of the pharmaceutical industry in France. France is recognized for having one of the best health care systems in the world and is equivalent to other OECD countries like the US, UK, Germany and Japan. Health expenditure accounted for 10.1 per cent of the GDP of France in 2005 (Table 1).

When a country has already attained such a high quality of health standards, the challenge for the different stakeholders such as the government and the pharmaceutical industry is to continue to maintain and sustain such high standards, even if the government is under compulsion to alter its expenditure pattern.

The organisation of the paper is as follows. As a background to the discussion on the pharmaceutical industry, the demographic features of France and its influence on health expenses are discussed in Section 2. Section 3 describes the drugs circuit and features of the drugs consumption. In section 4, the main characteristics of the French pharmaceutical industry are elaborated, discussing the regulatory aspects, R&D intensity and innovation potential. Section 5 discusses the evolution of generics and the last section presents the broad conclusions emerging from the analysis.

* Associate Professor, University 13, Paris.

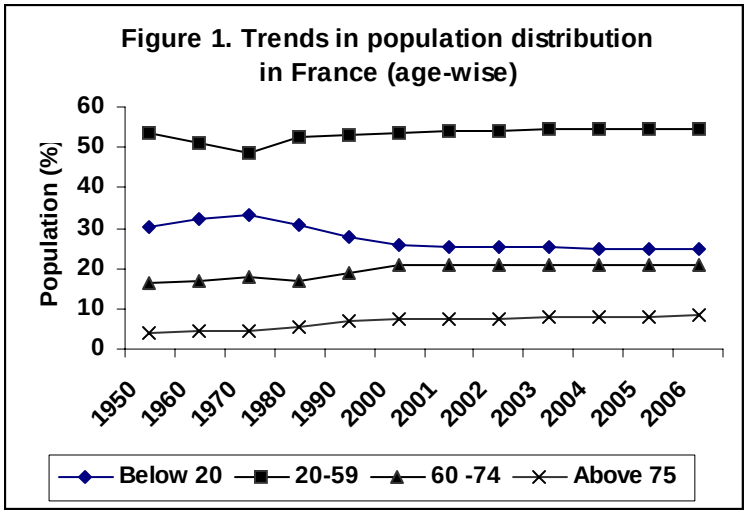
Table 1. Health expenditure/GDP in selected OECD countries (in %)

Countries	1960	1965	1970	1975	1980	1985	1990	1995	2000	2001	2002	2003
Germany	---	---	6.2	8.6	8.7	9.0	8.5	10.6	10.6	10.8	10.9	11.1
Austria	4.3	4.6	5.1	6.9	7.4	6.4	7.0	8.5	7.5	7.4	7.5	7.5
Belgium	---	---	4.0	5.8	6.4	7.2	7.4	8.4	8.7	8.8	9.1	9.6
Denmark	---	---	---	8.9	9.1	8.7	8.5	8.2	8.4	8.6	8.8	9.0
Spain	1.5	2.5	3.6	4.7	5.4	5.5	6.7	7.6	7.4	7.5	7.6	7.7
USA	5.0	5.5	6.9	7.8	8.7	10.0	11.9	13.3	13.1	13.8	14.6	15.0
Finland	3.8	4.8	5.6	6.3	6.4	7.2	7.8	7.5	6.7	6.9	7.2	7.4
France	**3.8**	**4.7**	**5.4**	**6.5**	**7.1**	**8.2**	**8.6**	**9.5**	**9.3**	**9.4**	**9.7e**	**10.1e**
Greece	---	---	6.1	---	6.6	---	7.4	9.6	9.9	10.2	9.8	9.9
Hungary	---	---	---	---	---	---	---	7.5	7.1	7.4	7.8	8.4e
Ireland	3.7	4.0	5.1	7.4	8.4	7.6	6.1	6.8	6.3	6.9	7.3	7.4
Italy	---	---	---	---	---	---	7.9	7.3	8.1	8.2	8.4	8.4
Japan	3.0	4.4	4.5	5.6	6.5	6.7	5.9	6.8	7.6	7.8	7.9e	7.9
Luxembourg	---	---	3.6	4.9	5.9	5.9	6.1	6.4	6.0	6.5	7.2	6.9
Netherlands	---	---	…	7.1	7.5	7.4	8.0	8.4	8.3	8.7	9.3	9.8
Poland	---	---	---	---	---	---	4.9	5.6	5.7	6.0	6.6	6.5
Portugal	---	---	2.6	5.4	5.6	6.0	6.2	8.2	9.2	9.4	9.3	9.6
Czech	---	---	---	---	---	---	4.7	6.9	6.6	6.9	7.2	7.5
UK	3.9	4.1	4.5	5.5	5.6	5.9	6.0	7.0	7.3	7.5	7.7	7.7
Slovakia	---	---	---	---	---	---	---	---	5.5	5.6	5.7	5.9
Sweden	---	---	6.9	7.6	9.1	8.7	8.4	8.1	8.4	8.8	9.2	9.4

Note : e- estimation *Source:* OECD. Eco-santé 2005.

2. Demographic features of France

The life expectancy of the French continues to improve over the years. Of the total population of closer to 60.3 million in 2004, 25 per cent were in the age group of below 20 years, 54 percent belonged to the age group of 20 to 59 years, 21 per cent belonged to the age group of 60 and above (of which, 7.9 percent were aged 75 years and above). Interestingly, this section of the population, which was 3.8 per cent in 1950, is expected to increase to 8.2 per cent in 2006, whereas the population in the age group of less than 20 years is expected to decline to 24.8 percent in 2006 (Figure 1). Due to the fact that nearly 30 per cent of the population is aged 60 years and above, health expenditure in France is only expected to increase in future.



In 2005, life expectancy at birth was 75.2 years for men and 82.7 for women as compared to the West European average of 73 years for men and 78 years for women. Infant mortality has reduced from 4.4 in 2000 to 3.6 in 2005 (Table 2).

Table 2. Life expectancy and infant mortality rate

Year	Life expectancy at birth (Years)		Infant mortality rate (%)
	Male	Female	
2000	75.3	82.8	4.4
2001	75.5	82.9	4.5
2002	75.8	83.0	4.1
2003	75.9	82.9	4.0
2004 T	76.7	83.8	3.9
2005 T	76.8	83.8	3.6

Note: T- temporary data
Source: INSEE, 2006, available on www.insee.fr,

Circulatory diseases account for the main cause of death among both men and women followed by cancer (Table 3). Hospitalisation accounts for 44.4 percent of the health expenditures and drugs account for 20.9 per cent of the health costs in France (Table 4). The break-up of the total consumption of medical care, products and services in 2004 shows that physicians and dentists account for 18.6 percent, drugs for 20.9 per cent, glasses and orthopaedic material accounted for 5.5 per cent, and the patient transportation accounted for the least, ie., 1.8 per cent.

Table 3. Main causes of death (2001)

Causes of death	Total		Male		Female	
	Number	%	Number	%	Number	%
Circulatory disease	160157	30.2	73966	27.2	86191	33.3
Infarcts	44542	8.4	24650	9.1	19892	7.7
Cerebro-vascular	37769	7.1	15723	5.8	22046	8.5
Cancer	150979	28.4	90436	33.2	60543	23.4
Lungs cancer	26847	5.1	22266	8.2	4581	1.8
Colon, rectum and anus cancer	15959	3.0	8448	3.1	7511	2.9
Breast cancer	11129	2.1	176	0.1	10953	4.2
Violent death	41066	7.7	24352	8.9	16714	6.5
Transportation accidents	7649	1.4	5591	2.1	2058	0.8
Suicides	10440	2.0	7655	2.8	2785	1.1
Respiratory disease	32081	6.0	16969	6.2	15112	5.8
Digestive disease	24167	4.6	12967	4.8	11200	4.3
Endocrinien disease	19382	3.6	8084	3.0	11298	4.4
Other causes	103240	19.4	45497	16.7	57743	22.3
All causes	531072	100.0	272271	100.0	258801	100.0

Source: Inserm, CépiDc – Centre d'épidémiologie sur les causes médicales de décès.

