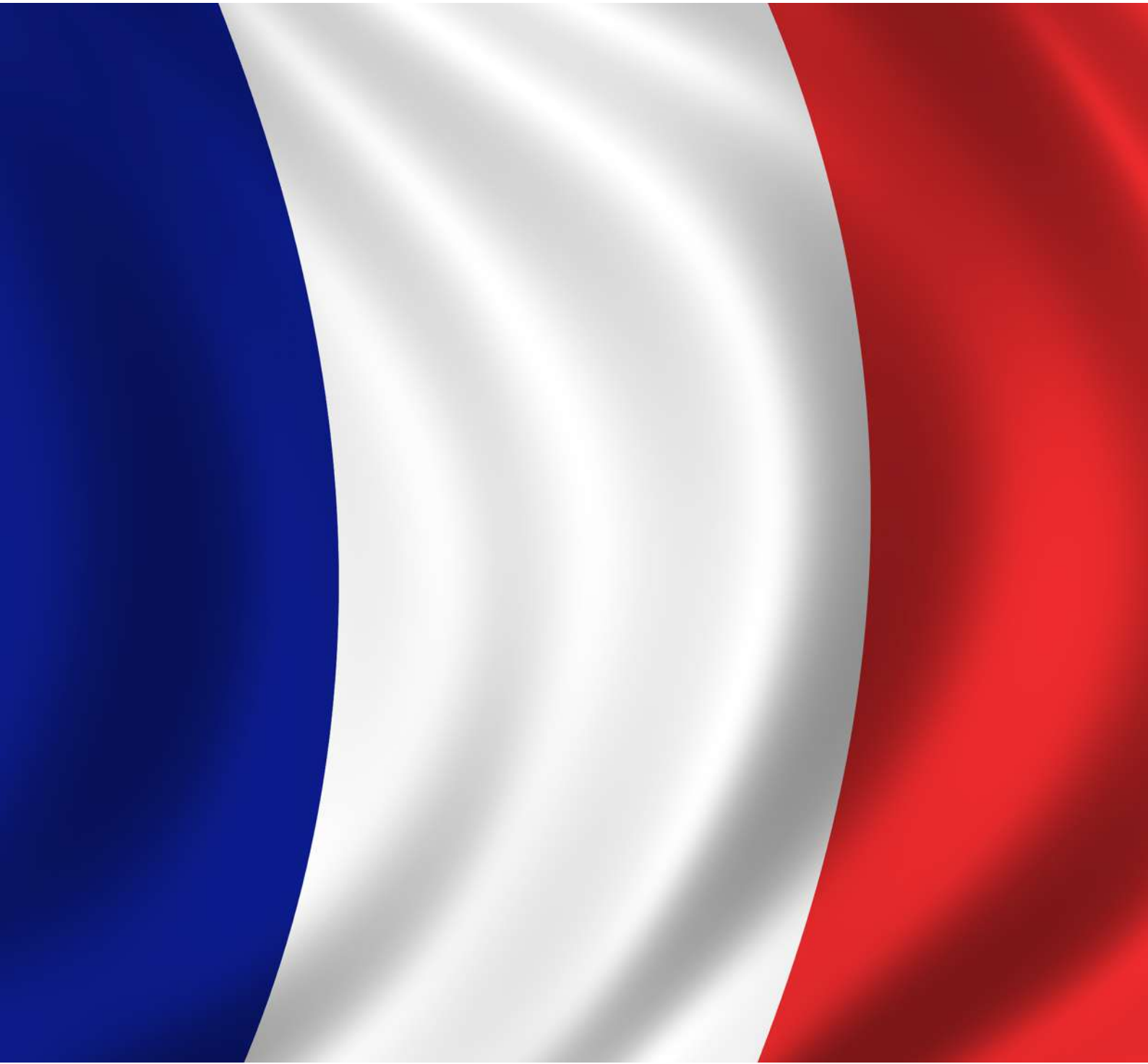


The French Market for Medical Devices.

Opportunities & Challenges for Swiss Companies.



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While this report is intended to provide an overview of this specific market and its opportunities at the time of its edition, each individual manufacturer, exporter or company may have to conduct their own analysis to get a better understanding of the possibilities and opportunities available to them. You are encouraged to explore and develop your opportunities based on research and in-depth analysis. Readers should take note that Medtech Switzerland does not guarantee the accuracy of any of the information contained in this report, nor does it necessarily endorse the organizations, associations, companies and individuals listed herein. Readers of this report should verify the accuracy and reliability of the information contained herein before making a business decision.

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Summary

1 Terminology	6
1.1 Acronyms	6
1.2 Definitions	7
2 Objectives of the report	7
3 Abstract	8
4 Dashboard	9
5 General Country overview	12
5.1 Background	12
5.2 Location	12
5.3 People and Society	12
5.3.1 Demography	12
5.3.2 Health	13
5.3.3 Education	14
5.4 Administrative divisions	14
5.5 Balance of trade in 2011	14
5.5.1 Exports	14
5.5.2 Imports	15
5.5.3 Exports from Switzerland 2011	15
5.5.4 Imports to Switzerland 2011	15
6 Doing Business in France	16
6.1 Setting up business in France successfully	16
6.2 Multiple solutions for your business	16
• Reducing administrative procedures: short-term solutions	16
• Liaison offices: representation without commercial activity	16
• If you wish to develop a commercial activity: sales representatives	16
• Another solution: sales agents	16
• Planning for the future – two key decisions	16
• French employment law	16
6.3 A favorable environment for international mobility	16
6.3.1 Business taxes in France	17
6.3.2 Government Support for Business	17
6.4 Business relations	17
6.4.1 Formality	17
6.4.2 Language	17
6.4.3 Meetings & Greetings	17
6.4.4 Cuisine	17
6.4.5 Meetings and Negotiations	18
6.4.6 Business Cards	18
7 Medical Technology Market	19
7.1 Size and growth rate	19
7.1.1 World 2008–2011	19
7.1.2 Europe–2008	20
7.1.3 France 2009–2008–2006	20
7.1.3.1 French MD market composition	21
7.1.3.2 French MD market evolution	21
7.2 Major players	23
7.2.1 World 2008	23
7.2.2 France 2010–2009	24
7.2.2.1 Ranking by value evolution between 2009 and 2010	25
7.2.2.2 Ranking by turnover % evolution between 2009 and 2010	25
8 Marketing and Distribution	26
8.1 Presentation form – Distribution	26
8.2 Competitors origin	27
8.3 Market entry requirements	27

9	Specifics by segment	28
9.1	Dental	28
9.2	Cardiology	28
9.3	Hearing aids	28
9.4	Ophthalmics	29
9.5	Diagnostics	29
9.6	Medical Imaging	29
9.7	Orthopedics	30
10	Most common diseases and causes of death	30
11	Health Economics – Costs and Financing	31
11.1	Relationship of patients, providers and payers	31
11.2	French healthcare system: Balance	32
11.2.1	Healthcare economics definition	32
11.2.1.1	Healthcare expenditure	32
11.2.1.2	Growth factors	33
11.2.2	Expenditure financing	33
11.2.2.1	Social Security financing – Public health care insurance	34
11.2.2.2	Complementary healthcare – Private healthcare insurance	34
11.2.3	Fraud	34
11.2.4	Public insurance financing evolution 1983–2006	35
12	French healthcare reforms – The Magical Quadrant	35
12.1	SROS 3 – Regional Organization	36
12.2	Certification and evaluation of professional practices – Facility Level	36
12.3	New Governance – Institutions Management	36
12.4	T2A – EPRD – Expenditure Control	37
13	Investment Programs – HOSPITAL PLAN 2012	37
14	Regulatory and Reimbursement	38
14.1	Setting on the market – CE marking in France and EU	38
14.1.1	Authorities presentation	38
14.1.2	HAS commissions and CNEDiMTS services	40
14.2	The process of MD market accreditation in France	41
14.3	CNEDiMTS clinical studies recommendations	42
14.4	European guidelines for CE marking	42
14.4.1	Medical device – EUROPEAN DIRECTIVE 93/42	43
14.4.2	In Vitro diagnostic Medical Device – EUROPEAN DIRECTIVE 98/79	43
14.4.3	Active implantable Medical Device – EUROPEAN DIRECTIVE 90/385	44
14.4.4	Evolution of CE marking – EUROPEAN DIRECTIVE 2007/47/EC	44
14.5	MD classification	44
14.6	Healthcare insurance reimbursement	45
14.6.1	MD incorporated in GHS (T2A)	45
14.6.2	MD listed LPPR	46
14.6.3	Innovative MD	46
14.6.4	MD supported under the medical act	46
14.7	CNEDiMTS medical technical evaluation	47
14.7.1	CNEDiMTS composition	47
14.7.2	Evaluation stages	47
14.7.3	Actual benefit	48
14.7.4	Added clinical value	48
14.8	Pricing – CEPS procedure	49
14.9	Possible penalties	49
14.10	Europe medical technical evaluation	49
14.11	Insurance systems in Europe	49
15	Patent protection	50
15.1	In France	50
15.2	In EUROPE	50

16 Healthcare providers	51
16.1 Public hospitals	51
16.1.1 Ranking by number of beds	51
16.1.2 Ranking by operating budget	53
16.1.3 Ranking by investment budget	54
16.1.4 Ranking by number of staff	55
16.2 Private clinics	57
16.2.1 Type of establishment (number of beds)	57
16.2.2 Number of establishment evolution	57
16.2.3 Groups ranking	58
16.3 Health and Care services establishments	59
17 Decision makers, Purchases and Purchasing process	60
18 Competitiveness Clusters	60
18.1 What is a Competitiveness Cluster?	60
18.2 Strategy	60
18.3 Goals	60
18.4 Public Support for Clusters	60
18.5 Few figures	61
18.5.1 Who are the clusters?	61
18.5.2 What sort of aid do clusters receive?	61
18.5.3 Focus on the BIOTECHNOLOGY AND HEALTH Clusters	61
18.6 Competitiveness Clusters Geographic Location	62
19 Usefull contacts	62
19.1 Government Agencies	62
19.2 Medical companies and Industry Associations	63
19.3 MD French exhibitions	64
19.4 Publications, Press	66
20 Sources	66

1 Terminology

1.1 Acronyms

AB	Actual benefit (SA «Service Attendu» and SR «Service Rendu» in french)
ACV	Added clinical value (ASA «Amélioration du Service Attendu» and ASR «Amélioration du Service Rendu» in french)
Afssaps	French Healthcare Safety Product Agency
AP-HP	Hospitals in Paris – Assistance Publique – Hôpitaux de Paris
CCAM	Joint classification of medical procedures
CHAP	Committee of hierarchical structures of procedures and services
CE	European conformity
CEPP	Committee for the evaluation of products and services
CMUC	Couverture Maladie Universelle Complémentaire
CNEDiMTS	National committee for the evaluation of medical devices and health technologies
CEAP	Committee for the evaluation of medical procedures
CEPS	Healthcare products pricing committee
CNAMTS	National Health Insurance Fund for Salaried Employees
COMEDIMS	Committee on medicinal products and sterile medical devices
CPOM	Contrats Pluriannuels d'Objectifs et de Moyens
DGS	Direction générale de la santé (part of the French Ministry of Health devoted to public health)
DHOS	Hospitalisation and Organisation of Care Directorate
DSS	Social Security Directorate
DRG	Diagnosis-Related Group
MD	Medical device
AIMD	Active implantable medical device
DMDIV	in vitro diagnostic medical device
ETM	Evaluation of medical technologies
GHM	Homogeneous group of patients
GHS	Homogeneous groups in health establishments
HAS	Haute Autorité de Santé (French National Authority of Health)
HTA	Health Technology Assessment
INCa	National Cancer Institute
INPI	Institut national de la propriété industrielle
ISP	Assessment of public health benefit
LPPR	List of products and services qualifying for reimbursement
MCO	Médecine, Chirurgie, Gynécologie-Obstétrique – Medicine, Surgery, Obstetrics
NABM	Nomenclature of procedures in laboratory medicine
NGAP	General nomenclature of medical procedures
OECD	Organisation for Economic Cooperation and Development
PSY	Santé mentale, la psychiatrie, la toxicomanie – mental health, psychiatry, addictions
SEAP	Department of medical procedures assessment
SED	Department of assessment of medical devices
SNITEM	Syndicat National de l'Industrie des Technologies Médicales
SLD	Les Soins de Longue Durée – long-term care
SROS 3	Schémas Régionaux d'Organisation des Soins de 3 ^{ème} génération
SSR	Les soins de suite et de réadaptation – follow-up care, rehabilitation
T2A – EPRD	New fee-for-service pricing system – La tarification à l'activité (T2A) et de l'état des prévisions de recettes et de dépenses (EPRD)
UNCAM	National Association of Health Insurance Funds
UNOCAM	Association of Co-payment Health Insurance Funds
UNPS	National Union of Health Professionals

1.2 Definitions

MEDICAL DEVICE (Directive 93/42/EEC): means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

ACCESSORY means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

ACTIVE IMPLANTABLE MEDICAL DEVICE (Directive 90/385/EEC): any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

IN VITRO DIAGNOSTIC MEDICAL DEVICES and their accessories (Directive 98/79/EC): These devices are products used for the in vitro analysis of tissues or substances (blood, specimens) from the human body. The types of analysis covered are as follows:

- state of health;
- congenital diseases or anomalies;
- checking the progress of courses of treatment;
- determining compatibility in the case of organ or blood donations.

2 Objectives of the report

This study covers all the medical technology market in France.

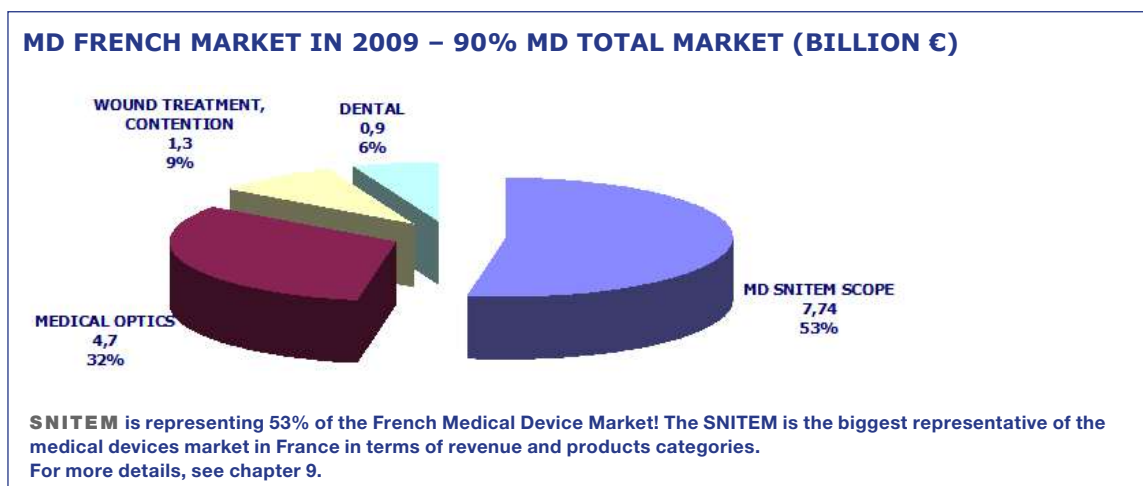
The objective of the study is to give the Swiss exporters of medical devices a global vision on the functioning of the French MD market – European and global markets, as the procedures are similar – make recommendations to promote the development of Swiss medical devices exports in France and Europe. The main objectives are:

1. Make an inventory of medical devices market in France, Europe and world
2. Present distribution patterns and segments specifics
3. Give the main concepts of health economics, balanced budgets, resources and expenditures
5. Analyze the process of Medical Device Regulatory Affairs in France and Europe
6. Present care providers in France (public hospitals and private clinics)

A particular attention will be drawn on SNITEM scope: SNITEM (The national association of the medical technology industry in France) is the most important trade association; it represents more than 230 member companies from France's medical technologies sectors such as:

- **Active implantable medical device**
 - Cardiology
 - Orthopedics
 - Ophthalmology
 - Other internal prosthesis
- **Medical device**
 - Audiology
 - Orthotics

- **Operating room materials, medical and surgical instruments**
 - Endoscopy
 - Scalpels and ultrasound machines
- **Consumables**
- **Imaging**
- **Dialysis**
- **Anaesthesia, resuscitation**
- **Orthopedic rehabilitation and replacement**
- **Information technology and communications equipment**
- **Miscellaneous**



3 Abstract

The role of medical devices in healthcare is essential. The diversity and innovativeness of this sector contribute significantly to enhance the quality and efficiency of healthcare.

Covering a wide range of products, from simple bandages to the most sophisticated life-supporting products, the medical devices sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities.

The French medical device market ranks the second biggest market in Europe and the fifth worldwide. The growth is expected to be moderate due to the new government measures on medical device. The French market is supplied by French-owned companies and by growing share of foreign sales subsidiaries of multinational companies. Most of these companies are small or medium sized. Imports have grown at a faster rate than the overall market; due partly to a rise in re-exports.

The Ministry of Health organizes the new hospital management, with emphasis on management by objectives; The tools available for the realization of this course are:

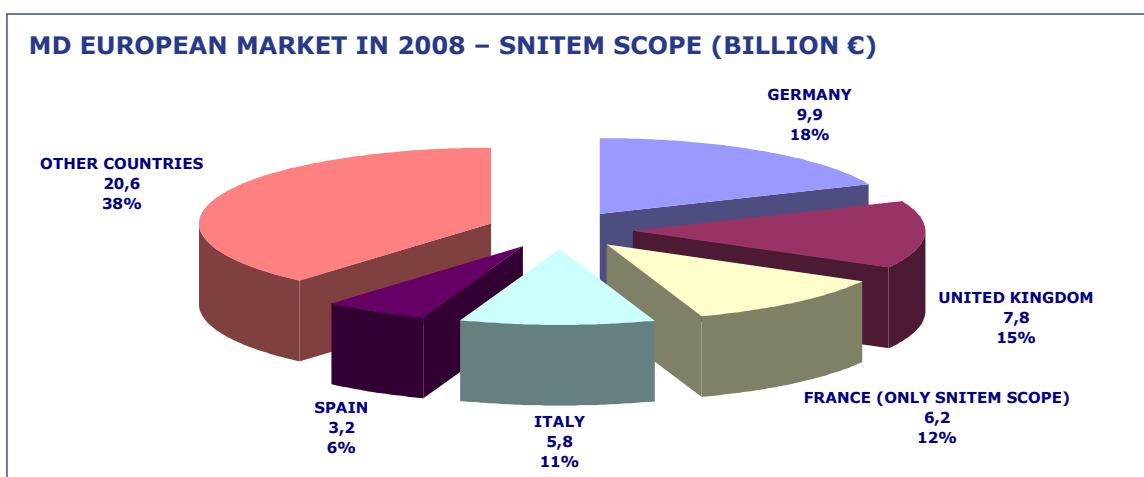
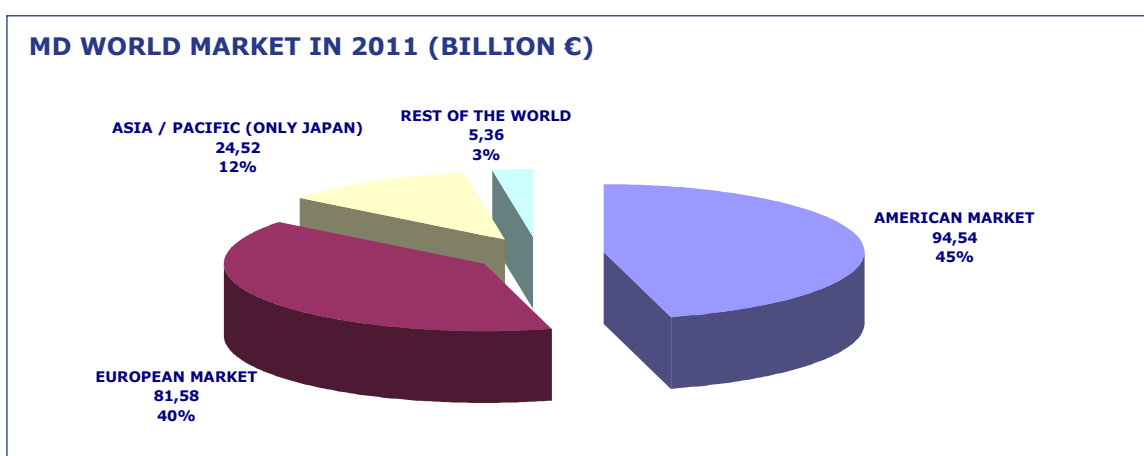
- Regional patterns of organization of care (currently SROS 3) that must be reflected in the multi-year contract objectives and resources (CPOM) of public health
- Certification, accreditation and evaluation of professional practices (quality and safety)
- The new governance institutions (reformulation of the power of authorities and decisions at the operational units, in other words, an internal contracting to the hospital with medical centers)
- A method of financing the development of pricing by activity (T2A), and the establishment of a forecasting tool (SPIE: Estimates of revenue and expenditure) in order to anticipate the financial flows and to adopt an asset-based approach.