Table 4. Percentage distribution of health expenditure in France

Sources of expenditure	1995	2000	2001	2002	2003	2004
1. In patient care	48.6	45.8	45	44.8	44.5	44.4
a) Public hospitals	36.2	35.4	35	34.8	34.6	34.4
b) Private hospitals	12.4	10.3	10.0	10.0	9.9	10.0
2. Ambulatory care	27.3	27.1	27.1	27.3	27.5	27.4
a) Physicians	13.2	13.2	12.9	13.0	13.0	12.8
b) Health auxiliaries	5.3	5.5	5.5	5.6	5.7	5.8
c) Dentists	6.1	5.8	6.0	5.9	6.0	5.9
d) Analysts	2.4	2.4	2.5	2.5	2.6	2.6
e) Hydrotherapy	0.3	0.2	0.2	0.2	0.2	0.2
3. Sick transportation	1.5	1.6	1.7	1.7	1.8	1.8
4. Medicines	18.8	20.5	20.9	20.8	20.8	20.9
5. Other medical commodities*	3.8	5.0	5.3	5.3	5.4	5.5
Care and commodities (1 to 5)	100	100	100	100	100	100

Note: *Include optical, Prosthesis, orthesis, vehicle for disabled, Small materials and bandages, etc
Source: Directorate of Research Studies, Evaluation and statistics (DREES), 2005.

The public hospital sector comprises of 1048 establishments consisting of 323,100 beds and employing 763,350 people. The private sector numbers 2113 establishments comprising 174,880 beds and employs 305950 people. Both the sectors however promote home medical care to control the costs and presently, this is the reason for a strong debate between the government and the industry to control the health costs. As far as the health professionals in France are concerned, in 2005, there were 203,487 practicing doctors, 41,083 dentists, 67,484 pharmacists, 16,550 midwives, 452,466 state qualified nurses and 60,364 physiotherapists (Table 5).

Table 5. Number of health professionals (in '000 nos)

Health professionals	1990	2000	2001	2002	2003	2004	2005	Density* in 2005
1. Physicians	161.4	194.0	196.0	198.7	201.4	203.5	---	---
2. Dentists	37.9	40.5	40.4	40.5	40.6	40.9	41.1	68
3. Midwife	10.7	14.4	14.7	15.1	15.7	16.1	16.6	114
4. Pharmacists	51.4	58.4	60.4	62.1	63.9	65.2	67.5	111
5. Nurses	304.5	382.9	397.5	410.9	423.4	437.5	452.5	747
6. Masseurs-physiotherapists	38.3	52.1	54.0	55.3	56.9	58.6	60.4	100
7. Speech therapists	10.0	13.5	13.9	14.3	14.8	15.4	15.9	26
8. Orthopedists	1.4	2.1	2.2	2.3	2.4	2.5	2.6	4

Note: * Density for 100000 inhabitants, without midwifes.
Source: Compiled from Directorate of Research Studies, Evaluation and statistics

3. The regulation of drug supply

Regulation concerning drugs in France is two fold. The first covers the innovations of the pharmaceutical sector and France has traditionally protected patents on the products. The second regulation concerns the process of marketing approval, which includes the way prices are fixed for the drugs that are reimbursed. These two aspects are discussed in the following paragraphs.

3.1. The French patent system for medicines

France adopted product patent system much before signing of the TRIPS agreement. It is evident from Table 6 that patent applications filed by non-residents are higher than residents in Canada, India, France, Republic of Korea and Germany. In this regard, the US and Japan are the two exceptions where the

number of patents filed by the residents is higher than the non-residents. However, the number of patents granted to residents and non- residents present a different picture. Whereas in Canada and France patents granted to non-residents were higher at 90 and 71 per cent, in Japan patents granted to non residents were only 10.8 per cent.

Table 6. Patent applications filed and patents granted for selected countries (2000)

Country	Patent Applications filed by			Patents granted to		
	Residents	Non-residents	Total	Residents	Non-residents	Total
1. Canada	5518	80408	85926	1117 (9.2)	11008(90. 8)	12125
2. India	90	60852	60942	--	--	--
3. France	21471	138707	160178	10303(27.2)	26101(71.7)	36404
4. US	175582	156191	331773	85071(54.1)	72425(45.9)	157496
5. R. Korea	73378	98806	172184	22943(65.6)	12013 (34.3)	34956
6. Japan	388879	97325	486204	112269(89.2)	13611(10.8)	125880
7. Germany	78754	183796	262550	16901(40.6)	24684 (59.4)	41585

Note: Figures in parentheses indicate percentage of patents granted to residents and non-residents.

Source: available at www.WIPO.org

The Institute National *de la Propriété Industrielle* (INPI) deals with granting patents and supplementary certificates in France. INPI office lacks depends on the European Patent Office's (EPO) database for scientific search. Basically INPI office grants patents to French companies. According to the sources in INPI, in order to facilitate filing more number of patents by French companies, the French government has kept the charges lower than the EPO charges. In 2004, for filing an application, the INPI charged 35 euros and the search report costs 320 euros. To keep the patent protection effective, the applicant has to pay 1500 Euros a year, which increases with the number of years. So using the EPO, scientific search for prior art is made and then if found valid, patent is granted. Usually it takes three years, where 18 months goes for processing and another 9 months is kept for challenge and then depending on the outcome of the opposition grant or denial of the patent takes place. Companies after getting the French patent, if funds allow, go for EPO patent also. According to INPI statistics, 16,858 patents were filed in France in 2003 out of which 11,587 were granted patents perhaps in the area of process patents. In 2004, 17,300 applications have been filed in the

field of drugs. These statistics show that France is in a better situation compared to other European countries in creating intellectual properties.

The Supplementary Protection Certificate (SPC) adopted by the French patenting authority is an interesting system applicable only for medicines. SPC is granted to compensate the companies for the time lost between the grant of the patent and the time that the product was ultimately marketed. So within 6 months of starting their marketing of products, firms can file their application for SPC, which will extend patent protection for another five years. However, the conditions are that: (1) a firm should have filed for SPC application within 6 months of starting its marketing of the product; (2) patent application should be clear and the producer has the monopoly of that product and no related product should have been patented; (3) only one SPC will be available per product even if a drug is found suitable for multiple uses;(4) this patent holder should be the first person to market the product in Europe; and (5) methods of treatment granted patent in the US will not be accepted for SPCs in France.

Such measures, which extend the market exclusivity for firms, act against the interest of the generic firms, because till the period of exclusivity, the entry of generics is delayed. In 1992, the number of applications (Table 7) had been more, as that was the terminal year of the French SPC which provided protection for seven years and the conversion to the present five years' SPC took place.

Table 7. Status of supplementary protection certificates

Year	No of SPCs granted
1992	539
1993	68
1994	26
1995	49
1996	50
1997	135
1998	46
1999	46
2000	41
2001	57
2002	54
2003	35

Source: Compiled from Institut National de la Propriete Industrielle.

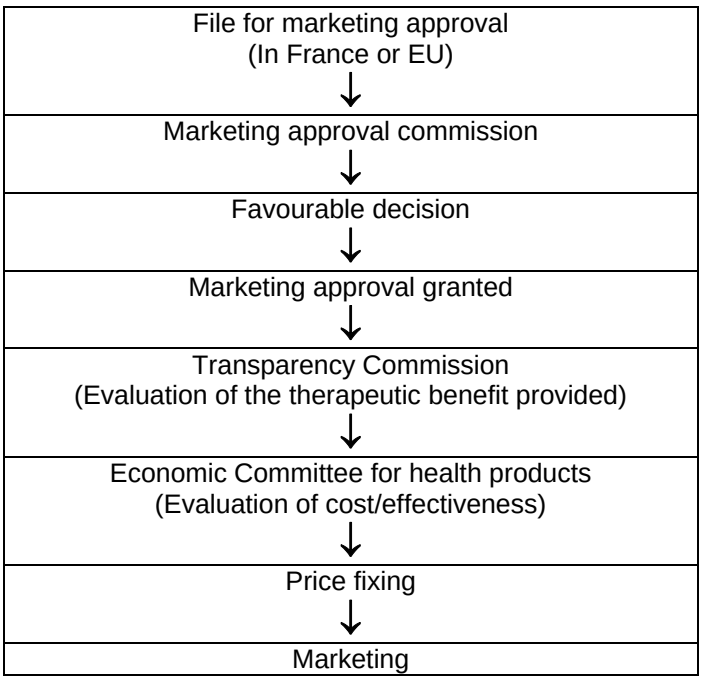
So many companies took advantage of that and were granted FSPC. French patent system like the Indian patent system does not provide utility patents. On the biotech front, due to the French government's restrictive stand on patenting human cells, DNA etc, not many biotechnology firms are filing patents and not many French firms are investing in biotechnology.

3.2. The regulation of drug supply

A pharmaceutical specialty is an industrially manufactured drug, sold under a brand name irrespective of the dosage strengths, administration forms and packaging. A presentation corresponds to the different dosage strengths administration forms and packaging of a specialty. According to LEEM (the French association of pharmaceutical companies) in 2005, there were about 5,000 pharmaceutical specialties on the market sold as about 9,000 presentations.

A stringent framework activated by health authorities regulates the activities of pharmaceutical industry (Chart 1).

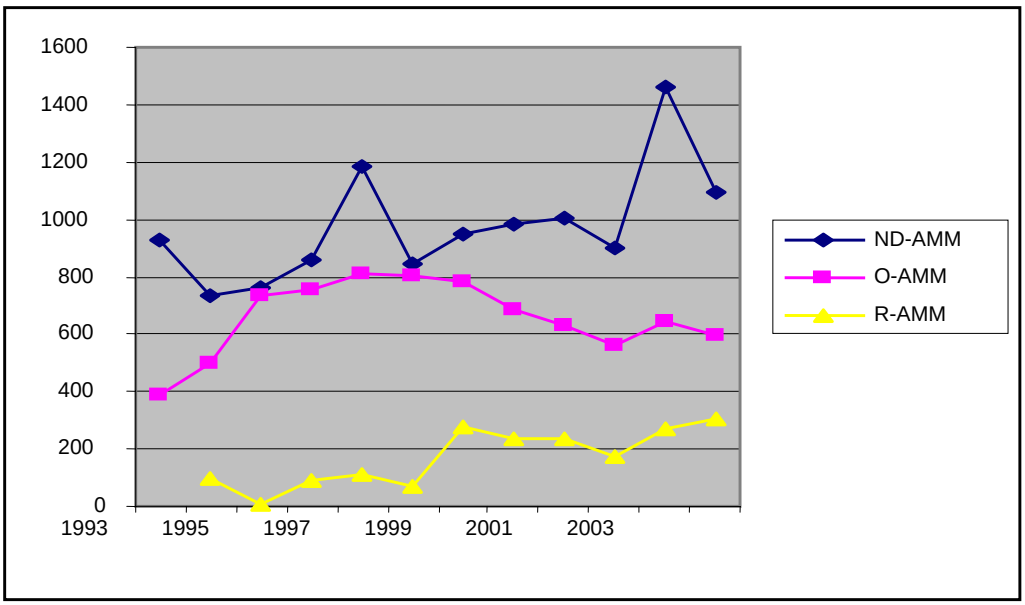
Chart 1. The drug circuit in France



In particular, a drug can be marketed if it has received a marketing approval delivered by the AFSSAPS, i.e. the French agency for the safety of health products. The procedure is, once the file consisting of the clinical data is submitted to the AFSSAPS, its technical advisory Commission evaluates the benefit/risk ratio of the drug according to three criteria, namely: quality, safety and effectiveness[1]. No economic consideration intervenes at this stage. The emphasis is only on the said drug's benefit/risk ratio, which should be equivalent to medicines that are already marketed. Within 120 days, the AFSSAPS must take a decision concerning the marketing approval of a drug.

The number of marketing approval has increased over the years: In 2005, AFSSAPS received 1,096 new applications for marketing approval against 926 applications in 1993 (Figure 2).

Figure 2. Marketing approvals between 1993 and 2004: filings and results



ND-AMM: new filings for marketing approval.
O-AMM: marketing approval granted.
R-AMM: marketing approval denied.
Source: AFSSAPS, Rapport annuel d'activité, 2004.

[1] The quality of a drug refers to the manufacturing practices. The AFSSAPS must ensure that these practices are in compliance with international standards labelled "good manufacturing practices". Thus, the agency has to control the manufacturing units.

Among these, 388 and 596 marketing approvals were granted in 1993 and 2005 respectively. Marketing authorization was also given to 782 drugs with 28 new active ingredients.

The AFSSAPS has control over the drug even after the marketing approval is provided since the phase IV of pharmacovigilance starts only after the marketing approval. In this phase, clinical data are collected under real conditions of use, to assert the safety, effectiveness and quality of the product. The marketing approval may be suspended, even withdrawn permanently if clinical data revealed dangerous side effects. Even if adverse impacts of the drugs are not present, the AFSSAPS provide additional information to the professionals. On the contrary, the marketing approval can be wide if data allows to enlarge therapeutic indications and/or to extend prescription to larger populations[2]. In 2005, 241 marketing approvals were withdrawn and 15,810 marketing approval were modified, which means that the therapeutic indications were enlarged or narrowed.

Once the marketing approval is gained, to ensure the reimbursement of its drug by the social security, a pharmaceutical firm must deposit a request to be examined by the "*Commission de Transparence*" (Transparency Commission). Under the supervision of the AFSSAPS, this commission pronounces a scientific opinion on the therapeutic benefit provided by the drug (Service medical rendu) defined at five levels that are mentioned below.

(i) Level 1 provides major therapeutic benefit

(ii) Level II indicates that the drug provides an important benefit concerning therapeutic efficiency and/or reduction of side effects;

(iii) For level III, the drug provides a moderate benefit concerning therapeutic efficiency and/or regarding the reduction of side effects;

(iv) Level IV states that the drug provides a minor therapeutic benefit;

[2] The AFSSAPS can exceptionally authorize the use of drugs before a marketing approval is obtained, for one year (duration renewable) to treat in hospital severe infections or neglected diseases for which no treatments are available. In particular, temporary authorization for individual or cohorts was issued to allow the use of the first anti-AIDS treatments, still under clinical studies stages.

(v) Under level V, the drug provides no benefit concerning therapeutic efficiency and/or reduction of side effects;

Moreover, the Commission gives an opinion concerning the registration (1) of the drug on the list of medicines approved for use in hospitals and (2) on the list of the medicines reimbursed at 35%, 65% or 100% by public health coverage.