For regulation, the new operators have to conduct a clinical assessment adapted not only to the demands of CE marking but also to that of reimbursement. Recent developments in the regulatory environment must be taken into account by the manufacturer who must also plan to conduct studies that are adapted to the expectations of the health authorities from the moment he starts to develop his product. To do this, he has to surround himself with expert clinicians and methodologists. A protocol will enable useable clinical data to be collected as soon as the first patients are recruited. A quality clinical evaluation whose methodology is adapted to the features of the MD is a key factor in the assessment of its overall value.

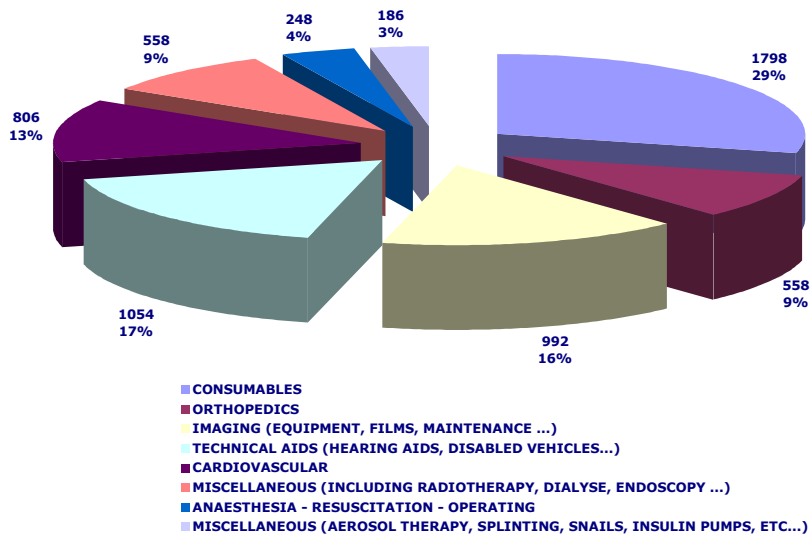
4 Dashboard

The dashboard below shows the main indicators of medical technology market in France and worldwide, we will find respectively:

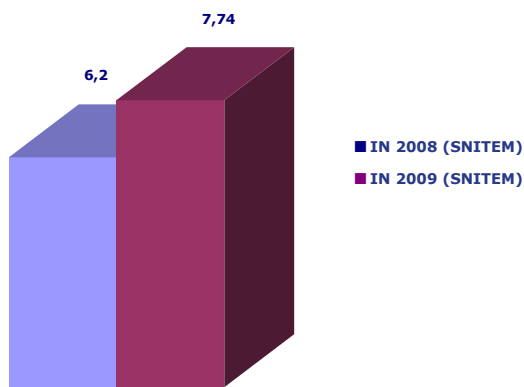
- The volume of the Global, European and French markets, and theirs evolutions
- The composition and evolution of the French market segments
- The Origin, marketing, distribution and rankings of players in the French market



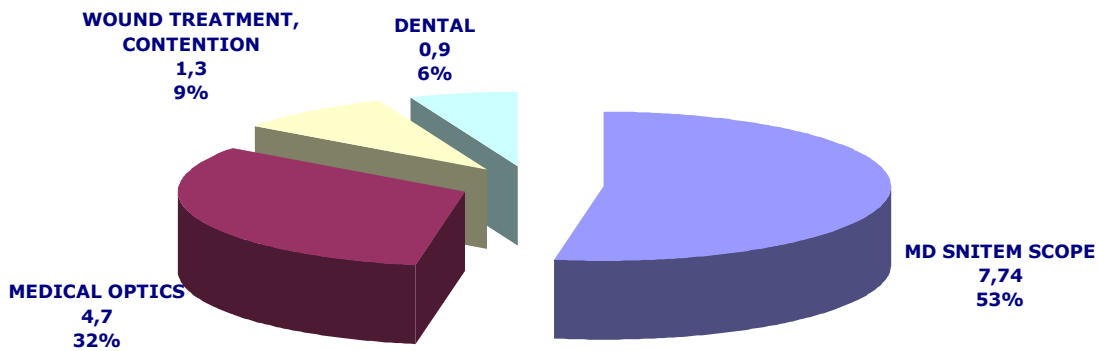
MD FRENCH MARKET COMPOSITION IN 2006 – SNITEM SCOPE (MILLION €)



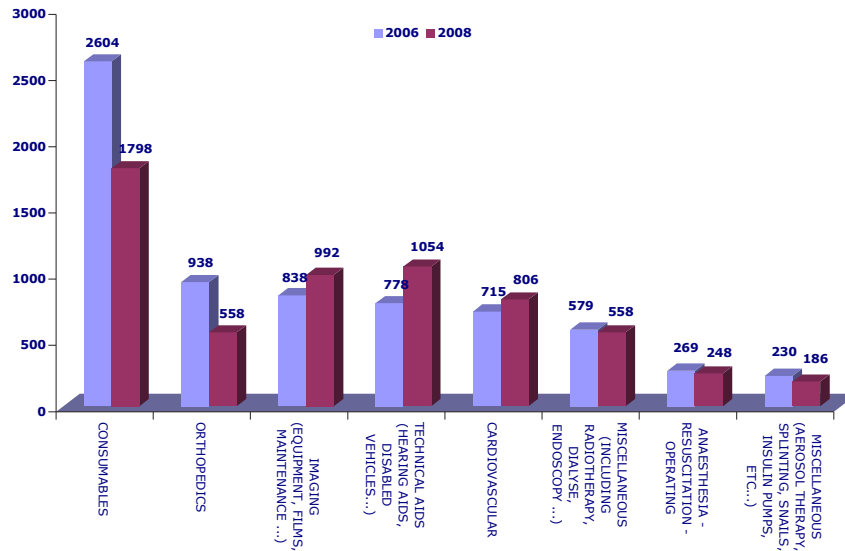
MD FRENCH MARKET EVOLUTION BETWEEN 2008/2009 – SNITEM SCOPE (BILLION €)



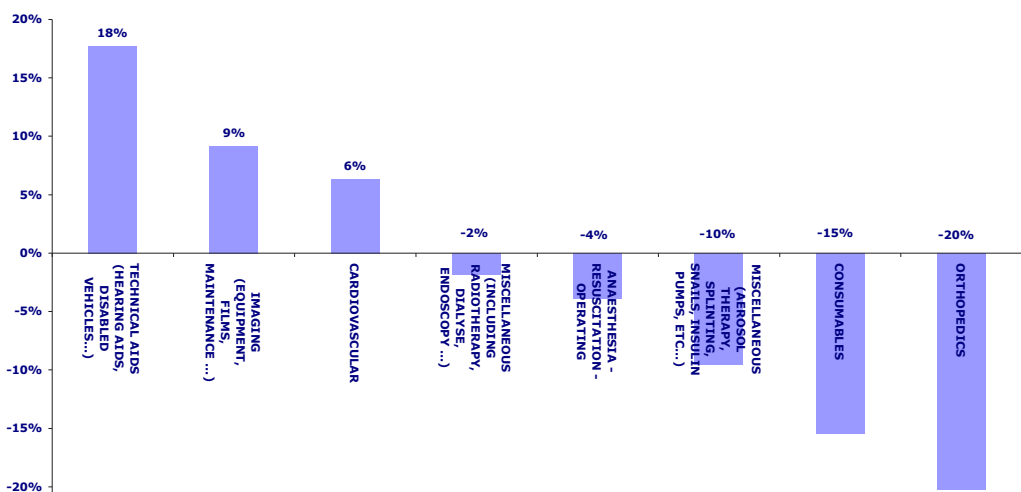
MD FRENCH MARKET IN 2009 – 90% MD TOTAL MARKET (BILLION €)



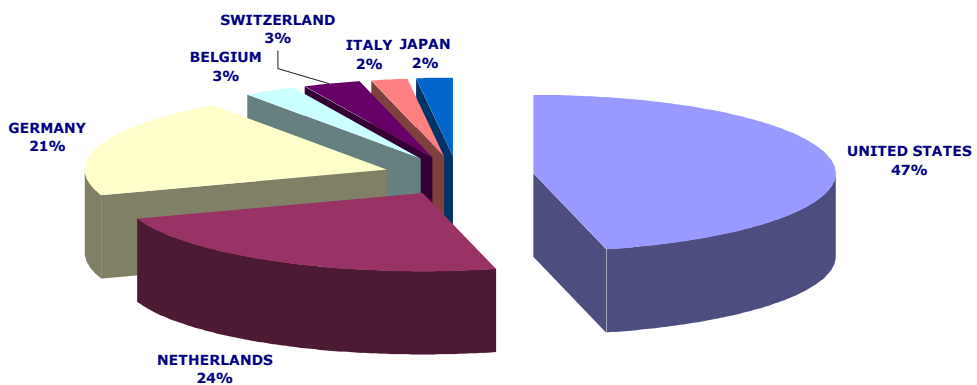
MD FRENCH MARKET SEGMENTS EVOLUTION BETWEEN 2006 AND 2008 – SNITEM SCOPE (MILLION €)



MD FRENCH MARKET SEGMENTS RANKING BY DECREASING AVERAGE ANNUAL EVOLUTION RATE BETWEEN 2006 AND 2008 – SNITEM SCOPE



ORIGIN OF FRENCH MD MARKET COMPETITORS



5 General Country overview

5.1 Background

France today is one of the most modern countries in the world and is a leader among European nations. Since 1958, it has constructed a hybrid presidential-parliamentary governing system resistant to the instabilities experienced in earlier more purely parliamentary administrations. In recent decades, its reconciliation and cooperation with Germany have proved central to the economic integration of Europe, including the introduction of a common exchange currency, the euro, in January 1999. In the early 21st century, five French overseas entities – French Guiana, Guadeloupe, Martinique, Mayotte, and Reunion – became French regions and were made part of France proper.

5.2 Location

Metropolitan France: Western Europe, bordering the Bay of Biscay and English Channel, between Belgium and Spain, southeast of the UK; bordering the Mediterranean Sea, between Italy and Spain. France is constituted of 96 metropolitan departments and 5 overseas departments which are:

French Guiana: Northern South America, bordering the North Atlantic Ocean, between Brazil and Suriname.

Guadeloupe: Caribbean, islands between the Caribbean Sea and the North Atlantic Ocean, southeast of Puerto Rico.

Martinique: Caribbean, island between the Caribbean Sea and North Atlantic Ocean, north of Trinidad and Tobago.

Mayotte: Southern Indian Ocean, island in the Mozambique Channel, about half way between northern Madagascar and northern Mozambique.

Reunion: Southern Africa, island in the Indian Ocean, east of Madagascar.



5.3 People and Society

5.3.1 Demography

Nationality

noun: Frenchman(men), Frenchwoman(women)
adjective: French

Languages

French (official) 100%, rapidly declining regional dialects and languages (Provençal, Breton, Alsatian, Corsican, Catalan, Basque, Flemish)
overseas departments: French, Creole patois, Mahorian (a Swahili dialect)

Religions

Roman Catholic 83%–88%, Protestant 2%, Jewish 1%, Muslim 5%–10%, unaffiliated 4%
overseas departments: Roman Catholic, Protestant, Hindu, Muslim, Buddhist, pagan.

Population

65,312,249 (July 2011 est.)
country comparison to the world: 21

note: the above figure is for metropolitan France and five overseas regions; the metropolitan France population is 62,814,233

Age structure

0–14 years: 18.5% (male 6,180,905/female 5,886,849)
15–64 years: 64.7% (male 21,082,175/female 21,045,867)
65 years and over: 16.8% (male 4,578,089/female 6,328,834) (2011 est.)

Median age

total: 39.9 years
 male: 38.4 years
 female: 41.5 years (2011 est.)

Population growth rate

0.5% (2011 est.)
 country comparison to the world: 150

Birth rate

12.29 births/1,000 population (2011 est.)
 country comparison to the world: 160

Death rate

8.76 deaths/1,000 population (July 2011 est.)
 country comparison to the world: 80

Net migration rate

1.46 migrant(s)/1,000 population (2011 est.)
 country comparison to the world: 46

Urbanization

urban
 population: 85% of total population (2010)
 rate of
 urbanization: 1% annual rate of change (2010–15 est.)

Major cities – population

PARIS (capital) 10.41 million; Marseille-Aix-en-Provence 1.457 million; Lyon 1.456 million; Lille 1.028 million; Nice-Cannes 977,000 (2009)

Sex ratio

at birth: 1.051 male(s)/female
 under 15 years: 1.05 male(s)/female
 15–64 years: 1 male(s)/female
 65 years
 and over: 0.72 male(s)/female
 total population: 0.96 male(s)/female (2011 est.)

5.3.2. Health**Maternal mortality rate**

8 deaths/100,000 live births (2008)
 country comparison to the world: 150

Infant mortality rate

total: 3.29 deaths/1,000 live births
 country comparison to the world: 214
 male: 3.61 deaths/1,000 live births
 female: 2.96 deaths/1,000 live births (2011 est.)

Life expectancy at birth

total population: 81.19 years
 country comparison to the world: 13
 male: 78.02 years
 female: 84.54 years (2011 est.)

Total fertility rate

1.96 children born/woman (2011 est.)
 country comparison to the world: 132

Health expenditure

3.5% of GDP (2009)
 country comparison to the world: 171

Physicians density

3.497 physicians/1,000 population (2008)
 country comparison to the world: 29

Hospital bed density

7.11 beds/1,000 population (2008)
 country comparison to the world: 13

Drinking water source

improved: urban: 100% of population
 rural: 100% of population
 total: 100% of population (2008)

Sanitation facility access

improved: urban: 100% of population
 rural: 100% of population
 total: 100% of population (2008)

HIV/AIDS – adult prevalence rate

0.4% (2009 est.)

country comparison to the world: 75

HIV/AIDS – people living with HIV/AIDS

150,000 (2009 est.)

country comparison to the world: 33

HIV/AIDS – death

1,700 (2009 est.)

country comparison to the world: 57

Obesity – adult prevalence rate

16.9% (2007)

country comparison to the world: 26

5.3.3 Education

Education expenditures

5.6% of GDP (2007)

country comparison to the world: 38

Literacy

definition: age 15 and over can read and write
total

population: 99%

male: 99%

female: 99% (2003 est.)

School life expectancy (primary to tertiary education)

total: 16 years

male: 16 years

female: 16 years (2008)

Unemployment, youth ages 15–24

total: 22.6%

country comparison to the world: 40

male: 23.4%

female: 21.7% (2009)

5.4 Administrative divisions

27 regions (regions, singular-region); Alsace, Aquitaine, Auvergne, Basse-Normandie (Lower Normandy), Bourgogne (Burgundy), Bretagne (Brittany), Centre, Champagne-Ardenne, Corse (Corsica), Franche-Comte, Guadeloupe, Guyane (French Guiana), Haute-Normandie (Upper Normandy), Ile-de-France, Languedoc-Roussillon, Limousin, Lorraine, Martinique, Mayotte, Midi-Pyrenees, Nord-Pas-de-Calais, Pays de la Loire, Picardie, Poitou-Charentes, Provence-Alpes-Cote d'Azur, Reunion, Rhone-Alpes.

note: France is divided into 22 metropolitan regions (including the “territorial collectivity” of Corse or Corsica) and 5 overseas regions (French Guiana, Guadeloupe, Martinique, Mayotte, and Reunion) and is subdivided into 96 metropolitan departments and 5 overseas departments (which are the same as the overseas regions)



5.5 Balance of trade in 2011

5.5.1 Exports

\$ 581.8 billion

country comparison to the world: 6

\$ 517.2 billion (2010 est.)

Exports – commodities:

machinery and transportation equipment, aircraft, plastics, chemicals, pharmaceutical products, iron and steel, beverages

Exports – partners:

Germany 16.5%, Italy 8.1%, Spain 7.3%, Belgium 7.2%, UK 6.6%, US 5.6%, Netherlands 4.3%, China 3.2%, Switzerland 3.1% (rank 9)

5.5.2 Imports

\$ 701.7 billion

country comparison to the world: 6

\$ 588.4 billion (2010 est.)

Imports – commodities:

machinery and equipment, vehicles, crude oil, aircraft, plastics, chemicals

Imports – partners:

Germany 16.9%, China 8%, Belgium 7.8%, Italy 7.2%, Spain 6%, US 5.6%, UK 4.4%,

Netherlands 4.3%, Russia 2.8%, Switzerland 2.3% (rank 10)

5.5.3 Exports from Switzerland 2011

	In CHF
Chemicals and associated products	5,523,232,906
Precision instruments, watches and jewellery	3,192,851,133
Machinery, units, electronics	2,289,111,325
Metals	949,482,582
Agricultural and forestry products, fishery	840,757,783
Energy sources	809,049,405
Vehicles	379,075,210
Leather, rubber, plastics	361,095,925
Paper, stationery and graphic products	337,911,539
Precious metals, precious and semi-precious stones	318,870,058
Textiles, clothes, shoes	213,363,527
Furnishings, toys, etc.	154,315,476
Works of art and antiques	115,275,662
Stone and soils	88,966,818

5.5.4 Imports to Switzerland 2011

	In CHF
Chemicals and associated products	2,385,601,120
Precision instruments, watches and jewellery	1,920,748,654
Machinery, units, electronics	1,905,494,398
Agricultural and forestry products, fishery	1,862,395,756
Energy sources	1,849,497,856
Vehicles	1,826,890,153
Metals	873,389,277
Textiles, clothes, shoes	698,084,257
Paper, stationery and graphic products	597,487,311
Leather, rubber, plastics	594,226,346
Furnishings, toys, etc.	378,516,423
Stone and soils	324,831,808
Precious metals, precious and semi-precious stones	214,843,759
Works of art and antiques	166,809,922

6 Doing Business in France

6.1 Setting up business in France successfully

There are no administrative restrictions on foreign investment in France, although mandatory declarations or permits are required in some cases (see “In detail” section below).

Whatever your business development strategy, in France you will find an appropriate legal structure for the kind of business you wish to set up. Investors can set up a permanent or temporary structure and enjoy full legal peace of mind; they are then free to drive their project forward in an uncomplicated and inexpensive environment.

6.2 Multiple solutions for your business

Choosing a business structure in France depends on the investor’s strategy and the degree of independence that the French operations are to have from the parent company.

- Reducing administrative procedures: short-term solutions

A foreign company wishing to prospect for business in France can start by hiring a single employee or by opening a liaison office. This option involves a specific tax and company status.

- Liaison offices: representation without commercial activity

A foreign company may recruit or send an employee to France to represent it through a local liaison or representative office.

- If you wish to develop a commercial activity: sales representatives

Sales representatives may be a VRP (voyageur de commerce, représentant ou placier – business traveler, representative or travelling salesperson) which is a company employee with a special legal status.

- Another solution: sales agents

Foreign companies may also use the services of a sales agent, i.e. a self-employed individual or a company that acts on their behalf.

- Planning for the future – two key decisions

Companies can set up a branch or a subsidiary to conduct manufacturing or sales operations in France through a permanent principal or secondary establishment.

- French employment law

France is an industrialized country with employment laws designed to both protect the interests of employees and match the economic priorities of business. Employment relations are governed by the French Labor Code (Code du Travail) and by industry-specific collective agreements that reflect the practices of each sector. Flexible working hours and shift patterns can be organized to suit production requirements. Employee profit-sharing schemes are encouraged through tax and social security contribution exemptions.

6.3 A favorable environment for international mobility

The laws of July 24, 2006 and November 20, 2007 were introduced to improve France’s economic attractiveness, placing international mobility at the heart of a series of innovative measures to meet companies’ needs. Residence permits valid for more than one year were introduced for the first time, providing foreign nationals with a complete legal framework to live and work in France.

The extension of the “Skills and Expertise” residence permit to company directors and the launch of the “Expatriate Employee” residence permit for employees transferred within their group are two further illustrations of these changes. Moreover, the families of foreign nationals holding these residence permits are also granted favorable residence and working conditions.

A trial is being conducted in the départements of Paris, Hauts-de-Seine and Rhône, where a ‘one-stop shop’ has been introduced to improve the quality of service to companies expatriating their employees to France or bringing in corporate directors and highly skilled employees through intra-group transfers. Run by the French Immigration and Citizenship Office (OFII), this ‘one-stop shop’ is streamlining immigration formalities and providing services tailored to the requirements of transferred corporate directors and highly skilled employees, as well as their families.

From a social security and tax viewpoint, expatriate personnel can now benefit from measures specifically designed to offset the costs of expatriation.

6.3.1 Business taxes in France

A large part of France’s corporate tax system is designed to promote business investment, regional development and international expansion. France’s efforts to develop a fair tax system are also evident in its policies designed for corporate groups. France has signed bilateral tax treaties with most of the countries it is likely to maintain trade relations with (more than 100 countries) and thus provides foreign investors with outstanding protection against double taxation.

6.3.2 Government Support for Business

The 27 Member States of the European Union (1) are subject to EU laws which determine how state aid is allocated to businesses. These rules provide an EU-wide framework in support of fair competition within the Single Market. Rules concerning government intervention, eligible expenditure and aggregate aid apply to all EU Members, with no exceptions made. Within this broader framework, Member States remain free to adopt the most appropriate economic development measures in their country.

For detailed informations: <http://www.invest-in-france.org/>

6.4 Business relations

6.4.1 Formality

Public life in France can appear quite formal. This is manifest in greetings, manners and the language. When doing business in France, the adhesion to protocol and a formal means of communication can appear stuffy, cold and unfriendly. However, despite appearances, business takes place on two levels. On the surface it appears orderly, professional and uncluttered by personal relationships. Yet, beneath the surface, a complicated network of personal relationships, ties, alliances and factions actually drives things.

6.4.2 Language

This is one of the first conditions to succeed in France. English is the first foreign language indeed, but is not as widely used as it is in Switzerland.

Perhaps no other culture so highly regards its language as a symbol of itself. The French are extremely proud of their language. This pride makes the use of French a sensitive issue. Above all the inability to speak even some French may be counted against you. It is important to at least learn some basic civilities prior to doing business in France.

6.4.3 Meetings & Greetings

When doing business in France, use first names only after being invited to do so. Use Monsieur or Madame followed the surname. The French will sometimes introduce themselves using their surname first, followed by their first name. If you speak French stick to the “vous” form until told to use “tu”.

Dress well. The French draw information on people based on their appearance. Your business attire is a reflection of your success and social status. Always try to be tasteful, stylish and conservative. Women are advised to dress simply but elegantly. Accessorizing and wearing make-up is practiced widely by business women.

6.4.4 Cuisine

The French are passionate about food, so lunches are the norm when doing business in France. These usually consist of an appetizer, main meal (with wine), cheese, dessert and coffee and normally take up to two hours. This is a time for relationship building.

Do not begin eating until the host says, “bon appétit”. Pass dishes to the left, keep wrists above the table and try to eat everything on the plate. Be careful with adding salt, pepper or sauces to your food as this may imply you find the food tasteless. If eating in a restaurant, the person extending the invitation always pays. Be sure to reciprocate this gesture.

6.4.5 Meetings and Negotiations

If you plan to travel to France on business, meetings should be booked in advance in writing or by phone. Holidays in France are usually taken in July or August so these months should be avoided. Christmas and Easter are also periods where business winds down.

Punctuality is a relaxed affair. Being fifteen minutes late is perfectly acceptable and the further south you travel, the more flexible this becomes.

When doing business in meetings remain polite and courteous at all times. Avoid personal questions. Try not to appear over friendly as this may be construed as suspicious. The French communication style is direct, questioning and probing. Ensure you have a carefully planned proposal that has been logically organized and presented. The French are most receptive to low-key, rational presentations and arguments that clearly highlight benefits.

Negotiations can become passionate. Argumentation is not meant to be confrontational but rather a means to analyzing your case logically. You will be judged on your behaviour combined with your ability to present your arguments coherently. Avoid exaggerations as the French do not appreciate hyperbole.

If a stalemate has been reached when doing business, the French will continue to state their position. The emphasis is on you to take apart their arguments and approach the issue from a different angle. Similarly, once decisions have been reached the only means of overturning it would be through a well argued defence of your case.

6.4.6 Business Cards Business cards are exchanged after the initial introductions without formal ritual

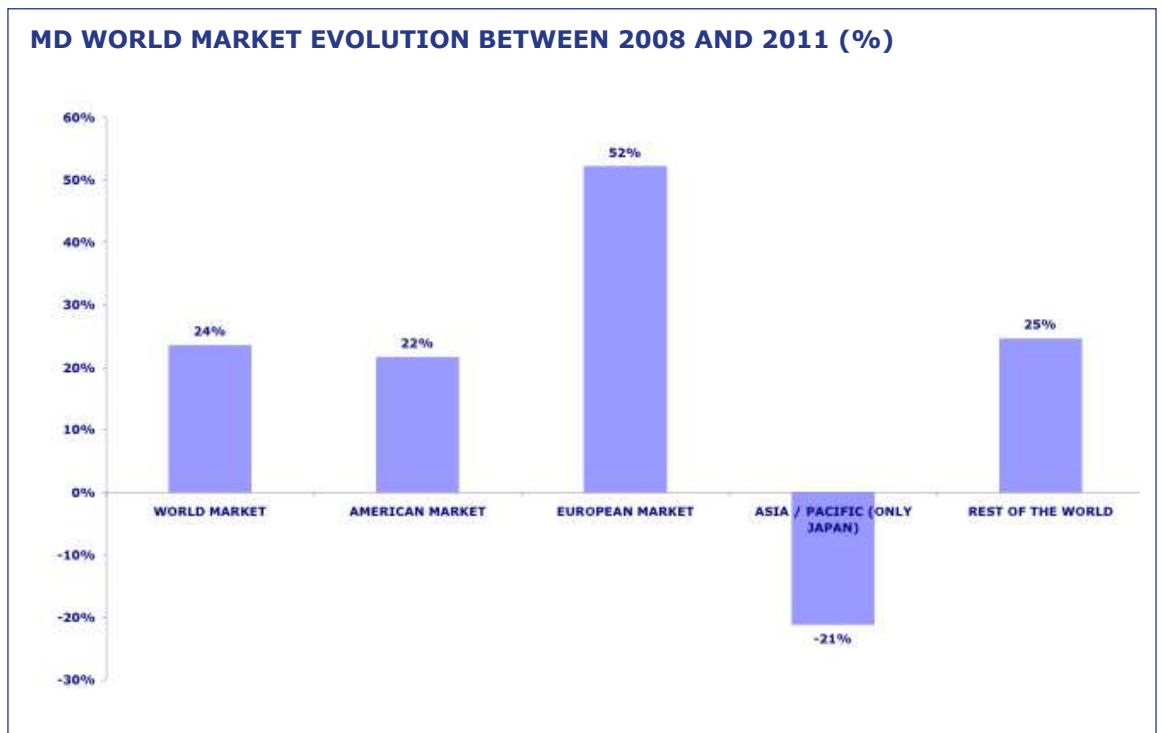
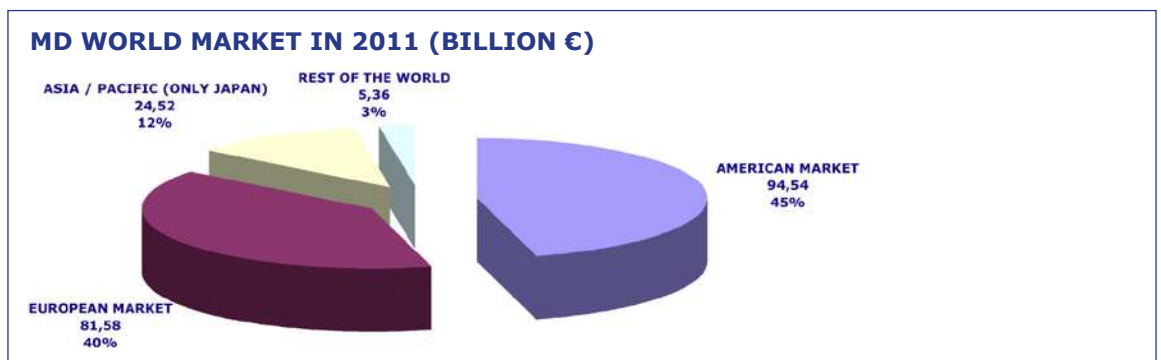
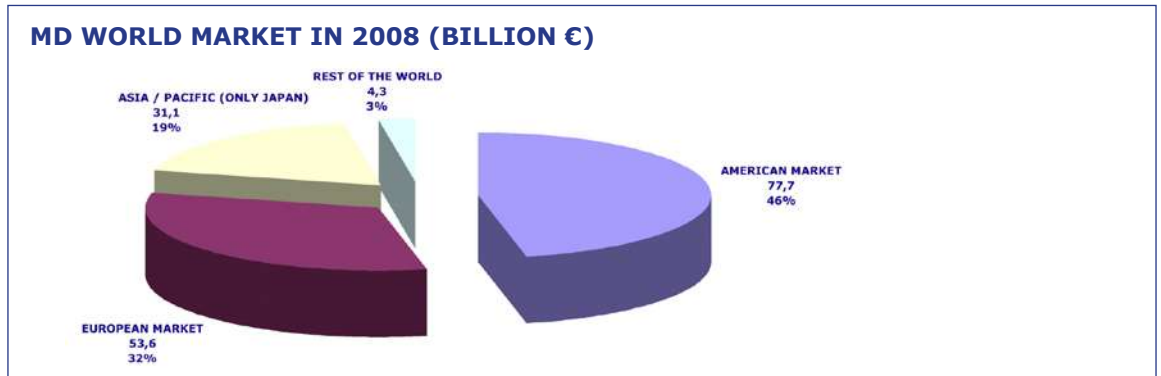
- Have the other side of your business card translated into French. Although not a business necessity, it demonstrates an attention to detail that will be appreciated.
- Include any advanced academic degrees on your business card.
- French business cards are often a bit larger than in many other countries.

Source: Kwintessential Ltd

7 Medical Technology Market

7.1 Size and growth rate

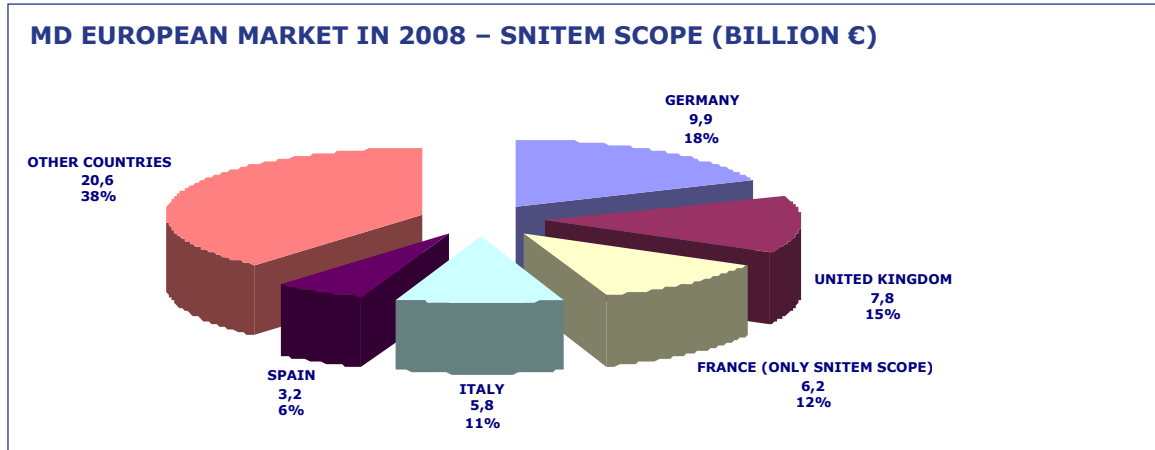
7.1.1 World 2008–2011



MD WORLD MARKET (BILLION €)	2008	2011	EVOLUTION
WORLD MARKET	166,7	206	24%
AMERICAN MARKET	77,7	94,54	22%
EUROPEAN MARKET	53,6	81,58	52%
ASIA/PACIFIC	31,1	24,52	-21%
REST OF THE WORLD	4,3	5,36	25%

Source: SNITEM

7.1.2 Europe – 2008

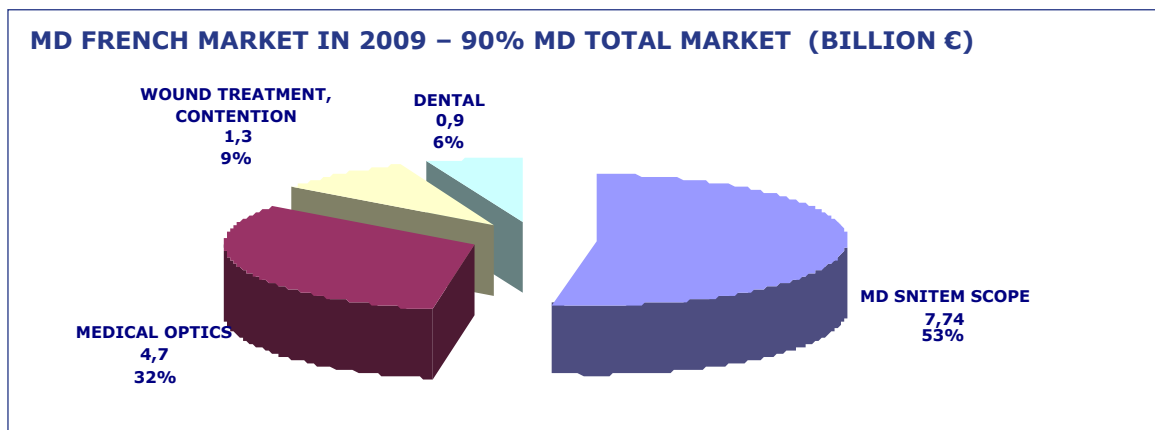


MD EUROPEAN MARKET IN 2008 – SNITEM SCOPE (BILLION €)

GERMANY	9,9
UNITED KINGDOM	7,8
FRANCE (ONLY SNITEM SCOPE)	6,2
ITALY	5,8
SPAIN	3,2
OTHER COUNTRIES	20,6

Source: SNITEM

7.1.3 France 2009–2008–2006

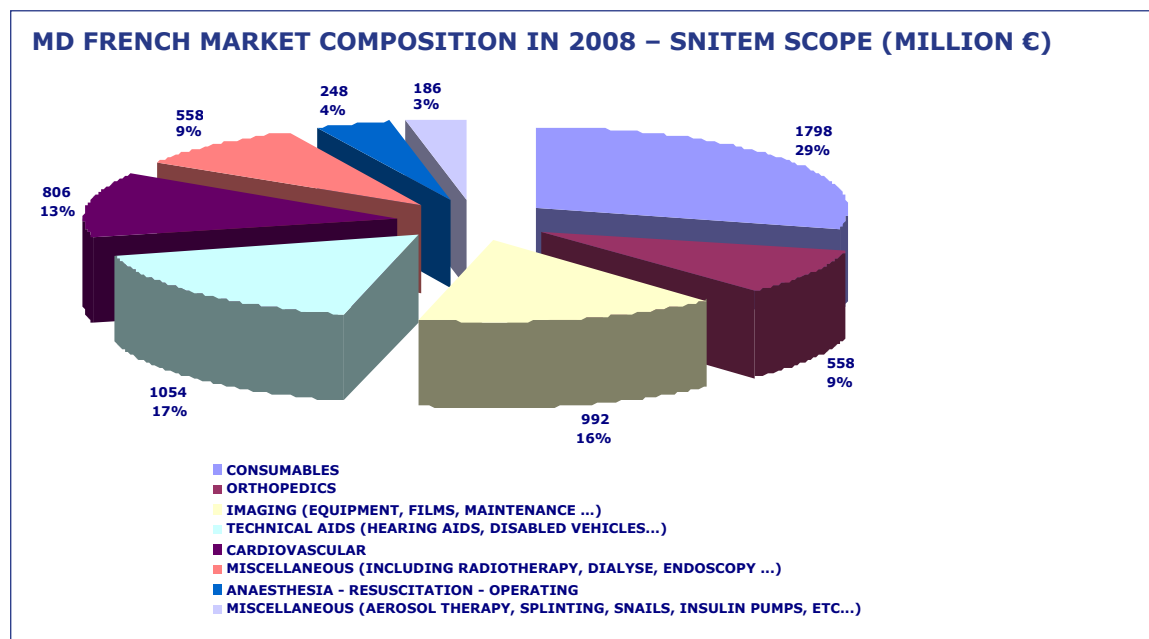


Source: SNITEM

FRENCH MD MARKET IN 2009 – 90% MD TOTAL MARKET – (BILLION €)	% EVOLUTION	
MD SNITEM SCOPE	7,74	53%
MEDICAL OPTICS	4,7	32%
WOUND TREATMENT, CONTENTION	1,3	9%
DENTAL	0,9	6%
Total 2009	14,64	100%
Total 2011 (Source: Développement et Conseil)	15,7	

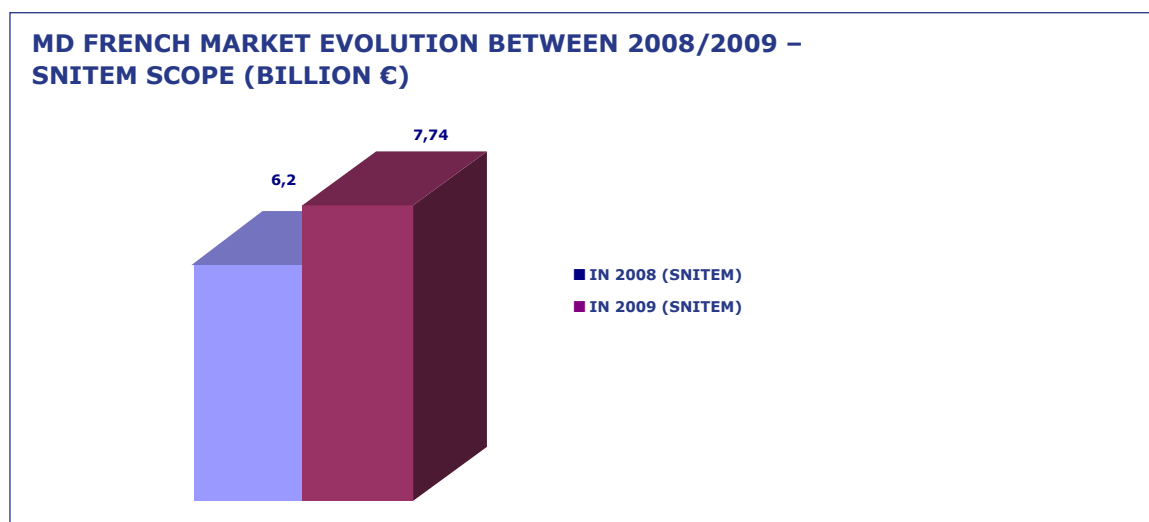
Source: SNITEM

7.1.3.1 French MD market composition



Source: SNITEM

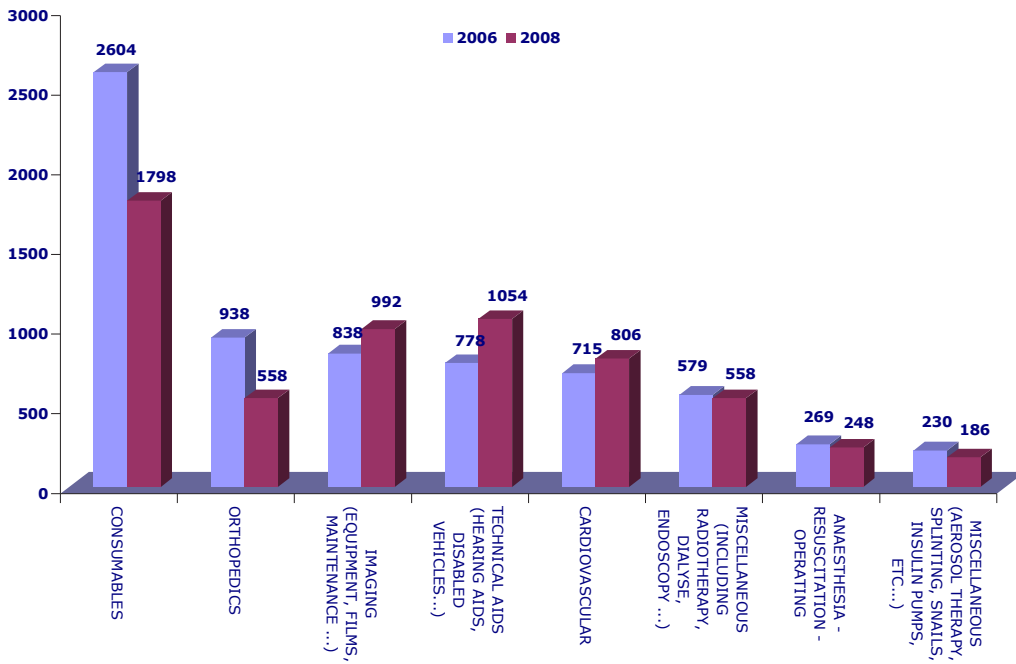
7.1.3.2 French MD market evolution



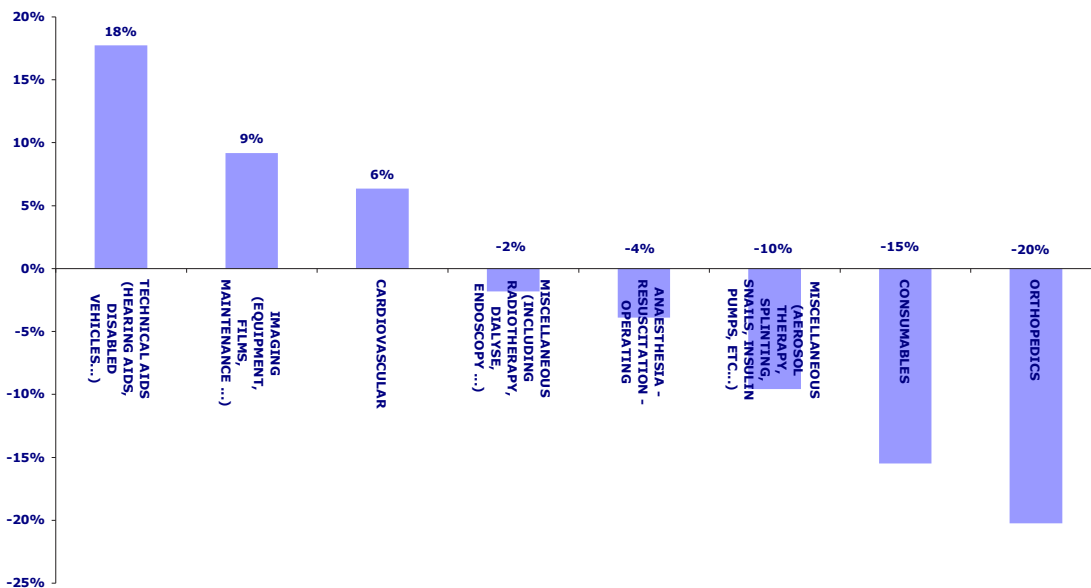
FRENCH MD MARKET EVOLUTION BETWEEN 2008/2009 – SNITEM SCOPE (BILLION €)	
IN 2008 (SNITEM)	6,2
IN 2009 (SNITEM)	7,74
VALUE EVOLUTION	1,54
% EVOLUTION	25%

Source: SNITEM

MD FRENCH MARKET SEGMENTS EVOLUTION BETWEEN 2006 AND 2008 – SNITEM SCOPE (MILLION €)



MD FRENCH MARKET SEGMENTS RANKING BY DECREASING AVERAGE ANNUAL EVOLUTION RATE BETWEEN 2006 AND 2008 – SNITEM SCOPE



MD FRENCH MARKET COMPOSITION IN 2006 – SNITEM SCOPE (BILLION €)

SINGLE USE MD	2006	2008	EVOLUTION BETWEEN 2006 AND 2008	ANNUAL AVERAGE EVOLUTION RATE BETWEEN 2006 AND 2008
ORTHOPEDICS	938	558	-41%	-20%
CARDIOVASCULAR	715	806	13%	6%
TECHNICAL AIDS (HEARING AIDS, DISABLED VEHICLES...)	778	1,054	35%	18%
CONSUMABLES	2,604	1,798	-31%	-15%
MISCELLANEOUS (AEROSOL THERAPY, SPLINTING, SNAILS, INSULIN PUMPS, ETC ...)	230	186	-19%	-10%
EQUIPMENTS				
IMAGING (EQUIPMENT, FILMS, MAINTENANCE ...)	838	992	18%	9%
MISCELLANEOUS (INCLUDING RADIOTHERAPY, DIALYSE, ENDOSCOPY ...)	579	558	-4%	-2%
ANAESTHESIA – RESUSCITATION – OPERATING	269	248	-8%	-4%
TOTAL	6,951	6,200	-11%	-5%

Source: SNITEM

7.2 Major players

7.2.1 World 2008

Manufacturers of medical devices for 12 countries (Germany, Brazil, Canada, China, Spain, USA, France, Italy, Japan, United Kingdom, Sweden, Switzerland) generate a combined turnover of € 185 billion, representing nearly 90% of worldwide revenue.