The opinion of the Commission is then transmitted to the "*Comité économique des produits de santé*", i.e. the Economic Committee for health products. In the event of a favourable scientific opinion, this committee then negotiates the price of the drug with the firms. Here, economic considerations intervene following the agreement signed in 1994 between public health authorities and the pharmaceutical industry. This agreement states that the price is given by taking into account the: (i) forecasts of drug sales; (ii) promotional campaigns and the therapeutic strategies of the firms; and (iii) savings generated by the prescription of the drug. Thus, public authorities play an important role in fixing the prices of the drugs by taking into consideration such as the budget allotted for social security expenses, the planned volume of sales and the therapeutic benefit provided by the drug.

4. The market for drugs

Within the European market, the market for drugs in France was US$ 28 million in 2005 ranked after Germany with US$ 29 million and it ranks fourth in the world (IMS health, 2006). In fact, break up of household expenses in 2003 indicate that on average a French spent 5.73 Euros on food and non alcoholic beverages, 1.31 on tobacco and alcoholic drinks, 1.79 on clothing, 9.57 on housing, heating and lighting, 3.59 euros on hobbies and culture and 1.35 francs on pharmaceuticals which was 0.58 francs in 1970 (INSEE, 2006). In addition, drugs consumption rose from 0.09 Euros per person per day in 1970 to 1.35 Euros per person per day in 2003 due to the ageing of population.

The drugs supply goes through two main circuits: hospitals and pharmacies. The hospital market absorbs approximately 19 per cent of drug sales against nearly 80 per cent for the retail pharmacy market, which accounts for 4.42 and 18.8 billion euros respectively. It should be emphasised that sales in hospitals increased in value terms from 13.2 per cent in 1994 to 19.1 in 2004 while sales in pharmacy declined from 86.2 to 80.9 per cent during the same period. The two

markets go through contrasted evolutions, which make the hospital market the most dynamic. Indeed, between 1993 and 2004, the hospital market progressed on average and in value by 10.5 per cent per year whereas the retail pharmacy market increased by 5.7% annually, a rate close to the overall drugs consumption (AFSSAPS, 2006).

One of the objectives of hospitals is to improve patients' accessibility to latest therapeutic innovations. The average `age' of drugs sold in hospitals is 7.5 years against 13.5 years in pharmacies. However, these innovative drugs supplied by hospitals are also the most expensive, especially anti-cancer, anti-HIVAIDS treatments or medicines prescribed for neglected diseases[3]. Third, in hospitals, the pharmacist and the pharmaceutical firms freely negotiate prices on the basis of volume. Compared to the strict fixing of prices for reimbursed medicines sold in pharmacists, hospitals display higher prices and high expenditures in value. Yet, hospitals pricing system is actually undergoing several reforms to lower prices and reduce expenditure on drugs spending.

Besides, from 1995 to 2004, the drug expenditure increased in France from 18.4 to 30.3 billion euros whereas the total health expenditure rose from 100 to 147.6 billions on the same period (DREES, 2005). However, the rising of drug consumptions over the years is more related to the increase in volume consumed than an increase of drug prices. Indeed, the consumption of drugs increased on an average by 5.1 per cent during 1995 to 2000, and 5.7 per cent in 2004 (Table 8).

Table 8. Evolution of medicines consumption in France

Value/ volume	Average and annual rate in per cent			
	1995/2000	2002	2003	2004
Value	5.1	5.6	6.4	5.7
Price	0.0	-1.1	-0.4	-1.2
Volume	5.0	6.8	6.9	7.0

Source: DREES, 2005.

In comparison, in volume, the drug consumption increased by 5 per cent per year between 1995 and 2000 and reached 7 per cent in 2004. But, as shown in the

[3] For instance, at the early stage of the HIV/AIDS epidemic, people infected had to go to hospitals for treatment. Antiretrovirals as new medicines were sold at high costs: thousands of euros per year and per patient, which induce a huge increase in hospital expenditures for the supply of drugs.

table, prices do not account for the increased drug expenditures. In contrast, the reduction in price seems to have softened the rising drug expenditure (Table 9).

Table 9. Price index of medicines in France (Base 1998 =100)

Medicines	1998	1999	2000	2001	2002	2003	2004
1. Reimbursed medicines	100	99.5	98.8	97.5	96	95.2	93.6
Annual evolution (in %)		-0.5	-0.7	-1.5	-1.5	-0.8	-1.7
2. Non reimbursed medicines	100	102.4	104.7	106.3	109.4	113.3	117.3
Annual evolution (in %)		2.4	2.2	1.5	2.9	3.6	3.5
3. Altogether	100	99.8	99.4	98.3	97.2	96.8	95.7
Annual evolution (in %)		-0.2	-0.4	-1.1	-1.1	-0.4	-1.2

Source: Compiled from Institute national de la statisque et des etudes economiques (INSEE)

This feature is confirmed by the evolution of price index of drugs from 1998 to 2004 in the category of (a) all the drugs, (b) reimbursed drugs and (c) non-reimbursed drugs. In France, the drugs prescribed by the physicians are reimbursed by social security scheme at different rates according to the type of drugs. For instance, while 100 per cent reimbursement is available for drugs that are meant for severe and disabling diseases, 65 per cent reimbursement is available for drugs meant for severe diseases. Only 35 per cent of the drug expenditure is reimbursed for drugs that are meant for symptomatic treatments of less severe diseases.

As noted in Table 9, the price index of medicines was negative during this period: –0.2 in 1999 and -1.2 in 2004. Precisely, the price index for reimbursed drugs has undergone further reduction as compared to the price index of non-reimbursed drug. On average, per year, the price index of reimbursed drugs was –1.08 and 2.68 for non-reimbursed drugs. So, compared to other European countries and OECD countries like Japan and the US, the French market is definitely characterized by high consumption of medicines in terms of volume per capita. An average prescription in France contains 4.2 drugs against only 0.8 in Northern European countries.

In 2004, reimbursed medicines had a market share of 93.4 per cent as against 91.2 per cent in 1995, while the share of non-reimbursed medicines reduced from 8.8 per cent in 1995 to 6.6 in 2004. Average break-up of turnover at market price of reimbursable medicines sold by pharmacists in 2000 was as follows:

manufacturers' turnover 64.4 per cent; pharmacist 26 per cent; wholesaler 3.4 per cent and state 6.2 percent (which includes taxes on advertising, specialities, direct sales, discount to ACOSS (Agence Centrale Des Organismes De Securite Sociale), wholesale contribution and VAT).

Table 10 gives the percentage of amount spent on the three categories of reimbursed drugs over a period of time, and drugs reimbursed at 35, 60 or 100 per cent following the severity of the infection.

Table 10. Percentage of pharmaceuticals according to the reimbursement

Year	Pharmaceuticals reimbursed at		
	35 per cent	65 per cent	100 per cent
1993	10.4	72.8	16.8
1994	7.3	75.3	17.3
1995	6.4	75.6	18.0
1996	5.2	75.7	19.1
1997	5.2	78.2	16.6
1998	9.3	80.9	9.8
1999	4.2	80.8	14.9

Source: Syndicat National de l'industrie Pharmaceutique (2000)

The table also reports that between 1993 and 1998, drugs for less severe diseases constituted about 6 per cent have shown a declining trend. On the other hand, drugs that treat severe diseases accounted for a major share of 75 per cent. And the drugs that are meant for 100 per cent reimbursement constituted around 14 per cent. It is evident that while on an average about 75 per cent of the drug expenditure is reimbursed, the drugs that are reimbursed at 65 per cent account for a larger chunk followed by fully reimbursed drugs. In value terms those that are reimbursed at 35 per cent declined from 5260 million francs in 1992 to 4729 francs in 1999. As against this, those drugs, the value of those which are reimbursed fully, increased from 20885 million francs in 1992 to 31847 million francs in 1999.