The global business ranking:

TOP 30 WORLDWIDE MEDICAL DEVICE COMPANIES BY TURNOVER, 2008*

	Company	Headquarters	Turnover US \$ (Millions)
1	Johnson & Johnson	United States	23,225
2	GE Healthcare	United States	17,392
3	SIEMENS Healthcare	Germany	15,526
4	Medtronic	United States	13,515
5	Baxter International	United States	12,400
6	Covidien	Ireland	9,910
7	Philips Healthcare	Netherland	9,227
8	Boston Scientific	United States	8,050
9	Becton Dickinson	United States	7,156
10	Stryker	United States	6,718
11	B. Braun	Germany	5,263
12	Cardinal Healthcare	Ireland	4,600
13	St. Jude Medical	United States	4,363
14	3M Healthn Care	United States	4,293
15	Zommer	United States	4,121
16	Olympus	Japan	3,920
17	Smith & Nephew	United Kingdom	3,801
18	Hospira	United States	3,620
19	Terumo	Japan	3,400
20	Danaher Corporation	United States	3,227
21	Synthes	United States	3,206

22	Bechman Coulter	United States	3,099
23	Alcon	Switzerland	2,881
24	Fresenius Medical Care	Germany	2,875
25	C.R. Bard	United States	2,452
26	Abbott	United States	2,241
27	Dentsply	United States	2,194
28	Varian Medical	United States	2,070
29	Biomet	United States	2,135
30	Dräger	Germany	1,729
TOTAL			188,609

* Turnover includes other products and services outside the scope of this study.

Source: Data derived from companies' annual reports

The players well established in the World are also present in the French market.

7.2.2 France 2010–2009

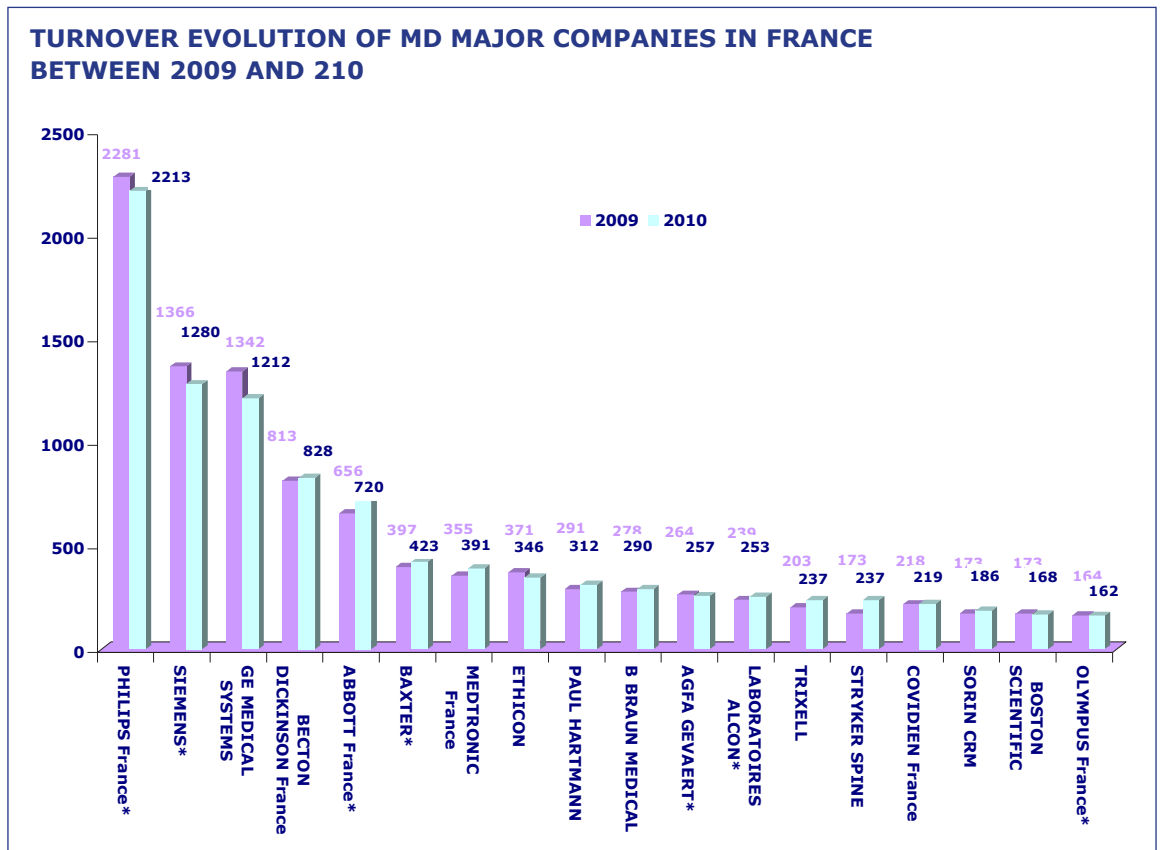
TOP 18 FRENCH MEDICAL DEVICE COMPANIES BY TURNOVER*, 2010

RANKING	COMPANIES	TURNOVER 2010	TURNOVER 2009	VALUE EVOLUTION	% EVOLUTION	ORIGIN
1	PHILIPS France*	2,213	2,281	-68,0	- 3%	NETHERLANDS
2	SIEMENS*	1,280	1,366	-86,0	- 6%	GERMANY
3	GE MEDICAL SYSTEMS	1,212	1342	-130,0	-10%	UNITED STATES
4	BECTON DICKINSON France	828	813	15,0	2%	UNITED STATES
5	ABBOTT France*	720	656	64,0	10%	UNITED STATES
6	BAXTER*	423	397	26,0	7%	UNITED STATES
7	MEDTRONIC France	391	355	36,0	10%	UNITED STATES
8	ETHICON	346	371	-25,0	- 7%	UNITED STATES
9	PAUL HARTMANN	312	291	21,0	7%	GERMANY
10	B BRAUN MEDICAL	290	278	12,0	4%	GERMANY
11	AGFA GEVAERT*	257	264	- 7,0	- 3%	BELGIUM
12	LABORATOIRES ALCON*	253	239	14,0	6%	SWITZERLAND
13	TRIXELL	237	203	34,0	17%	NETHERLANDS/ GERMANY
14	STRYKER SPINE	237	173	64,0	37%	UNITED STATES
15	COVIDIEN France	219	218	1,0	0%	UNITED STATES
16	SORIN CRM	186	173	13,0	8%	ITALY
17	BOSTON SCIENTIFIC	168	173	- 5,0	- 3%	UNITED STATES
18	OLYMPUS France*	162	164	- 2,0	- 1%	JAPAN

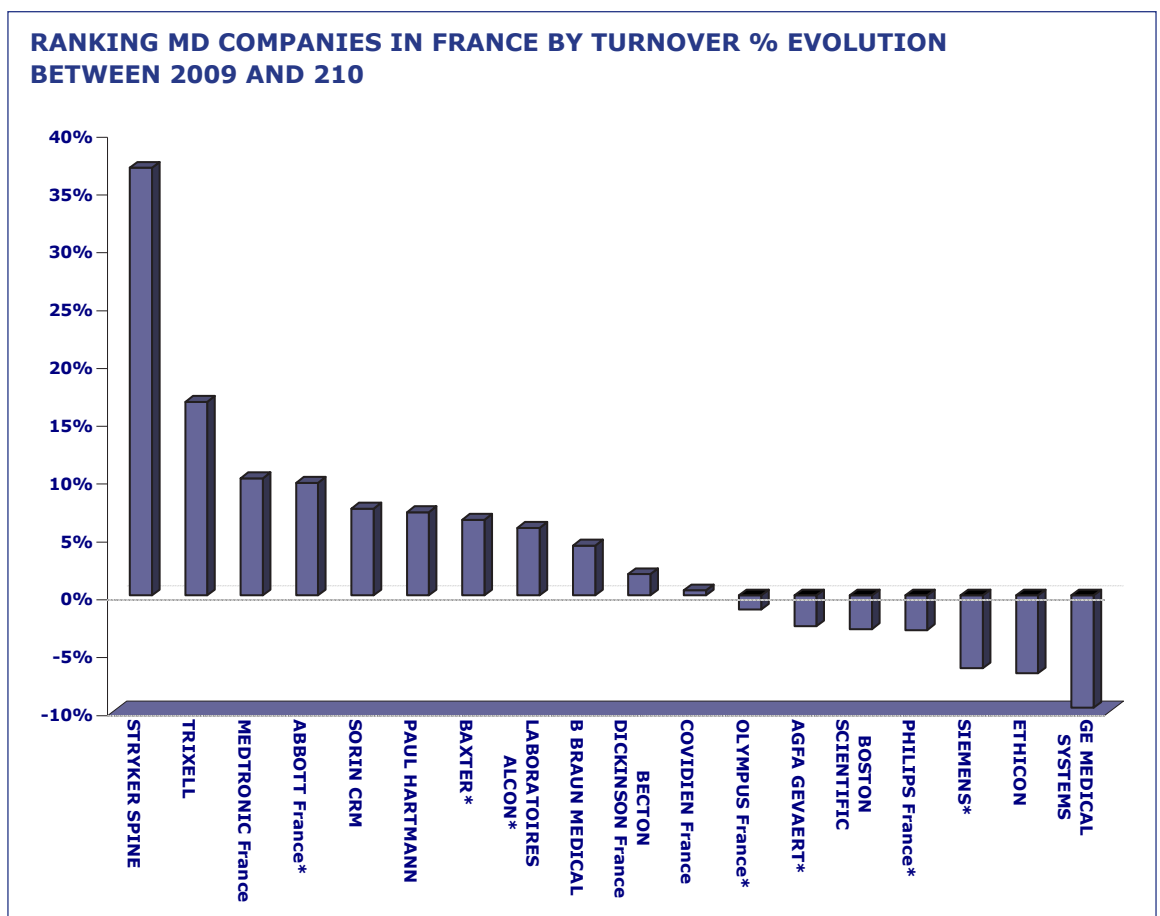
* TURNOVER included other products and services outside the scope of this study.

Source: XERFI, HALTYS

7.2.2.1 Ranking by value evolution between 2009 and 2010



7.2.2.2 Ranking by turnover % evolution between 2009 and 2010

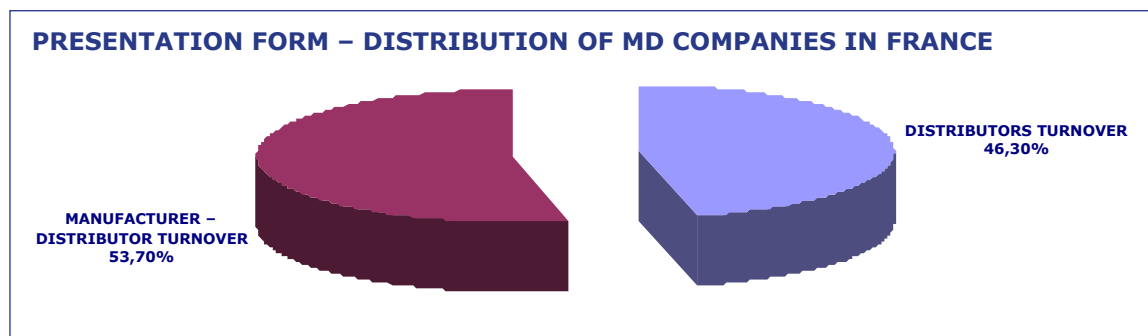


8 Marketing and Distribution

8.1 Presentation form – Distribution

COMPANIES	PRESENTATION FORM IN FRANCE
PHILIPS FRANCE	DISTRIBUTOR
SIEMENS	MANUFACTURER – DISTRIBUTOR
GE MEDICAL SYSTEMS	MANUFACTURER – DISTRIBUTOR
BECTON DICKINSON FRANCE	MANUFACTURER – DISTRIBUTOR
ABBOTT FRANCE	DISTRIBUTOR
BAXTER	DISTRIBUTOR
MEDTRONIC FRANCE	MANUFACTURER – DISTRIBUTOR
ETHICON	DISTRIBUTOR
PAUL HARTMANN	MANUFACTURER – DISTRIBUTOR
B BRAUN MEDICAL	MANUFACTURER – DISTRIBUTOR
AGFA GEVAERT	DISTRIBUTOR
LABORATOIRES ALCON	MANUFACTURER – DISTRIBUTOR
TRIXELL	MANUFACTURER – DISTRIBUTOR
STRYKER SPINE	MANUFACTURER – DISTRIBUTOR
COVIDIEN FRANCE	DISTRIBUTOR
SORIN CRM	MANUFACTURER – DISTRIBUTOR
BOSTON SCIENTIFIC	DISTRIBUTOR
OLYMPUS FRANCE	DISTRIBUTOR

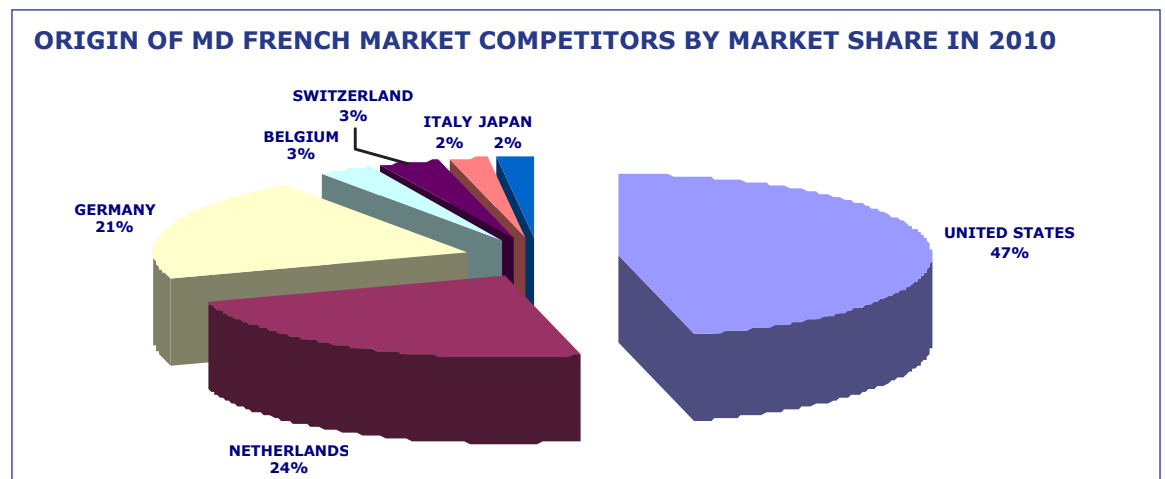
For more details about companies, see chapter 7.2.2.



8.2 Competitors origin

COMPANIES	ORIGIN
PHILIPS FRANCE	NETHERLANDS
SIEMENS	GERMANY
GE MEDICAL SYSTEMS	UNITED STATES
BECTON DICKINSON FRANCE	UNITED STATES
ABBOTT FRANCE	UNITED STATES
BAXTER	UNITED STATES
MEDTRONIC FRANCE	UNITED STATES
ETHICO	UNITED STATES
PAUL HARTMANN	GERMANY
B BRAUN MEDICAL	GERMANY
AGFA GEVAERT	BELGIUM
LABORATOIRES ALCON	SWITZERLAND
TRIXELL	NETHERLANDS / GERMANY
STRYKER SPINE	UNITED STATES
COVIDIEN FRANCE	UNITED STATES
SORIN CRM	ITALY
BOSTON SCIENTIFIC	UNITED STATES
OLYMPUS FRANCE	JAPAN

The French companies' turnovers do not allow their classification in the TOP 18.



Source: HALTYS

8.3 Market entry requirements

The French market requires a specific adaptation in the company's strategy. To summarize, the supplier has to follow accreditation process and technical requirements which are the main points which make the medical device a candidate to enter the market. We can list below the general requirements asked by the market:

- Completion of clinical trials and/or scientific literature that prove the equivalence.
- The best provided by the MD: usefulness, innovation, performance and scientific interest considering the existing solutions.
- Great value (Quality, Safety, Efficiency)/Price for a differentiation of enormous American and German groups.
- Ability to support the lengthy procedures of registration, evaluation, and pricing.
- Consideration of lower reimbursement rates and augmentation of burdensome and costly regulatory requirements.
- Consideration of the fact that the listing of products and reimbursed services is key for the future of DM.

9 Specifics by segment

9.1 Dental

- 40,930 is the number of dentists in 2009.
- The dentists provide two types of care: conservative and surgical care (Binding rate of 70% and reimbursed by social security) and prosthodontic or orthodontic (Honorary Fee).
- Dental Fees in 2010 are 8.4 billion euros (4.3 billion euros in extra billing).
- Evolution of 1.5% per year.
- Funding for dental households is 25.7% against 9.4% for the rest of medical care and goods.
- Support for dental care: 25.7% Households / health insurance and 37.1% CMUC/Agencies 37.2% complementary. (Source: Court of Auditors, 2009 data.)
- 15% of dental prostheses are imported from countries such as: North Africa (Tunisia, Morocco), China, Eastern Europe (The Czech Republic, Hungary and Romania), without lowering the prices, but increasing margins of practitioners (Eastern Europe: Dental Tourism from 50 to 80% less price).
- The French dental market has approximately 40,000 dentists and 95% work in private practice and 4,000 dental laboratories, employing 17,000 dental technicians. The purchasing power of dental materials and products is approximately 1 billion. €, of which ~ 85% are dental offices.
- The dental industry and distribution employ about 4500 people. The companies are mostly SMEs, only 10% of them make the annual turnover exceeding € 10 million, while 55% are at a level lower than 2 M €.
- The Comident brings together industries specializing in the manufacture and distribution of all materials and dental materials among dentists and dental technicians.

Source: COMMIDENT

9.2 Cardiology

- Cardiology has 13% of the market of medical devices in 2008 with 806 million euros of turnover.
- Heart Valves: Overall the market for valves (excluding valves percutaneous) decreases in value (- 4.4%). One factor may help explain this negative trend can be found in the integration of valves in March 2010 in the GHS (Homogeneous groups in health establishments).
- External Cardiac Defibrillators: this market is mature because of a park already installed. There is a decline in value of 20% compared to 2009, after declining 12% between 2008 and 2009.