4. 1 Consolidation of the pharmaceutical industry

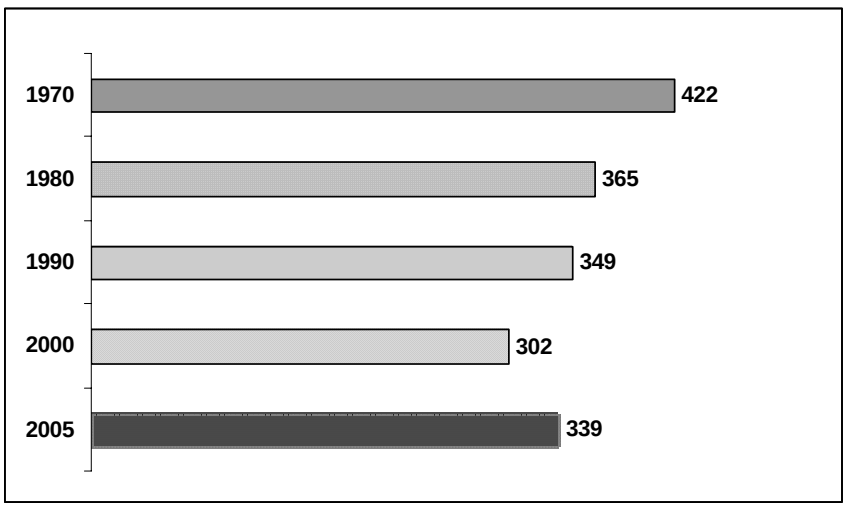
The major industries in France are automotive, electronics, Agro/food, cosmetics and pharma. Like other countries, France has also experienced a consolidation of its pharmaceutical industry. As indicated before, the AFSSAPS regulates the

drugs, health care products and food products. Its main responsibility is to inspect the manufacturing plants. As of 2002, there were 20 inspectors for chemical drugs, 18 for biological drugs, 15 for medical devices and 10 for pre-clinical and clinical drugs. Like other European countries, France has signed mutual recognition agreements for its drugs within Europe and the US.

Cruset (2002) observes that according to the French regulation, at the end of each year, every pharmaceutical production site has to complete or update a document called "Etat des Lieux" that summarizes the site description and organisation, products manufactured, materials used and contractors supplying materials. Furthermore, routine inspections are handled by one or two inspectors to verify the compliance with good manufacturing practices (GMPs), and the drug registration file etc. During the year 2001 about 750 inspections were performed, which was an increase of 50 per cent over 2000.

The number of pharmaceutical companies operating in France reduced from 1000 in the 1950s, to 300 in 2003 (Figure 3)[4]. This reduction is basically due to the consolidation of pharmaceutical companies in the form of mergers.

Figure 3. Evolution of the number of pharmaceutical units in France



Source: LEEM, 2006, available on www.leem.org

[4] Pharmaceutical companies are defined as those companies marketing at least one human-use speciality products having a marketing authorization.

The pharmaceutical sector is made up of a large number of small firms where firms employing less than 500 persons account for 67 per cent of the total number of companies whereas large firms (employing more than 500 persons) account for the rest. It is observed that 66 per cent of the companies have a total market share of only 8.3 percent, while 3.5 per cent of the companies have a huge market share of 48.2 per cent (Table 11).

Table 11. Consolidation of the French pharmaceutical industry based on market shares in 2005

Market shares	<0.25%	0.25 to 0.5%	0.5 to 1%	1 to 2%	>2%	Total
1. Number of companies	264	34	16	13	12	339
2. Total markets shares of those companies	8.3	12.1	11.2	20.2	48.2	100

Note: Turn-over in hospitals and pharmacists
Source: LEEM, 2006, available on www.leem.org

4.2. Employment and investment in pharmaceutical industry

The consolidation of pharmaceutical firms, which has resulted in the reduction of the number of companies, appears, however, not to have affected the employment. On the contrary, the number of jobs in the pharmaceutical industry has increased by 20 per cent in the last ten years with the creation of 2000 jobs on an average per annum. Presently, the pharmaceutical industry employs 100,000 persons. Employment increased by 0.8 per cent in 2003 and 1.55 in 2004, with a net creation of 500 jobs. Still, the pharmaceutical industry remains dynamic compared to the reduction of employment by 2.5 per cent in all industrial sectors between 2003 and 2004. While this sector consists of essentially of small units, big firms (employing more than 500 persons) hire 83 per cent of employees.

There is an increase in the employment in all segments of the pharmaceutical sector as evident from Table 12. While, employment in production and marketing has slightly reduced compared to the previous period (1989) perhaps due to the consolidation of companies but the modernisation trend has resulted in improvement in R&D employment even if it had been moderate. R&D employment has increased from 5100 in 1970 to 11,200 in 1990, i.e. employment has doubled after twenty years, which indicates that R&D has stagnated in France.

Table 12. Employment in the pharmaceutical firms

Firms	1989		2004		% change (1989-2004)
	No	(%) share	No	(%) share	
1. R&D	6098	7.9	12922	13.0	112
2. Production	26907	34.9	32802	33.0	22
3. Marketing	27963	36.3	33796	34.0	21
4. Management and others	16022	20.8	19880	20.0	24
Total	76990	100.0	99400	100.0	29

Source: LEEM, Enquête emploi, 2003, available on www.leem.org

After reaching a level of 15,200 in 1997 and 1998 from a level of 14,600 in 1995, R&D employment has been on the decline reaching 12,922 in 2004. The decline in employment was more pronounced between 2002 and 2004 (Table 13).

Table 13. Trends employment in R&D in pharmaceuticals

Year	Employment in R&D	Growth over the previous period (%)
1970	5100	---
1975	6100	19.6
1980	7000	14.8
1985	9000	28.6
1990	11200	24.4
1995	14600	30.4
1996	14900	2.1
1997	15200	2.0
1998	15200	0.0
1999	15020	-1.2
2002	14715	-2.0
2004	12922	-12.2

Source: Key Data Pharmaceuticals in France (www.leem.org)

Table 14 reports the investment in the pharmaceutical industry, which has increased at the rate of 0.05 per cent. Investment in the R&D shows that while the fundamental research gets the lowest allocation (5.1 per cent of R&D

expenditures), development research gets the highest order of preference with as much as 38.5 per cent of R&D expenditures[5].

Table 14. Investment in pharmaceutical industry

Year	Investment (in million euros)	Investment rate
1980	99	6.5
1985	240	8.2
1990	500	11.1
1991	457	9.4
1992	521	10.2
1993	600	10.7
1994	540	9.3
1995	521	8.0
1996	591	8.6
1997	727	10.3
1998	753	9.8
1999	725	8.8
2000	756	8.6
2001	856	8.6
2002	927	8.9
2003	829	7.9
2004	970	8.2
CGR	0.052	

Note: CGR – Compound Growth Rate,
Source: www.leem.org

R&D expenditure and investment in R&D as percentage of sales turnover in selected countries is provided in Table 15. US top the list followed by Japan, UK, Germany and France. In terms of R&D investment as percentage of sales turnover, Sweden tops the list followed by UK and US. French companies have invested 12.5 per cent of their sales in R&D. But in terms of invention of new molecules invented by different countries, US tops the list with the invention of 65 molecules in 1999 followed by France with 11 molecules and no other country is

[5] Basic or fundamental research is defined as work that advances scientific knowledge without a specific application in view. Applied research or developmental research is expenditure on manufacturing process, preclinical and clinical trials.

anywhere near the position of the US. According to a survey of major investments that were taking place in France in 2002, while the pharma/cosmetics/chemistry accounted for 206 projects and accounted for 3.26 billion euros, the pharmaceutical industry including device and drug delivery components accounted for 63 projects with a total capital spending of about 1.09 billion euros.