Source: SNITEM

9.3 Hearing aids

- In 2010, 482,155 hearing aids were sold in France against 463 118 in 2009, a growth of 4.11%.
- The survey SNITEM, National Union of the medical technology industry, confirms the supremacy of the contours, up +2.04% in 2010 on-ear losing more ground to -1.06% on the year -7.45% in the last quarter.
- The BTEs mark at the end of 2010 a retreat of -4.6% over the same period in 2009. In total, 265,247 contours that were sold in 2010 to 72,907 ITE. The contours stack 13 have the highest sales with 196,302 units sold in 2010 and represents a growth of 9.31%.
- Note the good sales performance of headphones deported, an increase of +9.48% in 2010 with 162,723 units sold (+5.57% in the fourth quarter).
- Remarkable sales of more and more prevalent charging stations for hearing aids, with sales recording an increase of 741.57% in 2010 + (+444.87% in the fourth quarter).
- Within the category of “emerging” products, it must be emphasized that Bluetooth interfaces are gradually taking place, which can be observed from an increase in sales from 4,916 units in 2009 to 6,124 in 2010, a growth of 24.57% (+16.14% in the fourth quarter of 2010).

- Finally, the CMU units are not booming and sales were down –13.88% over the year to represent only 10,070 units and only 2,347 sales in the fourth quarter of 2010.

Companies that participated in the survey of SNITEM are: Acourex/Widex Audiomedi, GN Hearing, Iso-Sonic, Phonak, Prodition, Siemens and Starkey.

Source: Audio Infos Primary source: SNITEM

9.4 Ophthalmics

- The market for optical was close to 5.4 billion euros in 2010. It represents 32% of the market for medical devices.
- An increase of 3% per year on average since 2002, is supported by heavy structural changes such as aging population, lifestyle (more time in front of computers) and the increasing attention of individuals to their health.
- The number of companies: 8,617
- Creation of companies in 2010: 589
- Number of stores: 10,520
- Average turnover per shop: 564,000 Euros
- Rate of gross margin is 59.2%
- Average budget per person: 82.7 EUR
- Average budget per household: 190.1 EUR
- The population of opticians almost doubled between 2000 and 2009
- The classification of retail:
 - Guildinvest (signs Krys, Vision Plus, Vision Original and Lun's Eyewear) – turnover exceeds 10% of the market
 - Alliance Optique (group of independents without common brand) – turnover exceeds 10% of the market
 - Gadol (Optic 2000 and Lissac) – exceeds 10% turnover of the market
 - Alain Afflelou – between 9% and 10% turnover of the market
 - Grand Vision – between 9% and 10% turnover of the market
 - Les Opticiens Mutualistes – between 9% and 10% turnover of the market

Source: Xerfi

9.5 Diagnostics

- Turnover of manufacturers of diagnostic products in 2010: 1.8 billion euros
- Evolution of turnover in 2010 was 4%
- Number of companies: 200
- Number of employees: 10,000
- The global market for diagnostic products is estimated at 30 billion euros in 2009
- The first 8 groups share 70% of global sales (leaders: France ABBOTT, HEALTH Bayer, Becton Dickinson France, BIOMERIEUX, BIO-RAD, France ORTHOCLINICAL DIAGNOSTICS, Roche Diagnostics)
- Distribution of sales by category:
 - Private medical biology laboratory: 44%
 - Hospitals: 28%
 - Wholesalers: 23%
 - Blood Transfusion Centre 4%
 - Other: 1%

Source: Xerfi

9.6 Medical Imaging

- The market for medical imaging in vivo is worth about 992 million euros in 2010.
- The global market is estimated at 20 billion euros in 2006.
- The medical imaging market is segmented into three main parts: 19% for endoscopy (invasive), 59% for conventional imaging (radiography, ultrasound ...), and up to 22% for large instruments (scanners X, MRI, PET).
- Few industrial French players occupy dominant positions with these technologies. However, some international actors have in France production sites or R & D.

- Number of radiologists in activity is 7,903 in January 2010, 9.5% up since 2001 (7164 Diagnostic Radiology and Medical Imaging/683 Radiation Therapy and onco-radiotherapy/ Diagnostic Radiology and Radiotherapy).
- The income of a radiologist in France: 214 KEuros.

Source: Ministère de l'économie, des Finances et de l'industrie

9.7 Orthopedics

The global market for hip replacement is estimated of \$ 3.5 billion. Its growth was 13% between 2004 and 2005. The dominant players are Johnson & Johnson, Biomet, Stryker, Zimmer, and S & N.

In Europe, 730,000 hip replacements were laid in 2004 for a value of \$ 1.08 billion (863 million €) is:

- € 190 million – 22% in France
- € 233 million – 27% in Germany
- € 112 million – 13% in the UK
- € 104 million – 12% in Italy
- € 43 million – 5% in Spain

The European market for Reconstruction (hip, knee, elbow and shoulder) was \$ 2 billion in 2004, which is divided between:

- hip prostheses (53%)
- knee prostheses (45%)
- the remaining 2% for the joints of the elbow and shoulder.

Source: ARTEB Primary source: AVICENNE DEVELOPPEMENT

10 Most common diseases and causes of death

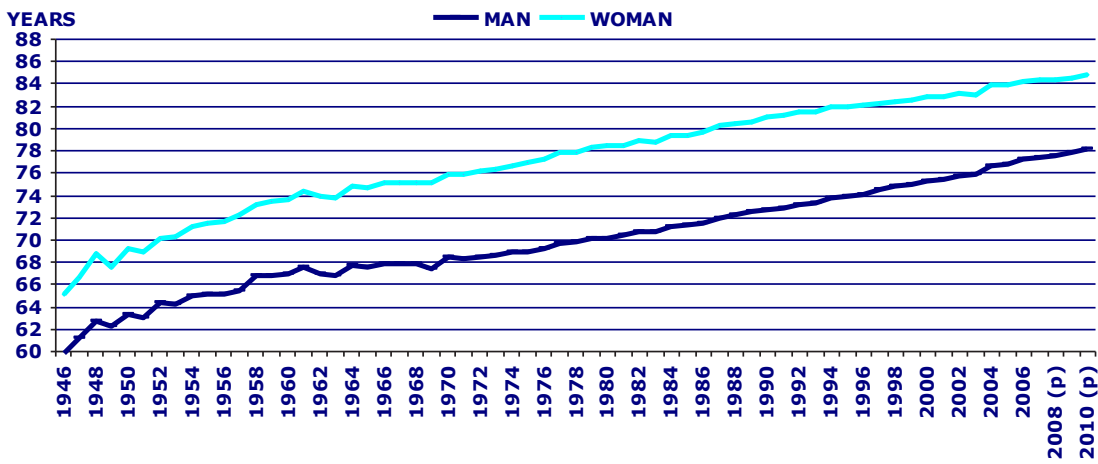
Definition: The mortality rate is the ratio of deaths in the year to the average total population of the year. Unit in the thousands.

Mortality rates by cause of death and sex in France in 2008, 2007 and 2006.

MORTALITY RATES BY CAUSE OF DEATH AND SEX IN FRANCE IN 2008							
	Malignant tumors	Circulatory diseases	Respiratory diseases	Digestive diseases	External causes	Including transport accidents	Including suicides
METROPOLITAN France BY 1000 POPULATION							
Man	2,321	1,63	0,4	0,337	0,645	0,109	0,232
Woman	1,176	0,946	0,189	0,168	0,259	0,028	0,075
Total	8,515						
MORTALITY RATES BY CAUSE OF DEATH AND SEX IN FRANCE IN 2007							
Man	2,382	1,686	0,409	0,336	0,649	0,115	0,228
Woman	1,161	0,964	0,192	0,172	0,265	0,032	0,075
Total	8,666						
MORTALITY RATES BY CAUSE OF DEATH AND SEX IN FRANCE IN 2006							
Man	2,426	1,743	0,409	0,35	0,662	0,118	0,236
Woman	1,202	1,021	0,192	0,177	0,276	0,033	0,08
Total	8,925						

Source: Institut National d'études démographiques

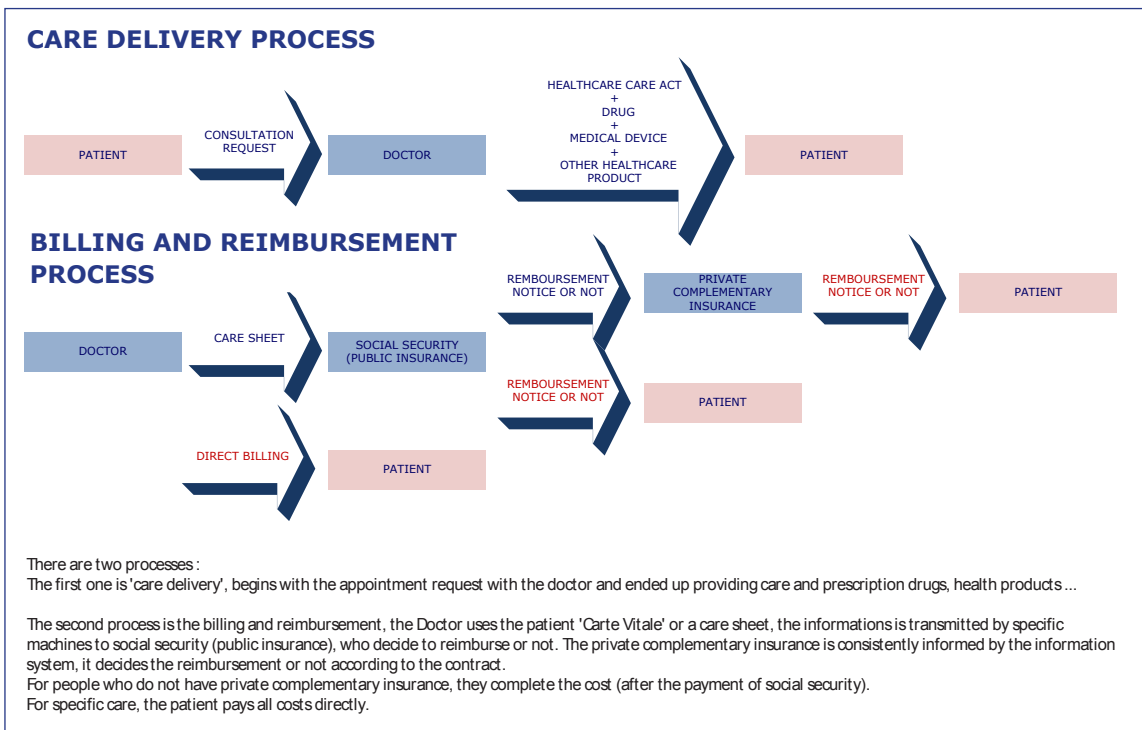
LIFE EXPECTANCY EVOLUTION IN METROPOLITAN FRANCE BETWEEN 1946 AND 2010



Source: Institut National d'études démographiques

11 Health Economics – Costs and Financing

11.1 Relationship of patients, providers and payers



11.2 French healthcare system: Balance

11.2.1 Healthcare economics definition

The health economics is concerned with the production, dissemination and use of health in a population through prevention, care and changing attitudes:

- Inputs: resources used, hospitals, ambulatory care, drugs ...
- Outputs: care, state of health

$$\begin{array}{lll}
 \text{Offre} & = & \text{Demand} & = & \text{Expenditure} \\
 \text{Income of Professionals} & = & \text{Healthcare spending} & = & \text{Financial means} \\
 (H+S) \times N & = & P \times Q & = & (I + C) + M + A
 \end{array}$$

H+S = Honorary and/or Salary et N = Number of caregivers

P = Unitary Price of care Prix et Q = Care consumed volume

I+C = Taxes and/or Contributions, M = Cost paid by patient and A = Costs paid by insurance

11.2.1.1 Healthcare expenditure

	2008*
Hospital	75,16
Ambulatory care	46,80
Medical Transportation	3,39
Drugs	34,90
Other medical goods	10,24
CSBM**	170,49
Individual preventive medicine	3,16
TOTAL MEDICAL CONSUMPTION	173,65
CURRENT HEALTH EXPENDITURE	215,04

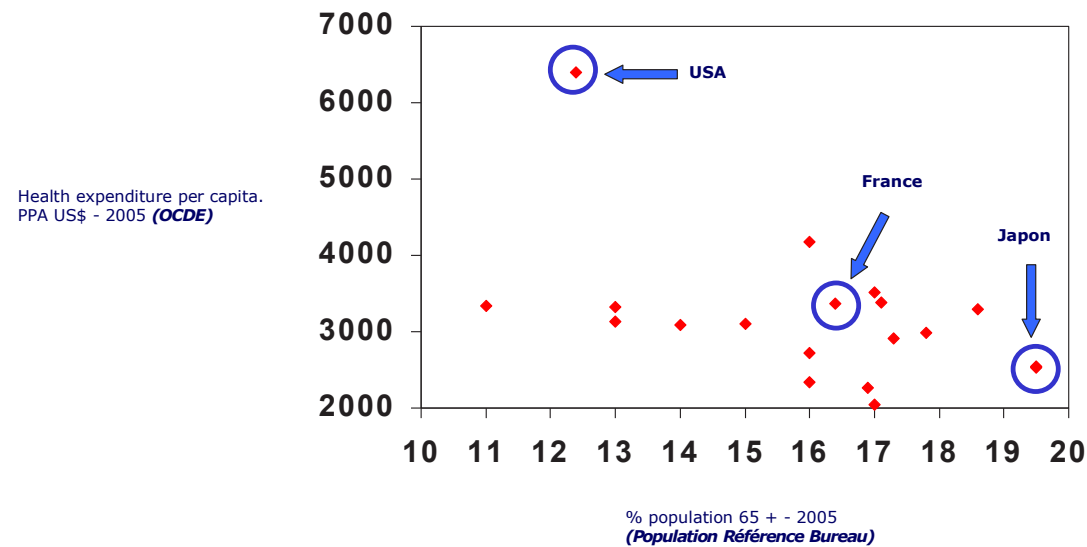
* Billions of Euros

** Consumption of Care and Medical Goods, in French 'La consommation de soins et de biens médicaux (CSBM)'

Source: Drees, Comptes nationaux de la santé

CURRENT HEALTH EXPENDITURE/CAPITA = 3444 EUROS/YEAR

Health spending per capita international comparison:

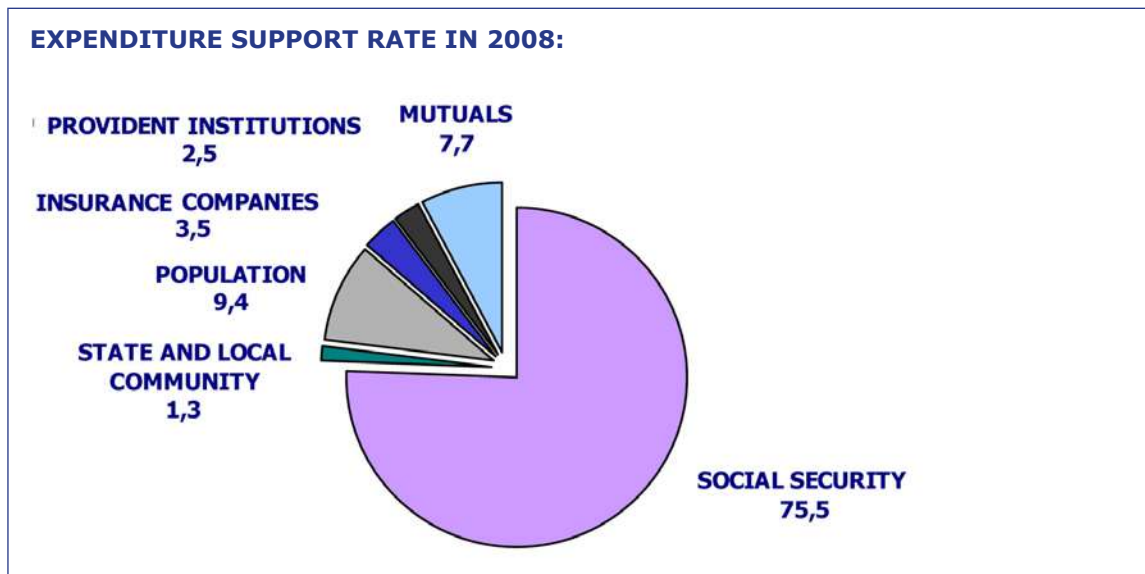


11.2.1.2 Growth factors

Growth factors are varied and complex, we cite mainly:

- The aging of the population ~ 1% / year (30% of the French population will be 60 + years in 2030, 25% in 2015, 23% in 2010) Source: INSEE
- The increase in life expectancy
- The development of technology ~ 1.5–2% / year (A lot of exams are performed in order to assess the state of health)
- Effect (volume and price): ‘It is the production that opens markets to the products featured’ on Political Economy – Jean-Baptiste Say – 1803
- The poor distribution of physicians (Alsace, Paris and the South)
- The “new” diseases: AIDS, obesity, diabetes, ...
- Fees and prices

11.2.2 Expenditure financing

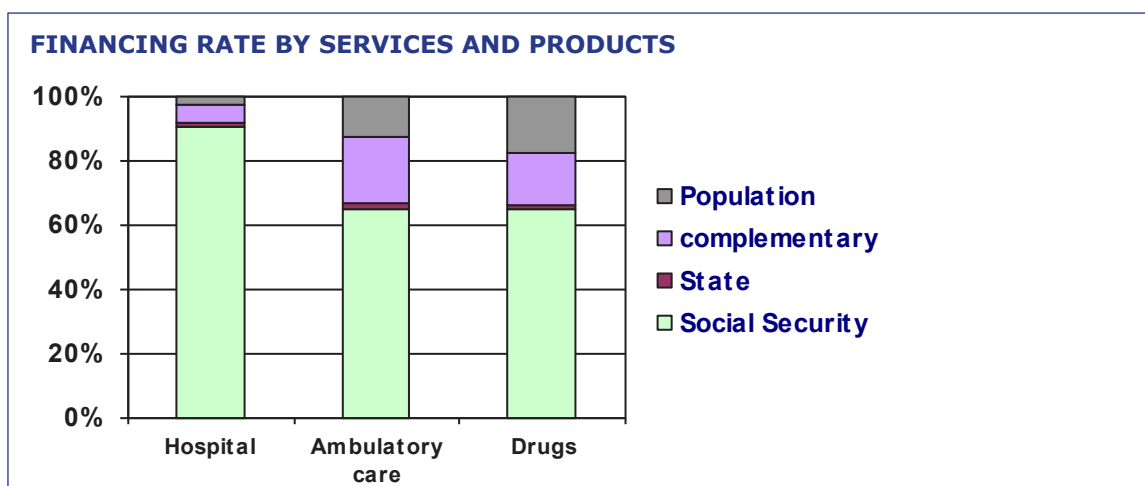


Source: comptes de la santé 2008 – DREES

Expenditure support in 2010:

SOCIAL SECURITY	75,8%
COMPLEMENTARY ORGANIZATIONS	13,5%
POPULATION	9,4%

Source: Comptes de la santé 2010 – DREES



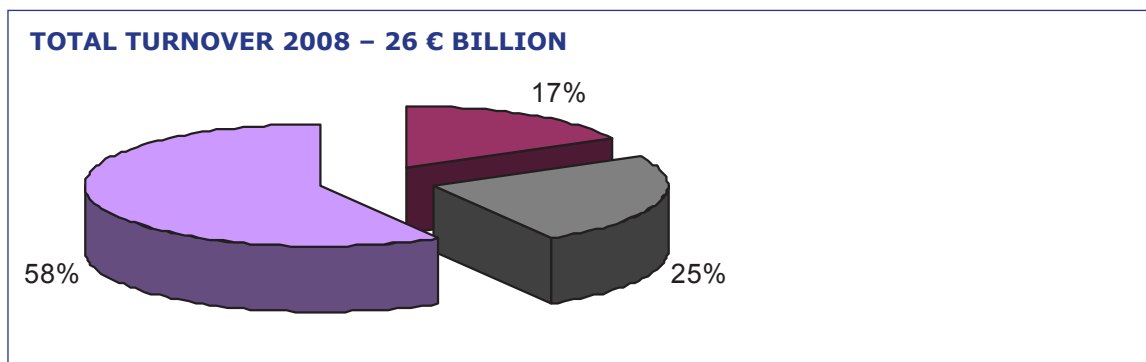
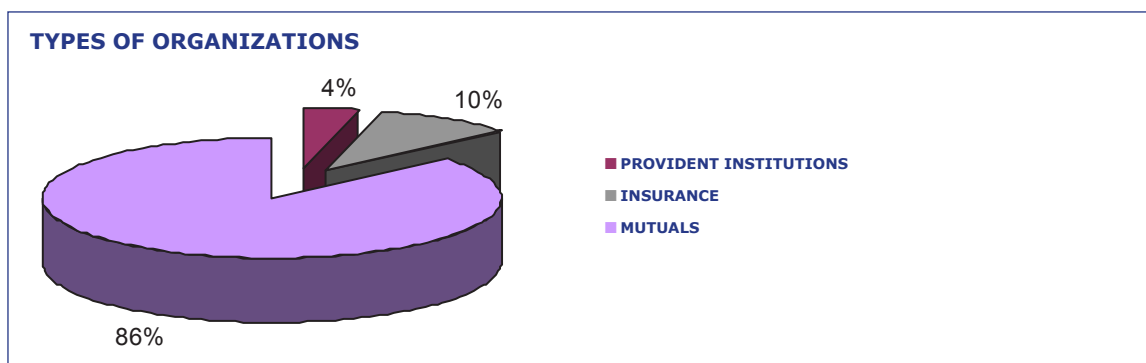
11.2.2.1 Social Security financing – Public health care insurance

ON TOTAL OF SALARY				
Total	Sickness, maternity		Family allowances	Old age
	PP	PS	PP	PP + PS
20,95	13,10	0,75	5,40	1,60 + 0,10
ON LIMIT CEILING SALARY				
Total	Old age		FNAL	
	PP	PS	PP	
15,05	8,30	6,65	0,10	
ON 97% OF ALL INCOME				
CSG			CRDS	
7,50			0,50	

PP: employer's share – PS: employee's share – FNAL: National Fund for Housing Assistance – Ceiling: € 2,773/month at 01/01/2008 – CSG: general social contribution – CRDS: Contribution to the Social Debt Repayment

11.2.2.2 Complementary healthcare – Private healthcare insurance

This the complementary reimbursement of the public insurance.