Table 15. R&D expenditure in pharmaceuticals & new molecule innovations in select countries

Country	R&D expenditure (in million euro)	R&D/sales (%)	No of new molécules
1. United States	18787	20.1	65
2. Japan	4641	8.1	7
3. Germany	2758	15.6	4
4. UK	2696	22.3	7
5. France	2499	12.5	11
6. Switzerland	1726	14.5	6
7. Italy	759	6.1	1
8. Sweden	1022	27.2	2

Source: Syndicat National de l'Industrie Pharmaceutique, 2000.

The details of these 63 projects are given in Table 16. This Table shows that in value terms 26 pharmaceutical formulations projects accounted for 49 per cent of

Table 16. Pharmaceutical projects and their investment

Pharmaceutical projects	Number	Value of capital invested (% share)
1. Pharmaceutical formulations	26	49
2. Vaccines	4	17
3. Active ingredients	6	11
4. Skin/eye/foot care products	5	9
5. Medical device/components	9	5
6.Solutions/transfusion/blood derivatives	4	4
7. Contract manufacturing	4	2
8. Radioactive/diagnostics/ development	4	2
9. Distribution/warehousing	1	1

Source: Cruset, 2002.

value or total capital invested, followed by vaccines where just 4 projects accounted for 17 per cent of the value of investment. Six active ingredients or bulk drugs accounted for 11 per cent of the total value of the project. Ten projects were involved in revamping/upgrading that accounted for 18 per cent of the capital employed that were mostly undertaken by the existing facilities in order to comply with good manufacturing practices systems (GMPs).

However, further break up of these investments as reported in Table 17 reveal that as many as 34 projects were meant for increasing the capacity that accounted for 55 per cent of the capital invested and the investment in R&D facilities numbered only 6 and accounted for 12 per cent of the capital invested. This entire investment is spread in the various regions of the country, yet, Rhone Alpes, Alsace, Provence Alpes Cote Azur and Haute Normandie account for investment worth 203, 175, 121, 95 million Euros respectively.

Table 17. Details of pharmaceuticals investment in 2002

Project category	Number	Value (% share)
1. Capacity increase	34	55
2. Revamping/upgrade	10	18
3. R&D facilities	6	12
4. Logistics	11	3
5. New site	2	2

Source: Cruset, 2002.

Interestingly, the domestic sales turnover, which contributed about 82 per cent of the total turnover in 1990, has steadily declined to contribute only 59 per cent in 2005. On the other hand, turnover from exports increased from 18 to 41 per cent by which the French pharmaceutical industry has become the third exporter in the world. In 1990 much of the pharmaceutical products were exported to French speaking Europe, other European countries and French speaking African countries (Table 18).

Table 18. Pharmaceutical sales turnover (in million euros)

Year	Turnover (Million Euros)			Turnover (%)	
	Domestic sales	Exports	Total	Domestic sales	Exports
1990	9588	2096	11684	82	18
1991	10397	2561	12958	80	20
1992	11068	2958	14025	79	21
1993	12089	3079	15169	80	20
1994	12402	3476	15878	78	22
1995	13348	4029	17378	77	23
1996	13789	4619	18408	75	25
1997	14292	5564	19856	72	28
1998	15047	6784	21831	69	31
1999	16045	7805	23851	67	33
2000	17263	9621	26894	64	36
2001	18675	12861	31536	59	41
2002	19991	14467	34378	58	42
2003	21320	14529	35849	59	41
2004	22760	15340	38100	60	40
2005	23838	16747	40585	59	41
CGR	0.06	16	0.09		

Note: CGR – Compound Growth Rate
Source: LEEM, GERS, available on www.leem.org.

4.3. A positive effect on turnover and trade surplus

The turnover of the pharmaceutical industry steadily increased over the decades. Between 1990 and 2005, the turnover went from 11.6 billion euros to 40.5 billions. In detail, the turnover on domestic sales increased from 9.5 billions euros to 23.8 billion in the same period, with an impressive growth of 148.6 per cent over the period (Table 19). Meanwhile, exports turnover increased from nearly 2.1 billion euros to 16.7 billion. Thus, the total turnover increased by nearly 130 per cent over the ten-year period. While the export turnover increased by about 247 per cent, domestic sales turnover increased by 148.6 per cent.

Table 19. Destination of pharmaceutical products exports from France, 1990-2005

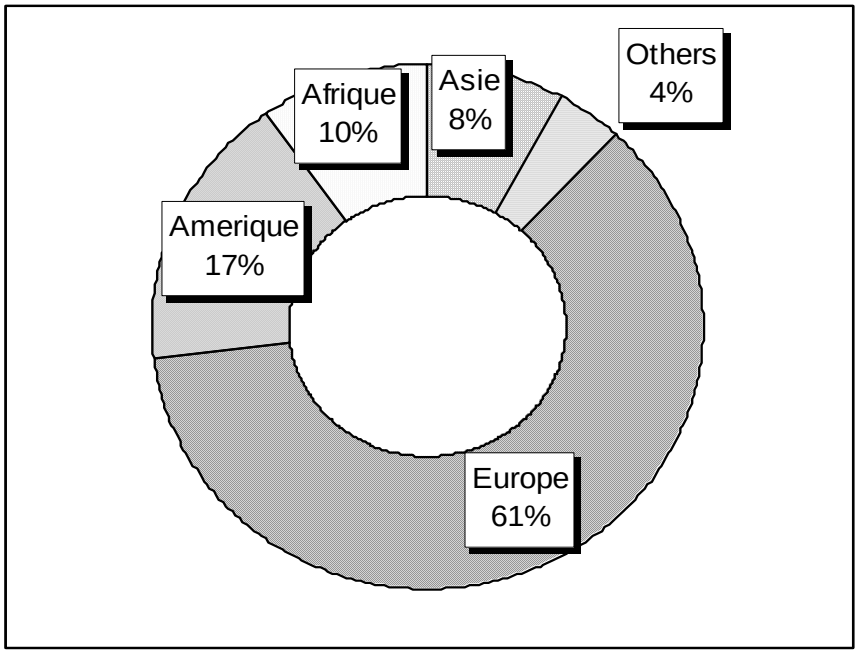
Country	1990 Exports (Million euros)	Country	2000 Exports (Million euros)	Country	2005 Exports (Million euros)
Germany	278 (13.3)	UK	1014 (10.5)	USA	2148 (12.8)
Netherlands	178 (8.5)	Germany	966 (10.0)	Belgium	1711 (10.2)
Algeria	176 (8.4)	Benelux	2 (0.0)	Germany	1456 (8.7)
Benelux	171 (8.2)	USA	834 (8.7)	UK	1247 (7.4)
UK	132 (6.3)	Italy	671 (7.0)	Italy	1216 (7.3)
Italy	112 (5.3)	Spain	520 (5.4)	Spain	970 (5.8)
Tunisia	88 (4.2)	Switzerland	440 (4.6)	Switzerland	767 (4.6)
Switzerland	77 (3.7)	Netherlands	361 (3.8)	Algeria	520 (3.1)
Ivory coast	76 (3.6)	Algeria	312 (3.2)	Netherlands	433 (2.6)
Cameroon	64 (3.1)	Poland	199 (2.1)	Japan	412 (2.5)
La Reunion	60 (2.9)	Greece	181 (1.9)	Greece	354 (2.1)
Martinique	39 (1.9)	Ireland	139 (1.4)	Poland	320 (1.9)
Spain	36 (1.7)	Japan	134 (1.4)	Australia	267 (1.6)
USSR	36 (1.7)	Austria	126 (1.3)	Canada	254 (1.5)
USA	35 (1.7)	Australia	121 (1.3)	Hungary	238 (1.4)
Total export	2096 (100)		9621 (100.0)		16747 (100.0)

Note: Figures in parentheses are respective percentage shares.
Source: Custom data, available on www.leem.org

However, this trend has been changing. As pharmaceutical exports have increased over the decades, the USA has emerged as the major buyer accounting for 10 per cent of the French drug exportations in 2005. Meanwhile, the share of the exports to French speaking Europe and French speaking Africa has declined. As compared to this, exports to rest of the Europe increased largely.