11.2.3 Fraud

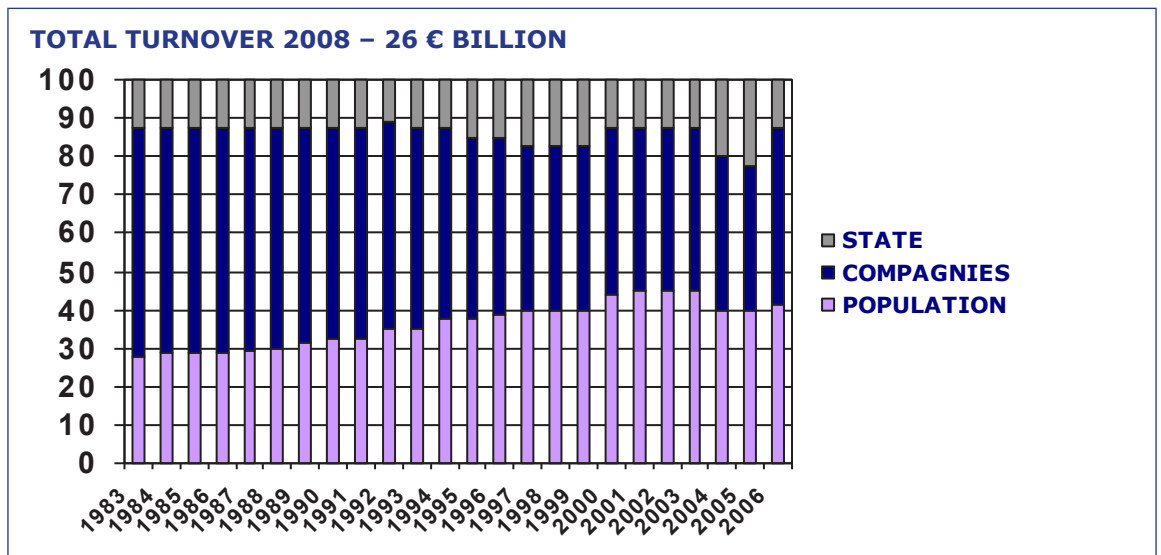
The amount of fraud detected and stopped in all categories, amounted in 2010 to 156.3 million euros:

- 71.1 million came from hospitals and clinics
- 12.7 million Liberal nurses
- 6.8 million ambulance
- 4.9 million doctors
- 3.8 million dentists
- 3.5 million pharmacists
- 2.5 million physiotherapists

Health facilities charge fault insurance stays more expensive than those actually performed. Medical or paramedical professionals and ambulance charge mainly for a fictitious activity.

Source: L'Express

11.2.4 Public insurance financing evolution 1983–2006



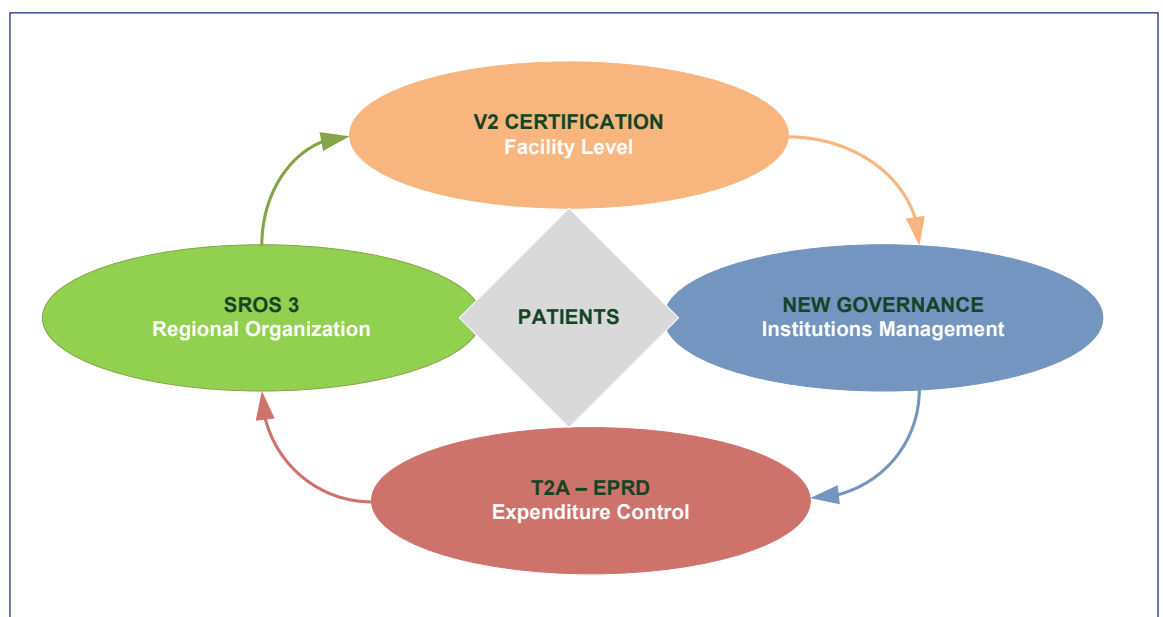
We can note that the companies are tending to pay less within the time period and the state and population to pay more.

12 French healthcare reforms – The Magical Quadrant

THE “MAGIC” SQUARE OF THE REFORMS

The national statement presented by the Ministry of Health (and translated into various signed contracts) is exposed in the Hospital Plan 2007 (introduced in 2003) and the Hospital Plan 2012 (introduced in 2007). They organize the new hospital management, with emphasis on management by objectives. According to the Ministry of Health, the foundation of reform results in improved care pathways in four areas:

- ensuring access to health care for all,
- improving the quality and safety of care,
- increasing the efficiency of the management,
- utilizing better the resources.



The tools available for the realization of this course are:

- i. Regional patterns of organization of care (currently SROS 3) that must be reflected in the multi-year contract objectives and resources (CPOM) of public health.
- ii. Certification, accreditation and evaluation of professional practices (quality and safety).
- iii. The new governance institutions (reformulation of the power of authorities and decisions at the operational units, in other words, an internal contracting to the hospital with medical centers).
- iv. A method of financing the development of pricing by activity (T2A), and the establishment of a forecasting tool (SPIE: Estimates of revenue and expenditure) in order to anticipate the financial flows and to adopt an asset-based approach.

12.1 SROS 3 – Regional Organization

The hospital planning SROS 3 or third generation is based on the health needs of the population and develops a spatial distribution of activities and heavy equipment. Among the tools of SROS, the third generation develops quantitative targets for the provision of care (OQOS).

These concern both the public and the private sector. It is management tools for sizing supply needs and distribute it among institutions. Goals are set by area of the health care, activity, and by heavy equipment. This concerns a regulatory mechanism in the hands of the guardianship. Institutions theoretically have limited objectives of activity expressed in number of visits, days, and acts which are framed by lower and upper limits of activity.

A hospital is punishable if it exceeds its upper bound. If it does not reach the lower limit, a study is conducted to examine the causes. These OQOS allow also some regulation between the market share of private and public, but it depends on the political authorities.

12.2 Certification and evaluation of professional practices – Facility Level

The second axis of the framework of the director of the hospital is the increasing research of quality through certification and accreditation of its hospital. It should emphasize the following components: reinforcement of the fight against nosocomial infections, adverse events (including epidemic) and the implementation of the evaluation of professional practices of health workers.

According to the supervision, evaluation of the quality and professional practice is as important as the reform of the financing of the health system. The director should be part of this approach (which inspired some quality approaches developed in the industrial or service), and consider the adaptation of its establishment.

12.3 New Governance – Institutions Management

Another line of the square “magic” is the new governance, which defines the reform of the internal organization of the hospital. In this reform, the scope of the director and his team is more important than before. In addition, the integration of hospital doctors in the decision-making and implementation is a key point.

The main points are divided as follows:

- i. A Board refocused on setting strategic direction and control of implementation, with particular emphasis on evaluation.
- ii. The creation of an executive council, composed of doctors and a part of the management team, which becomes a steering body for the development and implementation of the Project to establish multi-year contract and Objectives and Means.
- iii. The establishment of centers of clinical activity and medico-technical (cardiology, geriatrics, emergency ...), reflecting how the organization meets its mission, with a medical coordinator and a board elected from pole. The division shall contract with the in-house director of the institution and the contract spells out the goals of activity, quality and finance, and specifies the means that the pole may have. Indicators for monitoring and evaluation of performance

are provided, and it is also envisaged in the reform of the opportunity to develop a profit-sharing.

- iv. The development of a process of decentralization, which provides that the pole has a certain level of management delegation. This delegation is considered by the Executive Council and decided by the director of the hospital. Thus, the focus for the management of financial means, of physical means and human resources that are medical and nonmedical. This delegation is expected to develop a major responsibility of the operators, especially the coordinator of the cluster and the various medical officers.

12.4 T2A – EPRD – Expenditure Control

Funding for the facility is primarily the result of its activity and this is supplemented by an allocation of general interest missions and aid to contracting institutions. For pricing, patients are classified as HGS, homogeneous groups of hospital stays, where the tariff is set at the national level. This funding mechanism is accompanied by a modernization of financial tools (budget and accounting) to emphasize the link between financial resources and the production activity of care.

As a part of the pricing by activity, the government has maintained a national regulatory capacity. This is based on the principle of a national financial envelope closed and can increase only after a vote in Parliament. This envelope is called the ONDAM (Target National health insurance expenditure). It is divided into envelopes corresponding to specific spending targets under which the hospital component.

13 Investment Programs – HOSPITAL PLAN 2012

The 2012 Hospital Plan for 2008–2012 will involve nearly 10 billion Euros of investments, of which 5 billion provided by the State, in direct support of health insurance.

The plan continues as a double objective: to improve the efficiency of hospital services, and to continue the technical modernization of health facilities involved with the 2007 Hospital Plan where it provides its continuation.

The projects selected for the first phase of the 2012 Hospital Plan:

Nearly 2000 projects were received in the regions, where nearly half came from public institutions. 343 projects (less than 20%) were presented at the first national validation window. Of the 343 projects submitted, 250 projects were approved (divided among 93 real estate projects, 155 Information Systems projects, and 2 operations up to standard) totaling up to 1.7 billion of investments, or 34% of the amount of the first part and 17% of the total Plan. This initial assessment of the 2012 Hospital Plan covers less than 20% of the amount of planned investment.

The follow-up for the 2012 Hospital Plan is well underway since the second window of deposit is currently being expertise. The number of projects is even higher than in the first window with nearly 500 projects appraised by the end of the year. Subsequently, the institutions may still submit new operations dated 2010

Afssaps French Healthcare Safety Product Agency

Afssaps was created by the Act of 1 July 1998 instituting a system of monitoring and sanitary safety. Its mission is essential to assess the risks and benefits associated with the use of health products.

Taking into account the therapeutic needs and the requirements of continuity of care, it contributes, through its various forms of intervention, that the risks inherent in each product can be identified, analyzed and controlled to the most possible ways.

Jurisdiction applies to medicines and raw materials, medical devices, and in vitro medical devices as diagnostic biological products of human origin (blood products, organs, tissues, cells, products of gene and cell therapies) and for therapeutic products, cosmetics and tattoo products...

CNEDiMTS National committee for the evaluation of medical devices and health technologies

One of the specialized committees of the HAS

- Mission: evaluation for reimbursement
- Scope: Health Products ≠ drugs
 1. Medical devices (+++)
 2. Allograft
 3. Dietary foods for special medical purposes
- Evaluation of the claim files
- Reevaluation of homogeneous groups of products
- Development of good practice documents

CEAP Committee for the evaluation of medical procedures

Responsible for decisions on the opinions of the professional acts (processes, techniques and methods used by health professionals for preventive, diagnostic or therapeutic) for their care by the health insurance and validation and publicizing the work of health technology assessment (excluding drugs and medical devices can be enrolled in the list of reimbursable products and services).

CEPS Healthcare products pricing committee

Responsible for setting drug prices and prices of single use medical devices covered by mandatory health insurance.

UNCAM National Association of Health Insurance Funds

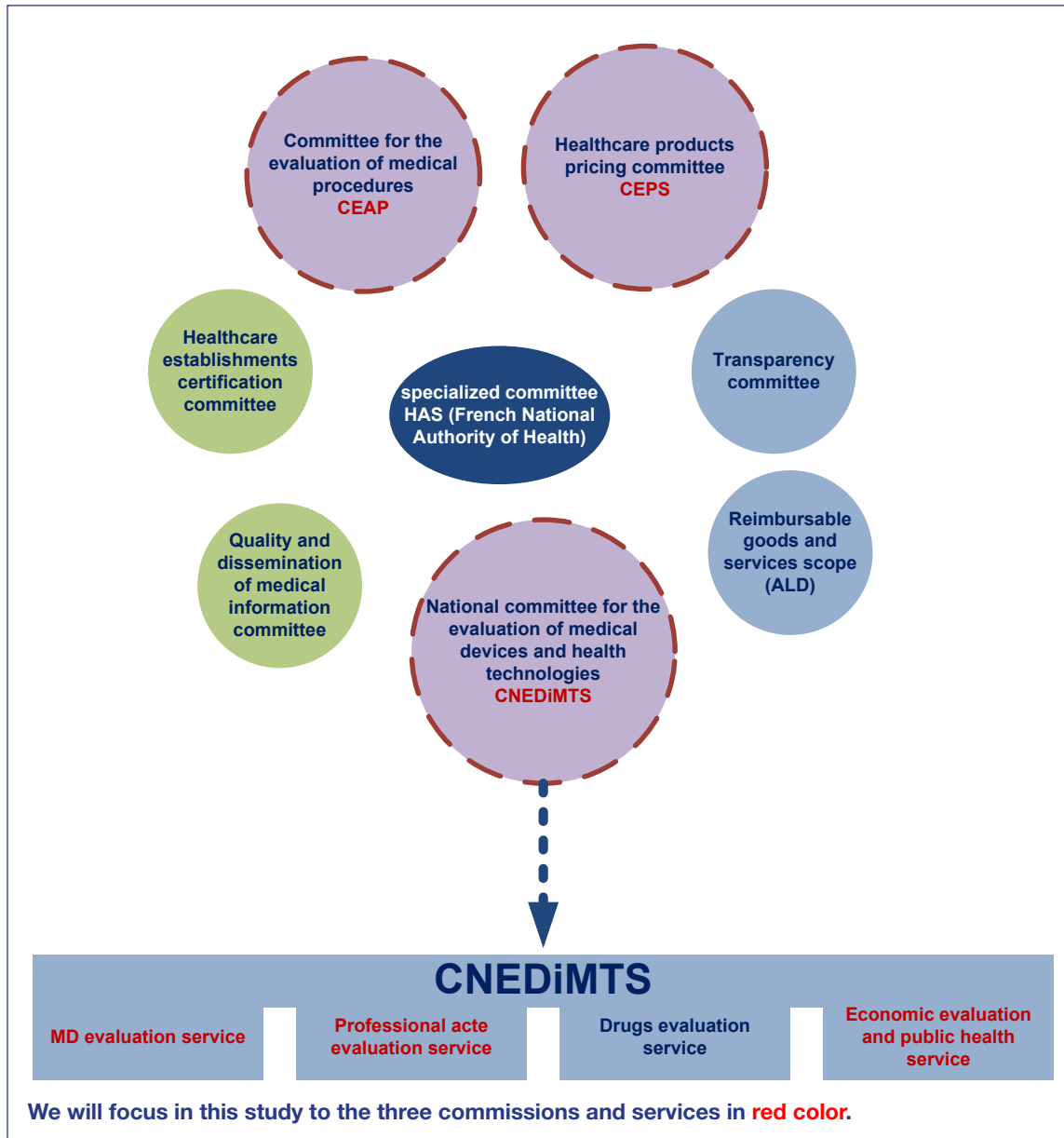
It includes the three main health insurance schemes: the general, the agricultural system (MSA) and the social system of independent (RSI).

The role of UNCAM is to:

- Conduct conventional politics.
- Define the scope of services eligible for reimbursement.
- Set the rate of management of care.

14.1.2 HAS commissions and CNEDiMITS services

HAS



14.2 The process of MD market accreditation in France

STEPS?	WHO?	WHAT?	Chapter?
Phases of the accreditation process	Entities involved in the process	For the purpose	Corresponding chapter in the report
CLINICAL STUDIES	THE INDUSTRIALS	CNEdIMTS recommendations	14.3
MARKET AUTHORIZATION REQUEST (CE MARKING)	Notified organization for CE marking in France is G.MED Mandated by AFSSAPS (Market control)	European Directives for CE marking MD classification	14.4 14.5
TYPE REMBOURSEMENT DEFINITION	HAS CNEdIMTS	MD integrated into GHS MD included on the LPPR Innovative MD MD supported as part of the health professional act	14.6
ACTUEL BENEFIT EVALUATION ADDED CLINICAL VALUE EVALUATION	HAS CNEdIMTS	Reimbursement application : http://www.has-sante.fr/portail/upload/docs/application/pdf/dossier_medico-tech_guide_fab_2006.pdf	14.6
TYPE PRICING DEFINITION	HAS CNEdIMTS	The assessment criteria for actual benefit	14.7
SUPPORT DECISION OF HEALTH INSURANCE	CEPS UNCAM	The assessment criteria for added clinical value	14.7
	CEPS UNCAM	CEPS : Pricing with manufacturers UNCAM : Fixing reimbursement rate of MD	14.8
	Health ministry UNCAM	UNCAM : Fixing reimbursement rate of Health acts with representatives organizations of health professionals	14.8
	Health ministry UNCAM	Health ministry : List of reimbursable MD UNCAM : List of reimbursable health acts	14.8

14.3 CNEDiMTS clinical studies recommendations

CNEDiMTS recommendations for clinical studies:

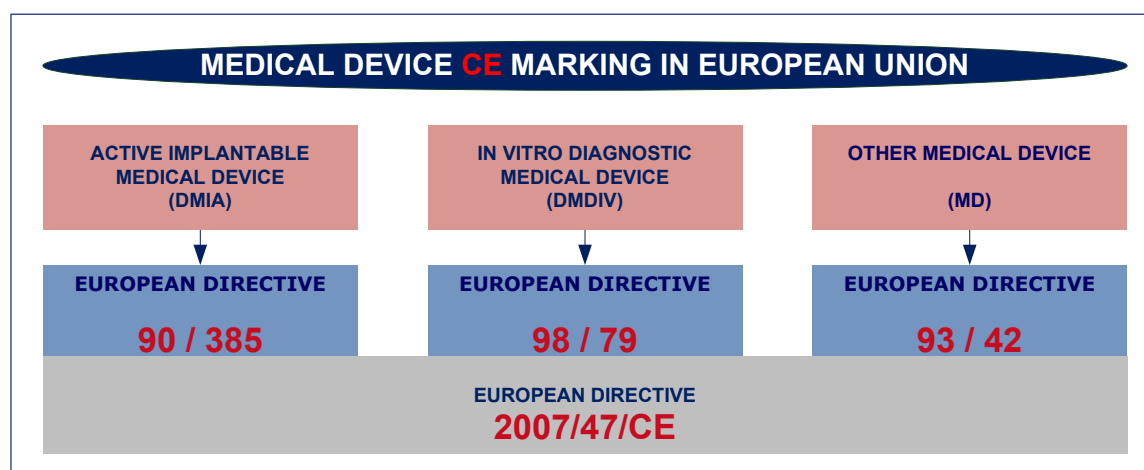
- Inclusion on the list is for a maximum duration of 5 years in a specific indication.
- For a new MD, the guidance of CNEDiMTS is based in particular on assessment of the actual benefit (AB) and, if the latter is sufficient, on the assessment of added clinical value (ACV).
- CNEDiMTS requests that the following be provided in the dossier submitted for inclusion in the list: relevant publications or reports, as well as a summary of each study in the form of a table containing among other things the study reference, type of study, date and duration of study, study objective, method and results.
- CNEDiMTS has published methodological requirements relating to comparative trials. The optimal type of study for this clinical investigation is the randomised controlled trial.

The challenges of clinical development

The stages of clinical development are described in the harmonised standard NF EN 14155. European Commission recommendations are also available on MEDDEV
http://ec.europa.eu/enterprise/medical_devices/meddev/meddev_en.htm

14.4 European guidelines for CE marking

European directives for CE marking



Exclusion: This requirement does not apply to devices intended for clinical investigation, to custom-made medical devices, or to in vitro diagnostic medical devices for evaluating performance.