The trade surplus of the pharmaceutical industry which was 97 million euros in 1980, reached a level of 5.6 billions in 2004 where the export turnover largely cover the import turnover (15.3 and 9.6 billions euros respectively). Figures 4 and 5 present the medicinal exports from France and the trade balance respectively.

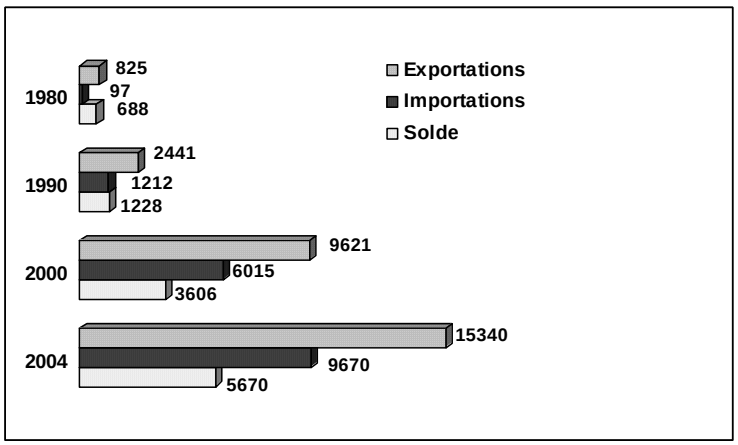
Figure 4. Exportation of French medicines by region



Note: Others include Oceanie and Moyan Orient, 2% each

Source: Custom data available on www.leem.org

Figure 5. Evolution of trade balance for medicines



Source: Customs data, available on www.leem.org

Table 20 summarizes the international market characteristics of French pharmaceuticals firms as compared to other OECD countries such as USA, Japan, Germany and UK. It reports that market size of French pharmaceuticals have shrunk in 1999 when compared with other OECD countries and compared

with its own performance in the earlier time points. R&D intensity of the French companies has however consistently increased in the three time points that are considered. This is also reflected in the number of new chemical entities brought out by the companies. However, the number of NCEs, which was 98 during 1971-80 and was next only to USA reduced to 37 during 1981-90 and further shrunk to 23 during 1990-1999.

Table 20. International pharmaceutical market characteristics

Characteristics	USA	Japan	Germany	France	UK
1. Market size in $ billion					
1987	39.3	30.2	11.8	10.2	8.2
1993	70.8	51.1	19.5	17.1	14.9
1999	130.1	53.5	19.9	17.8	18.6
2. R&D intensity in (%)					
1983	10.6	6.7	8.4	7.1	11.7
1992	14.3	9.8	9.2	8.7	16.3
1998	18.9	11.7	15.6	11.4	22.3
3. NCEs					
1971-80	154	74	91	98	29
1981-90	142	129	67	37	28
1990-99	161	113	40	23	32
4. Number of products in top 50					
1985	23	5	5	1	9
1990	27	2	5	0	12
1998	31	2	3	0	10
1995-99	24	3	4	3	8
5. Firms market share in the US (%)					
1989	62.0	0.1	14.0	0.2	8.8
1998	58.5	1.5	6.8	1.8	11.6
2001	64.0	4.0	6.0	4.0	15.0

Source: Casper and Matraves, 2003.

In fact except Japan, which shows a clear increase in the NCEs in 1981-90, NCEs from other OECD countries have reduced, which however was rectified by USA alone in 1990-99. The increase in R&D intensity which has not corresponded with the increase in NCEs suggest that perhaps sizeable R&D investment would have gone for improvements in the facilities such as good manufacturing requirements. Further, France has the least number of products that come in the top 50 products as compared to the US, Japan, Germany and the UK. In both 1990 and 1998, there was not a single product that was in the top 50 products list. However, it is clear from the table that the share of the French

pharmaceuticals in the US market has increased from 0.2 per cent to 4 per cent in 2001.

5. Encouraging the use of generics in France

As discussed earlier, in France, most of health care expenditure is reimbursed. Hence, since the end of the 90s, the government has been taking measures to control health expenditures. These measures concern merely the control of price, the reimbursement of medicines and the promotion of generics.

5.1. Measures for the promotion of generics in France

In order to contain the growing health care costs and favour a steady reduction of resources devoted to drugs, the French government has started providing incentives progressively to pharmacists, physicians and patients to obtain a prominent use of generic drugs at the end of the 90s. At that time, the French generics market was dormant at 2.4 per cent of the market for reimbursed drugs in 1999 (Généricam, 2003). Large possibilities for generics use exist as indicated in Table 21, where, compared to other developed countries, the generic market of France represented US$ 1.1 billion (3.3% in 2001) as against 3.3 billions in Germany (10.5%) or 4.8 billion (15.2%) in Japan.

Table 21. Market share of generics (in US $ billion)

Country	2001	Share (%)	2006	Share (%)
1. US	16.2	51.4	31.0	56.7
2. Japan	4.8	15.2	6.0	11.0
3. Germany	3.3	10.5	5.3	9.7
4. India	2.2	7.0	3.0	5.5
5. UK	1.6	5.1	2.4	4.4
6. France	1.1	3.5	1.8	3.3
7. Russia	0.6	1.9	1.5	2.7
8. Poland	0.7	2.2	1.4	2.6
9. Canada	0.9	2.9	1.2	2.2
10. Brazil	0.1	0.3	1.1	2.0
Sub total	31.5	100.0	54.7	100.0

Source: Key pharmaceuticals data in France, 2001-available at www.leem.org

Substitution right was first granted to pharmacists in 1999. Till then, physicians prescribed drugs by their brand name and the patients did not have any reason to ask for generic drugs because 92 per cent of patients were reimbursed for their prescribed drugs thanks to the social security and/or private insurance systems. Following the substitution right, anytime a physician prescribes a drug to a patient, the pharmacist can concretely substitute for a generic drug unless the physician specifies that substitution is not allowed because of the patient's specificities.

The low level of prices of generics in France also contributes the low level of generic market. Michel observes that, to encourage pharmacists to substitute generics for originators, the government modified their margin system, which was originally proportional to the selling price. Under the new system, they receive the same margin, in absolute terms for both the original brand and the corresponding generics. In addition, generic companies are allowed to give pharmacists discounts of up to 10.74 per cent of the wholesaler's price while 2.5 per cent is what the brand drugs offer. In fact, pharmacists receive much greater discounts from generics companies, which is about 40 per cent on average (Michel, 2003).
A second explanation given is that a repertory of International Non-proprietary Name (INN) was lacking to encourage substantial changes regarding the habit of physicians to prescribe using the trademark of medicines, and to ease substitution by pharmacists whenever a less expensive equivalent is available. While the substitution right was introduced in 1999, a comprehensive repertory was missing. This repertory is supposed to list all the pharmaceutical substance by INN and indicating all their therapeutic equivalents for every therapeutic class. Precisely, on the basis of the same therapeutic dosage and the same administration mode, the repertory is supposed to mention the most sold branded drugs with their price, and all the equivalent medicines available are ranked according to the discount price compared to the branded drugs. In 2000, this repertory was hardly covering 14 per cent of the market for reimbursed medicines. Basically, the practical resort to substitution was limited.

In 2002, physicians signed an agreement with the government under which their fees were increased and they committed to ensure that 25 per cent of their prescriptions would be written using their INN and 12.5 per cent concerned generic drugs. A survey conducted by Paris (2003) indicates that 82 per cent of patients agreed that their physician prescribe them generic drugs (while 75% agreed that pharmacists operate substitution for generics). However, in 2003, all

these measures did not induce significant increase of generic drugs: in value, the generic market reached 5.2 per cent and 10.8 per cent in volume (AFSSAPS, 2006).

Other than involving pharmacists and physicians in the promotion of generics, measures were also taken to change the behaviour of patients. In 2003, the French government introduced the "*tarif forfaitaire de responsabilité*". According to this reference pricing system, drugs are now reimbursed on the basis of the price of less expensive generic. Accordingly, patients have to choose between shifting for the generic equivalent of the prescribed branded drugs, or paying the surplus and keep on using the branded drugs. Today, 450 medicines are reimbursed on the basis of the reference price on a total of about 5000 drugs that are marketed. This reference price concerns only therapeutic classes where the generic penetration is between 10 and 45 per cent in volume.

Once more, the pertinence of this measure depends on the edition of a comprehensive repertory of generics, which is to be done by the AFSSAPS. While patients will be induced to ask their doctor for the prescription of the less expensive therapeutic equivalent, physicians must be provided with a comprehensive repertory of generics. The more comprehensive is the repertory, the larger will be the saving realised due to a higher penetration of generics on the market for reimbursed drugs (this is called the field effect). Efforts have been made by this AFSSAPS to cover more and more therapeutic class. Besides, the success relies also on the implication of private insurances. Patients might not change their behaviours if their private insurance would cover the difference between the price of a branded drug and the reference price. If the private insurance also prepares a list of drugs that would be covered for reimbursement, then there could be a large impact in favour of generics.

A reference price may also impact the growth of generics negatively. The brand name producers, in order to avoid reduction in sales, would prefer to price their products at the same level as generics, which may force the generic producers to reduce their prices. But Michel (2003) observes that the impact of this measure could be limited if the government decides to introduce reference pricing only for a few molecules. He however argues that with all these government measures, the generic market could grow from US $ 1.1billion in 2001 to 1.8 billion in 2006, which could lead to positive growth in profitability at 2 to 3 per cent in 2006 from a negative 4 per cent in 2001.

Measures taken by health authorities aimed at reducing the reimbursement rate (a) of some medicines or (b) according to the therapeutic benefit they may provide. As mentioned earlier, the evaluation of the therapeutic benefit has become a major tool for the Economic Committee for health products to negotiate the price of drugs with pharmaceutical firms. Since 2003, the evaluation of the therapeutic benefit made by the Transparency Commission is used by this committee to proceed to the de-reimbursement partially or totally of these drugs whose therapeutic benefit provided appears to be insufficient or nil. Following this logic aimed to cut health expenditures drastically, by increasing out of pocket expenditures for patients, the level of reimbursement was lower for 617 drugs and 80 drugs were no longer reimbursed in 2003. Then in 2006, health authorities have decided not to reimburse 152 drugs any more in order to save 254 million euros this year. Today, the penetration of generics on the market for drug reimbursed has reached 7.8 per cent in value and 15.7 per cent in volume.

Logically the rising health expenditures, and particularly drug consumption, should lead to increasing the profit of the pharmaceutical industry. Following the British example, in 1997, France has introduced a specific contribution of the pharmaceutical industry to the deficit of social accounts regarding health. Precisely, as stated above, public health authorities and the pharmaceutical industry on the basis (among others) of the forecasts of drug sales negotiate the price of the reimbursed drug. In case, of sales higher than the ones expected, which means a high level of drug consumption and health expenditures, the pharmaceutical industry will have to return part of the surplus earned. Introduced in 1997, the LEEM estimates that the amounts collected as specific contribution has tripled within three years. This contribution of the pharmaceutical industry increased from 472 million euros in 1999 to 784 millions in 2004 (LEEM, 2006).

Interestingly, the regulatory measures to promote generics such as substitute right, INN prescription, fast track approval, incentives for pharmacists and physicians introduced by the French government are yet to be introduced by other OECD governments (Table 22). For instance, UK, where 52 per cent of the total prescription is generics, is yet to introduce reference-pricing system, substitute right, INN prescription and incentives/constraints for physicians. Germany has introduced most of the regulatory measures but for Roche/Bolar provision, incentives for physicians and public campaign by health authorities. Thus, market for generics is brighter in France than a few countries mentioned in Table 22.

Table 22. Regulatory measures adopted to promote generics in different countries

Regulatory Measures favouring Generic market development	US	Germany	UK	Netherlands	Canada	France	Japan	Spain	Italy	Brazil
1. Reference pricing system		Yes	Y*	Yes	Y*	Yes		Yes	Yes	
2. Substitute Right	Yes	Yes	Y*	Yes	Yes	Yes		Y*	Yes	Yes
3. INN prescription		Yes	Y*		Y*	Yes		Yes	Yes	Yes
4. Fast track Approval	Yes	Yes				Yes				Yes
5. Roche/bolar Provision	Yes				Yes					
6. Incentives/Constraints for pharmacists				Yes	Yes	Yes	Yes	Yes		
7. Incentives/Constraints for physicians		Yes	Y*			Yes		Yes		
8. Constraints Imposed on patients	Yes									Y*
9. Public campaign by health authorities						Yes		Yes	Yes	Yes
10. Market size (US$ billion)@	31.0	5.3	2.4	0.6	1.2	1.8	6.0	0.6	0.3	1.1
11. Generic penetration as % of total prescription	54	54	52	42	40	12	11	7	2	2

Note: Yes and Y* refer to be implemented, partly implemented respectively, @- Refers to estimates for 2006.

Source: Michel Peny Jean, 2003.

6. Conclusion

This paper examines the status of the health care industry in France in detail. The French enjoy a good quality health care where the government spends nearly 10 per cent of its GDP on health. Out of the total health expenditure, 20 per cent is spent on drugs which is higher than some of the OECD countries like the US, UK and Canada. The pharmaceutical industry in France is the third largest in Europe and adopted product patents even before the TRIPS agreement. The pharmaceutical industry in the country is highly regulated. The branded drugs are costlier compared to the generics which in a way adds to the cost of the health expenditure. In order to control costs and promote generic drugs in the prescription, the government has introduced several regulatory measures, which even other OECD countries have not fully implemented yet. Because of number of mergers in the pharmaceutical industry, the number of firms has decreased. Further, though the investment in the industry has been fluctuating in the 1990s, investment in the R&D has been increasing. However, innovation in new molecules is not large, perhaps indicating that some of the R&D expenditures could be going towards improvement of the facilities. Due to this, employment in R&D has remained stagnant since the later part of 1990s.

Interestingly, of the total turnover of the pharma industry, turnover from the domestic sales has been declining while the exports turnover has been increasing. The balance of trade in pharmaceuticals has been positive. The French have also been filing large number of patents next to the US and also rank higher in terms of the number of patents granted. In order to compensate the firms for the loss of time in the patent application process, the governments grants another five-year term of exclusivity for companies satisfying certain criteria. Though this could delay the entry of generics, yet for pharma companies it provides an extended period of monopoly power over the product. The industry has also responded by investing in R&D to improve further. In nutshell, it can be said that government plays a significant role in providing health care and regulating the kind of drugs to be introduced in the public by the pharmaceutical industry. Particularly the regulatory measures concerning the approval of drugs in the market, if adopted effectively in developing countries such as India, it would lead to a reduction in irrational combinations sold in the market. Similarly, the measures aimed at promoting the generics would be useful for countries, which want to expand the reach of the health care at the same time controlling the health expenditure.

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