Essential requirements

Active implantable medical devices must not compromise the clinical condition or the safety of patients. In addition, they must not present any risk to the persons implanting them, or to other persons.

These devices must achieve the performances intended by the manufacturer. They must be designed in such a way as to withstand the storage and transport conditions.

Harmonised standards

Member States shall publish the national standards implementing the corresponding harmonised standards, which shall also include the monographs of the European Pharmacopoeia.

Any product manufactured in accordance with harmonised standards is presumed to conform to the essential requirements.

Conformity procedures

All devices must be subjected to a conformity assessment procedure. Member States shall designate independent bodies contributing to the application of these procedures.

Placing on the market and free movement

Member States shall take necessary steps to ensure that devices may be placed on the market and put into service only if they meet the requirements of this Directive and do not compromise the safety and health of patients, users and other persons when properly implanted, maintained and used in accordance with their intended purposes.

Member States must not impede the placing on the market, free movement and putting into service of devices meeting the essential safety criteria set out in the annexes to the Directive and bearing the CE mark.

European databank

The aim of the European databank is to store the data required by law. The latter shall be made available to the competent authorities and shall contain:

- data on registration of manufacturers;
- data relating to certificates issued, amended, suspended, withdrawn or refused;
- data obtained in accordance with the vigilance procedure;
- data on clinical investigations.

Vigilance

The manufacturer must immediately inform the competent authorities of any incident causing death or damage to the health of a patient, by applying the procedures of a technico-vigilance system. This information must be recorded and evaluated by Member States.

Surveillance

Notified bodies shall be authorised to carry out inspections of manufacturers. For their part, manufacturers must provide the inspectors with all relevant information.

Safeguard measures

Member States must take all appropriate measures to withdraw from the market devices conforming to the Directive which are liable to compromise the health and/or safety of patients, users or third parties. The provisional measures taken must be notified to the Commission.

14.4.1 Medical device – EUROPEAN DIRECTIVE 93/42

Scope

It does not apply to:

- devices used for in vitro diagnosis;
- active implantable devices;
- medicinal products for human use, including medicinal products derived from blood;
- cosmetic products;
- partly to human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells with the exception of devices referred to in paragraph 4a;
- transplants, tissues and cells of human origin or to products incorporating or derived from tissues or cells of human origin with the exception of devices referred to in paragraph 4a;
- transplants, tissues and cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

14.4.2 In Vitro diagnostic Medical Device – EUROPEAN DIRECTIVE 98/79

Scope

The Directive applies to in vitro diagnostic medical devices and their accessories.

These devices are products used for the in vitro analysis of tissues or substances (blood, specimens) from the human body. The types of analysis covered are as follows:

- state of health;
- congenital diseases or anomalies;
- checking the progress of courses of treatment;
- determining compatibility in the case of organ or blood donations.

14.4.3 Active implantable Medical Device – EUROPEAN DIRECTIVE 90/385

Scope

This Directive shall apply to active implantable medical devices.

It shall not apply to:

- medicinal products for human use;
- human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells with the exception of devices referred to in paragraph 4a;
- transplants, tissues or cells of human origin or to products incorporating or derived from tissues or cells of human origin with the exception of devices referred to in paragraph 4a;
- transplants, tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

14.4.4 Evolution of CE marking – EUROPEAN DIRECTIVE 2007/47/EC

Clinical evaluation, extract from Directive 2007/47/CE

“The demonstration of conformity with essential requirements must include a clinical evaluation (Annexe 1–6 b)”

“As a general rule, confirmation of conformity with the requirements concerning the characteristics and performance (...) under the normal conditions of use of the device as well as the evaluation of the side-effects and of the acceptability of the benefit/risk ratio (...) must be based on clinical data”.

“Evaluation of this data, hereinafter referred to as ‘clinical evaluation’, where appropriate taking account of any relevant harmonized standards, must follow a defined and methodologically sound procedure based on (...), (Annexe X–1–1.1)”.

14.5 MD classification

MDs are divided into four classes, as a function of their level of risk. This categorization takes into account:

- duration of use
- whether or not it is invasive and to what extent it is invasive
- whether or not it can be reused
- the therapeutic or diagnostic aim
- the body part in contact with the device.

The class is determined by the manufacturer as a function of the claims and classification rules of the directive.

To assist in determining the class of MD, there are MEDDEV 2.4/1 guidelines;
NANDO (New Approach Notified and Designated Organisations) Information System
<http://ec.europa.eu/enterprise/newapproach/nando>

Class I	Low degree of risk
Class IIa	Medium degree of risk
Class IIb	Increased potential for risk
Class III	Very significant potential for risk (includes active implantable MDs)

Non sterile MDs, or those with no measurement function, are self-certificated by the manufacturer.

The majority of MD classes require the intervention of a notified body (In France, there is G-Med “appointed by and supervised by the Afssaps – French Healthcare Product Safety Agency”), chosen from those on the European Commission list:

- Class IIa, IIb, III AIMDs and MDs and class I sterile MDs or those with a measurement function;
- IVDMDs specified in annex II of directive 98/79/CE as well as those intended for self-diagnosis.

The procedures certifying compliance include:

- Audit of the manufacturer’s quality system
- Control of the design dossier, which is only systematic for AIMDs, class III MDs and IVDMDs in annex II list A.

This process is long and restrictive; it should therefore be anticipated.

The certificate of compliance issued by the notified body is valid for a maximum of 5 years and is renewable. During this period, follow-up audits are carried out; and an in-depth audit takes place at the time a certificate is renewed. This process enables account to be taken of the continuous development of devices as well as data collected during this interval.

The more innovative a device, the more strategic the application of regulations. For this reason, Afssaps (the French Healthcare Product Safety Agency) has implemented a structure to accompany those conducting innovative projects to facilitate access to the market of devices which are of significant clinical benefit.

14.6 Healthcare insurance reimbursement

14.6.1 MD incorporated in GHS (T2A)

COMDIMS advice +/- HAS evaluation

Since 2004 and as a result of gradually scaling, public and private health establishments are financed within the framework of tarification T2A. As a result, expenditure on certain MDs is integrated into hospital services (in the DRG in health establishments).

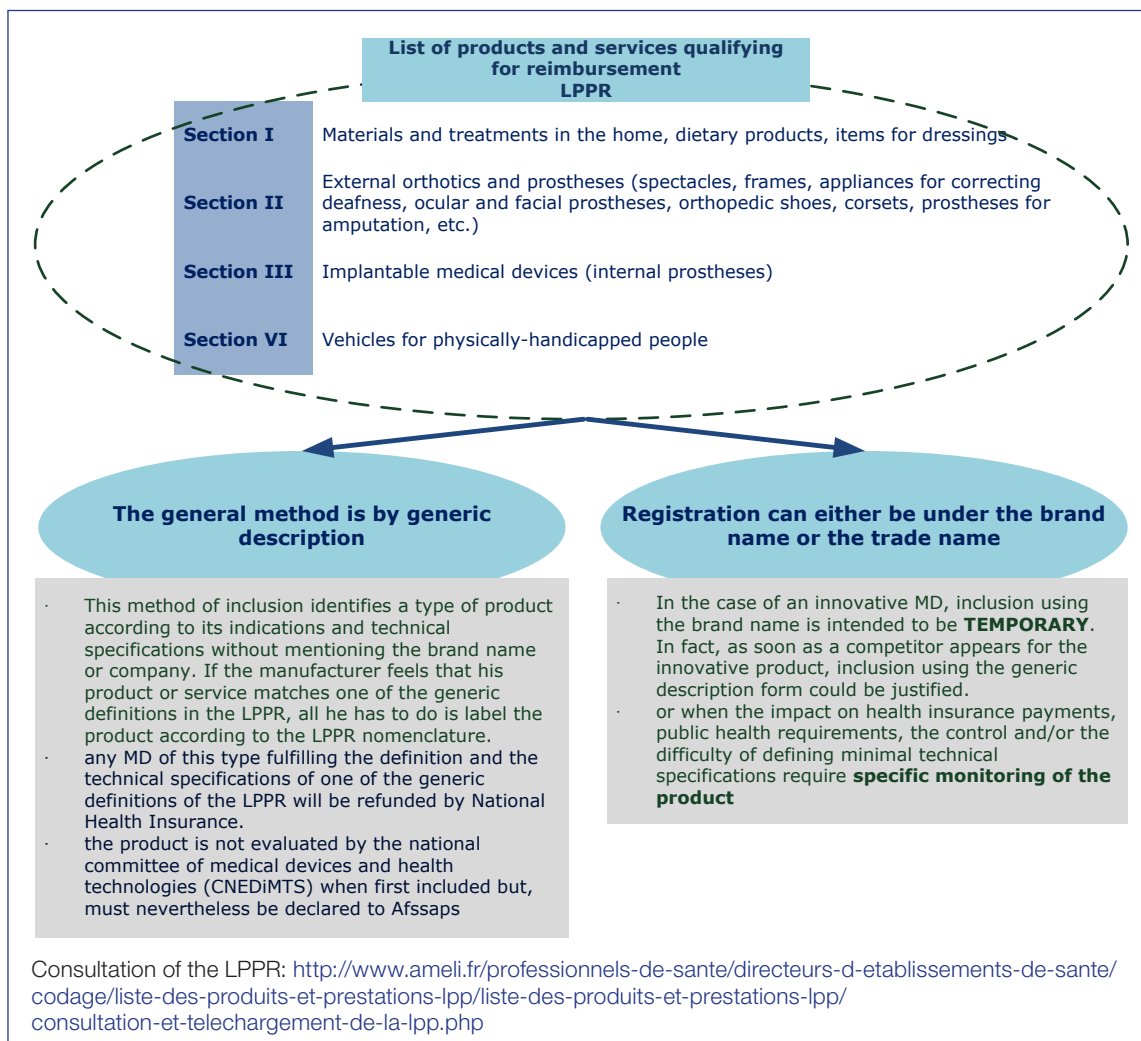
The committee on medicinal products and sterile medical devices (COMEDIMS) participates as an advisor in the drafting in particular of a list of sterile MDs, whose use is advocated within the health establishment.MDs.

Some MDs that are likely to introduce a heterogeneity in hospitalization costs because prescription of them within the same DRG varies, can be invoiced in addition to the hospital services tariff. Therefore these devices are included on an “**additional list**”

14.6.2 MD listed LPPR

CNEDI^{MTS} advice

The LPPR is characterized by the complementarity between the MD and the act of health.



14.6.3 Innovative MD

COMDIMS advice +/- HAS evaluation

MDs that are not integrated in the DRG in health establishments, and which could be considered to be **innovative MDs**, could be refunded **exceptionally and temporarily**.

Application of this mechanism remains exceptional.

14.6.4 MD supported under the medical act

CEAP advice

The assessment of medical procedures directed by CEAP enables one to give a guidance on the opportunity for including these in the refund procedure of National Health Insurance and on the conditions of this inclusion and possible removal from inclusion:

- NGAP, general nomenclature of medical procedures – Nomenclature générale des actes professionnels
- CCAM, joint classification of medical procedures – Classification Communes des Actes Médicaux
- NABM, nomenclature of procedures in laboratory medicine – Nomenclature des Actes de

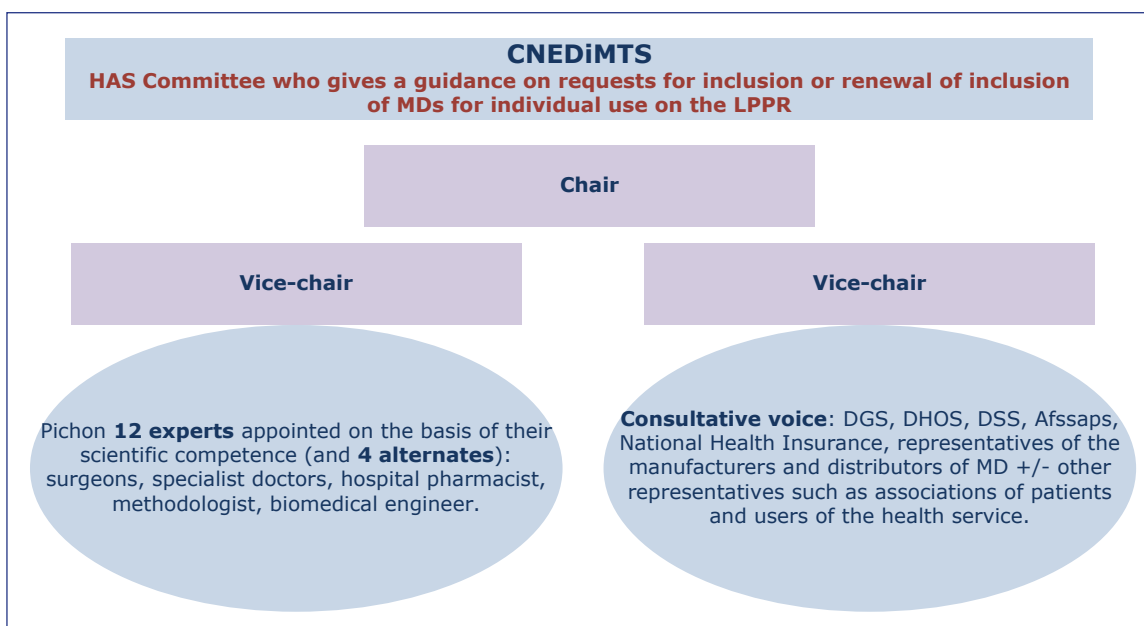
The purpose of **Committees of hierarchical structures of procedures and services (CHAP)** is to define the regulations for the hierarchical structures of procedures and services refunded or reimbursed by National Health Insurance and to validate the resulting hierarchical structure.

14.7 CNEDiMTS medical technical evaluation

14.7.1 CNEDiMTS composition

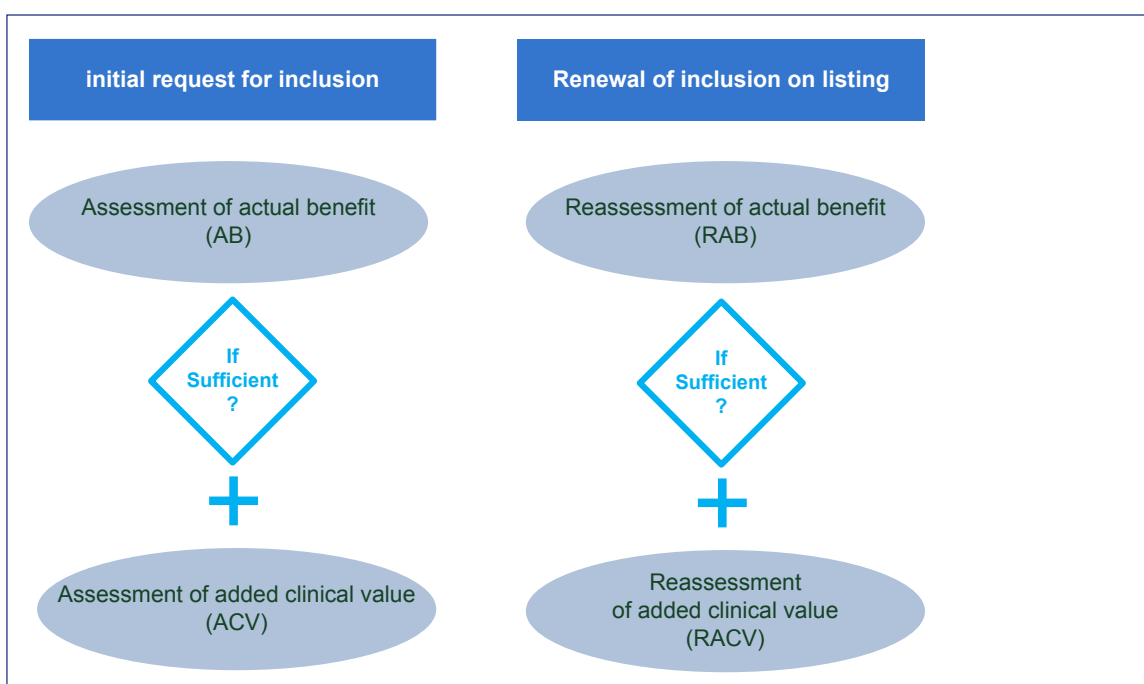
National committee for the evaluation of medical devices and health technologies

The Commission is composed of two poles: experts and consultative voice. They evaluate the MD with

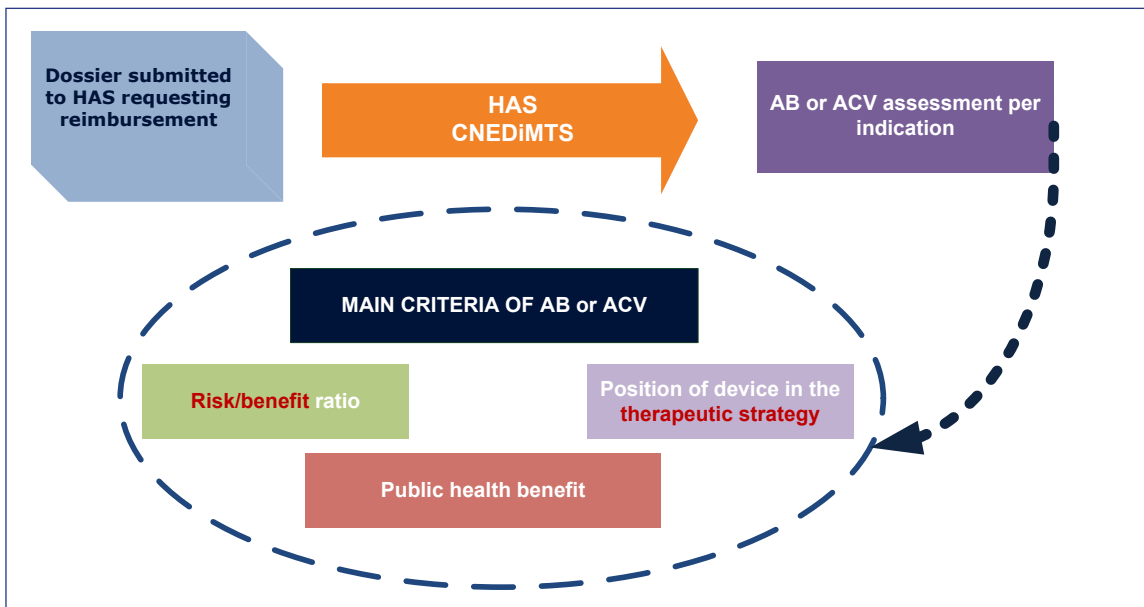


regards to its origin and its destination. For more information, see chapter 14.5

14.7.2 Evaluation stages



14.7.3 Actual benefit

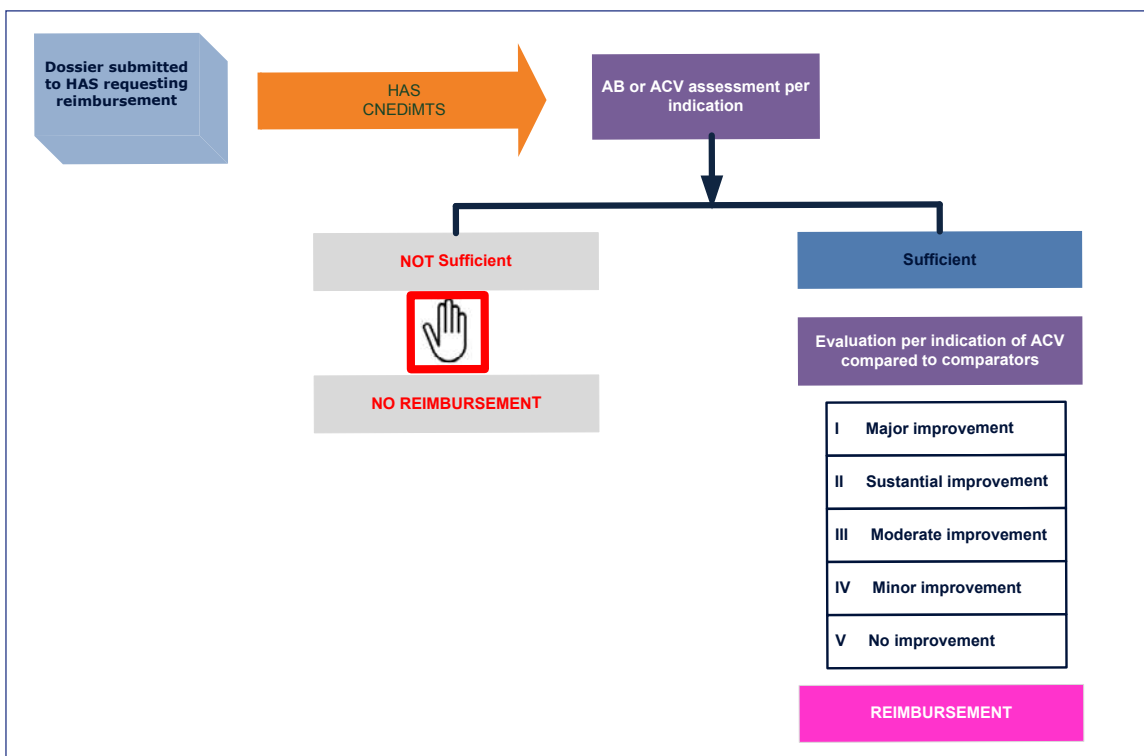


“The products and services for which the actual benefit is insufficient to justify inclusion for reimbursement do not appear on the list” Article R. 165-2 of the Social Security Code.

“Inclusion can only be renewed, according to CNEDiMTS, if the product or service provides sufficient actual benefit to justify continuing to reimburse it” Article R. 165-11-1 of the Social Security Code.

14.7.4 Added clinical value

- The relevant comparator is derived from the reference strategy, or the strategy used in routine practice in the absence of scientific evidence, or absence of treatment if the need for treatment is unfulfilled. It may correspond to another medical device, whether or not included on the LPPR, medicinal product, service or procedure whether or not accepted for reimbursement.
- These criteria are clinical criteria (mortality, morbidity, compensation for a disability, reduction in undesirable effects), relating to quality of life, convenience of use with clinical benefit to the patients.
- ACV is demonstrated with the aid of randomised, controlled clinical trials using a primary validated judgement criterion; except in situations where such data cannot be obtained and this is supported by sound bibliographic references.



14.8 Pricing – CEPS procedure

Setting tariffs and establishing prices within the framework of a procedure by the CEPS (Healthcare Products Pricing Committee).

Determination of the MD tariffs mainly takes into account:

- AB, and ACV
- When appropriate additional studies requested
- Tariffs and prices of comparable procedures
- Products and services included on the list
- The volume of anticipated sales
- Predicted and real conditions of use.

14.9 Possible penalties

The fact that the manufacturer of a device users and third parties having knowledge of an incident or potential incident involving a medical device causing or likely to cause death or serious deterioration in the health of a patient, a user or a third party, to refrain from immediately notify the administrative authority shall be punished by imprisonment for 4 years and a fine of 75,000 € (see L.5461-2 of the Code of Public Health, Law No. 94-43 of January 18, 1994).

Source: AFSSAPS

In Europe, Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health

<http://www.conventions.coe.int/Treaty/FR/Reports/Html/211.htm>

14.10 Europe medical technical evaluation

On a European level, as on an international level, **the evaluation of medical technologies (ETM)** or **Health Technology Assessment (HTA)** was designed to evaluate the wider repercussions of medical technologies, their benefits and their costs. HTA exists in the main European countries.

Assessment of medical technologies is based on the collection and analysis of scientific data with an assessment of the significance of the results which subsequently serve as a basis for the decision process.

The main institutions in Europe practising HTA are HAS in France, IQWiG (institute for quality and efficiency in healthcare) in Germany, KCE (healthcare knowledge centre) in Belgium and NICE (national institute for health and clinical excellence) in the United Kingdom.

HAS can refer to assessments made by other HTA institutions in Europe.

14.11 Insurance systems in Europe

The Bismarck model

This system is also called “professional” because it is funded by labor and social security contributions. It was introduced in Germany in the late nineteenth century, under the influence of Bismarck.

The German example has served as an inspiration to Austria, Belgium, France, Luxembourg and the Netherlands.

Since the 70s, the majority of countries that were inspired by this model have introduced measures to make access to a broader universal care.

The Beveridge model

This system is also called “national”, because the supervision of health services and funding are provided by the same organization, which depends on the state.

This model was developed in Britain after the Second World War under the aegis of Lord Beveridge. Denmark, Finland, Ireland and Sweden have adopted the foundations of this model.

Inspired by social-democratic model is based on universal access to care and the taxation of health spending.

The two great historic families (Beveridge and Bismarck) coexist in Europe:

- Universal social security (tax-financed) in the United Kingdom, Ireland, Finland, Sweden, Denmark, Italy, Portugal, and Spain.
- The compulsory social insurance (business systems related to work, financed by contributions): France, Luxembourg, Germany, and Austria.

The health system in some countries, like Belgium or the Netherlands, is a mixed system based on both previous systems. Outside of Europe, Canada has a Beveridge-inspired decentralized system (unlike the UK). Japan has a mandatory and universal health insurance, but with a system of professional affiliation based on the German model.

The Bismarckian systems, which are based on the work and who are generally older, are moving strongly today. Measures “Beveridge” are more limited aspect of the corporatist and inequitable access to care.

Since the introduction of Couverture Maladie Universelle (CMU), universal health coverage, the French system guarantees everyone access to care. Therefore, it is no longer the employer that determines access to care, as is the case in theory Bismarckian systems.

Source: Institut Polanyi France

15 Patent protection

15.1 In France

The INPI is a public, fully funded, under the Ministry of Economy, Finance and Industry. It grants patents, trademarks, designs and provides access to all information on industrial property and businesses. He is active in the development and implementation of public policies in the field of industrial property and combating counterfeiting.

INPI has 745 employees who are divided between the Paris region (Paris, Nanterre and Compiègne) and 23 regional offices.

In 2010, operating revenues were 195.8 million Euros against 172.35 million Euros in 2009.

2010 Key Figures

- 16,580 patents, 91,928 trademarks, 80,352 designs were submitted by the national route
- 353,451 registered in the Registre national du commerce et des sociétés (RNCS)
- 95,992 registered in the business directory

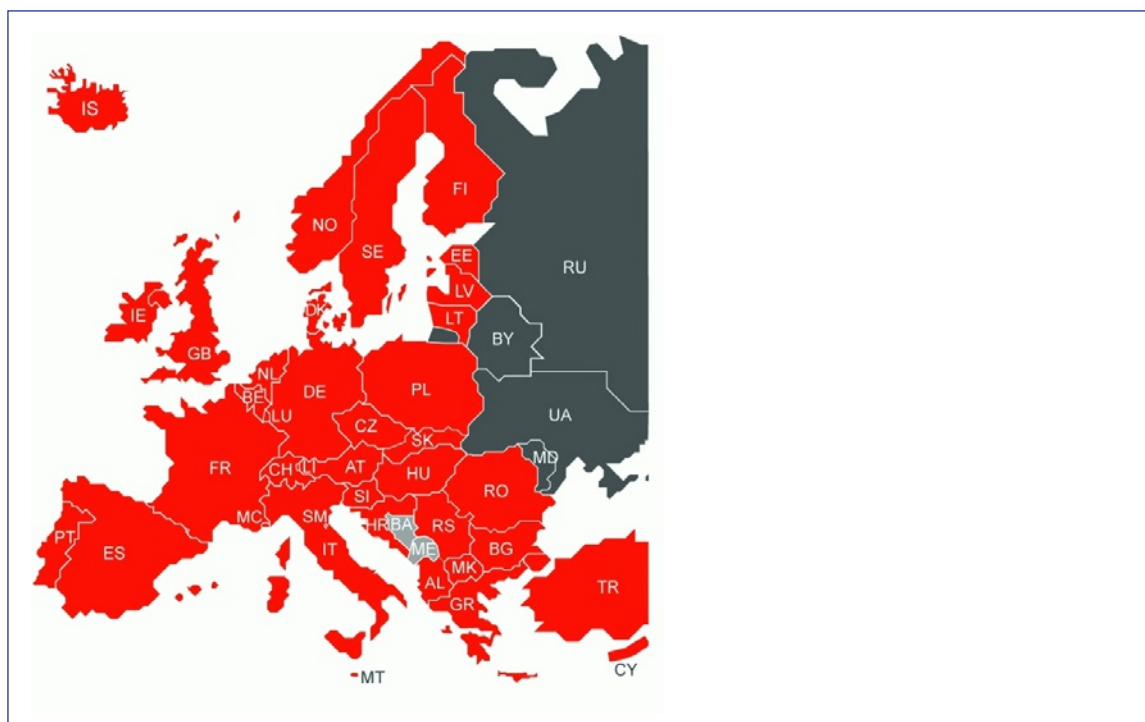
By filing your patent with the INPI, you get a monopoly operating on French territory for a maximum of 20 years. You are the only one to be able to use and you can prevent exploitation (use, manufacture, import ...) of your invention made without your permission. You can take infringers to court.

15.2 In Europe

The European Patent Office (EPO) offers inventors a uniform application procedure which enables them to seek patent protection in up to 40 European countries. Supervised by the Administrative Council, the Office is the executive arm of the European Patent Organisation.

The European Patent Organisation is an intergovernmental organisation that was set up on 7 October 1977 on the basis of the European Patent Convention (EPC) signed in Munich in 1973. It has two bodies, the European Patent Office and the Administrative Council, which supervises the Office's activities.

The following states are currently members of the European Patent Organisation:



16 Healthcare providers

16.1 Public hospitals

16.1.1 Ranking by number of beds

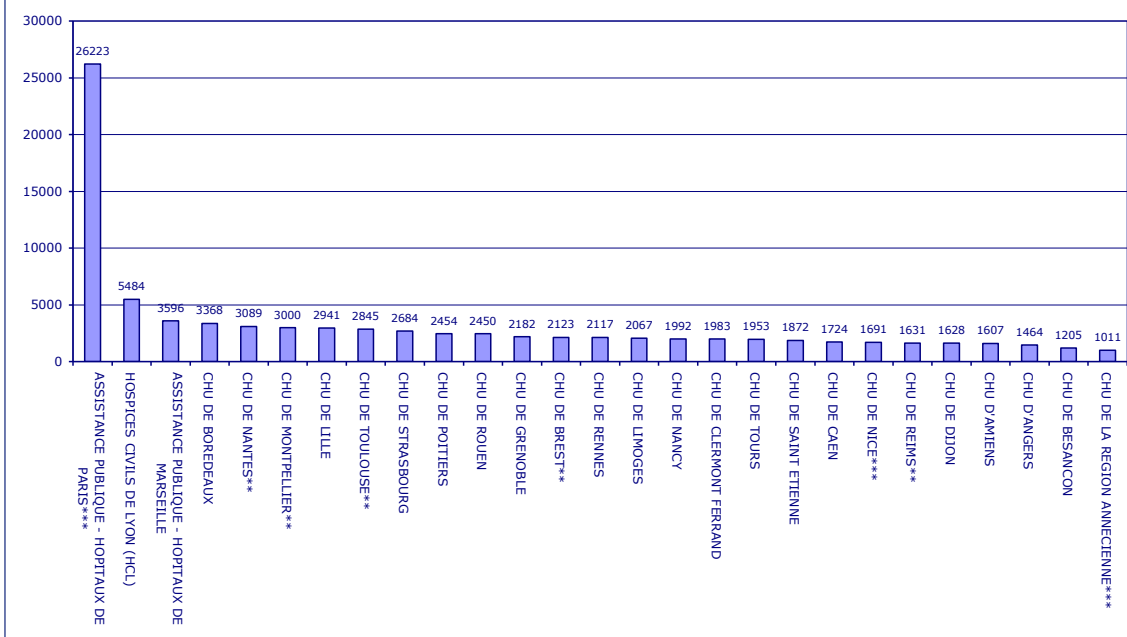
TOP 5 PUBLIC HOSPITALS RANKING BY NUMBER OF BEDS AND PLACES IN 2010

NAME	NUMBER OF BEDS, PLACES**
ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS*	24,155
HOSPICES CIVILS DE LYON (HCL)	5,583
ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	3,500
CHU DE BORDEAUX	3,268
CHU DE NANTES	3,049

*2008 **PLACE = Hospitalization <24 Hours

Source: HALTYS

PUBLIC HOSPITALS RANKING BY NUMBER OF BEDS AND PLACES IN 2003



N°	NAME	NUMBER OF BEDS, PLACES****
1	ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS***	26,223
2	HOSPICES CIVILS DE LYON (HCL)	5,484
3	ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	3,596
4	CHU DE BORDEAUX	3,368
5	CHU DE NANTES**	3,089
6	CHU DE MONTPELLIER**	3,000
7	CHU DE LILLE	2,941
8	CHU DE TOULOUSE**	2,845
9	CHU DE STRASBOURG	2,684
10	CHU DE POITIERS	2,454
11	CHU DE ROUEN	2,450
12	CHU DE GRENOBLE	2,182
13	CHU DE BREST**	2,123
14	CHU DE RENNES	2,117
15	CHU DE LIMOGES	2,067
16	CHU DE NANCY	1,992
17	CHU DE CLERMONT-FERRAND	1,983
18	CHU DE TOURS	1,953
19	CHU DE SAINT-ETIENNE	1,872
20	CHU DE CAEN	1,724
21	CHU DE NICE***	1,691
22	CHU DE REIMS**	1,631
23	CHU DE DIJON	1,628
24	CHU D'AMIENS	1,607
25	CHU D'ANGERS	1,464
26	CHU DE BESANÇON	1,205
27	CHU DE LA REGION ANNECIENNE***	1,011

2002 *2001 ****PLACE = Hospitalization < 24 Hours

Source: MSI

We find that the top 5 hospitals has kept the same ranking between 2003 and 2010, the number of beds and places has not changed much except for the AP-HP (reduction of 2068 beds and places between 2003 and 2008)

→ **AP-HP has 30% of the number of beds and places in France.**

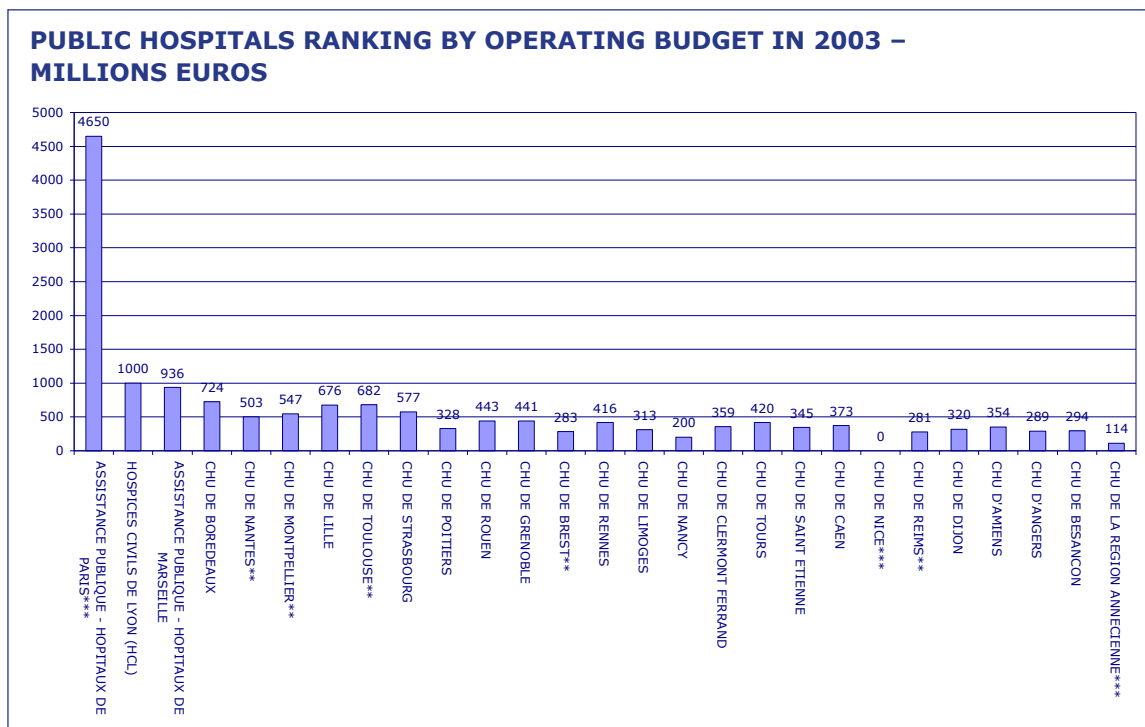
16.1.2 Ranking by operating budget

TOP 5 PUBLIC HOSPITALS RANKING BY OPERATING BUDGET IN 2010 – MILLIONS EUROS

NAME	OPERATING BUDGET
ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS*	6,352
HOSPICES CIVILS DE LYON (HCL)	1,514
ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	1,100
CHU DE BORDEAUX	941
CHU DE NANTES	732

*2008

Source: HALTYS



N°	NAME	OPERATING BUDGET
1	ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS***	4,650
2	HOSPICES CIVILS DE LYON (HCL)	1,000
3	ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	936
4	CHU DE BORDEAUX	724
5	CHU DE NANTES**	503
6	CHU DE MONTPELLIER**	547
7	CHU DE LILLE	676
8	CHU DE TOULOUSE**	682
9	CHU DE STRASBOURG	577
10	CHU DE POITIERS	328
11	CHU DE ROUEN	443
12	CHU DE GRENOBLE	441
13	CHU DE BREST**	283
14	CHU DE RENNES	416
15	CHU DE LIMOGES	313
16	CHU DE NANCY	200
17	CHU DE CLERMONT-FERRAND	359
18	CHU DE TOURS	420

19	CHU DE SAINT-ETIENNE	345
20	CHU DE CAEN	373
21	CHU DE NICE***	ND
22	CHU DE REIMS**	281
23	CHU DE DIJON	320
24	CHU D'AMIENS	354
25	CHU D'ANGERS	289
26	CHU DE BESANÇON	294
27	CHU DE LA REGION ANNECIENNE***	114

***2001 **2002

Source: MSI

→ AP-HP has 29% of hospital budgets in France.

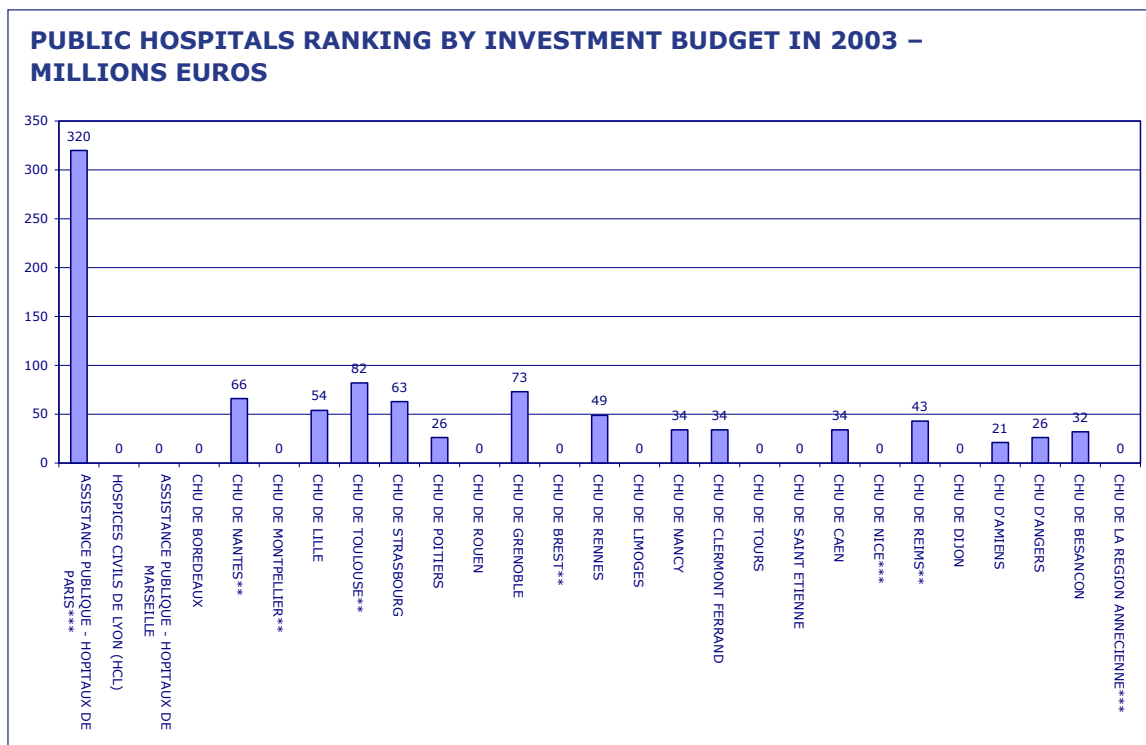
16.1.3 Ranking by investment budget

TOP 5 PUBLIC HOSPITALS RANKING BY INVESTMENT BUDGET IN 2010 – MILLIONS EUROS

NAME	INVESTMENT BUDGET
ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS*	551
HOSPICES CIVILS DE LYON (HCL)	ND
ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	ND
CHU DE BORDEAUX	ND
CHU DE NANTES	50

*2008

Source: HALTYS



N°	NAME	INVESTMENT BUDGET
1	ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS***	320
2	HOSPICES CIVILS DE LYON (HCL)	ND
3	ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	ND
4	CHU DE BORDEAUX	ND
5	CHU DE NANTES**	66
6	CHU DE MONTPELLIER**	ND
7	CHU DE LILLE	54
8	CHU DE TOULOUSE**	82
9	CHU DE STRASBOURG	63
10	CHU DE POITIERS	26
11	CHU DE ROUEN	ND
12	CHU DE GRENOBLE	73
13	CHU DE BREST**	ND
14	CHU DE RENNES	49
15	CHU DE LIMOGES	ND
16	CHU DE NANCY	34
17	CHU DE CLERMONT-FERRAND	34
18	CHU DE TOURS	ND
19	CHU DE SAINT-ETIENNE	ND
20	CHU DE CAEN	34
21	CHU DE NICE***	ND
22	CHU DE REIMS**	43
23	CHU DE DIJON	ND
24	CHU D'AMIENS	21
25	CHU D'ANGERS	26
26	CHU DE BESANÇON	32
27	CHU DE LA REGION ANNECIENNE***	ND

***2001 **2002

Source: MSI

16.1.4 Ranking by number of staff

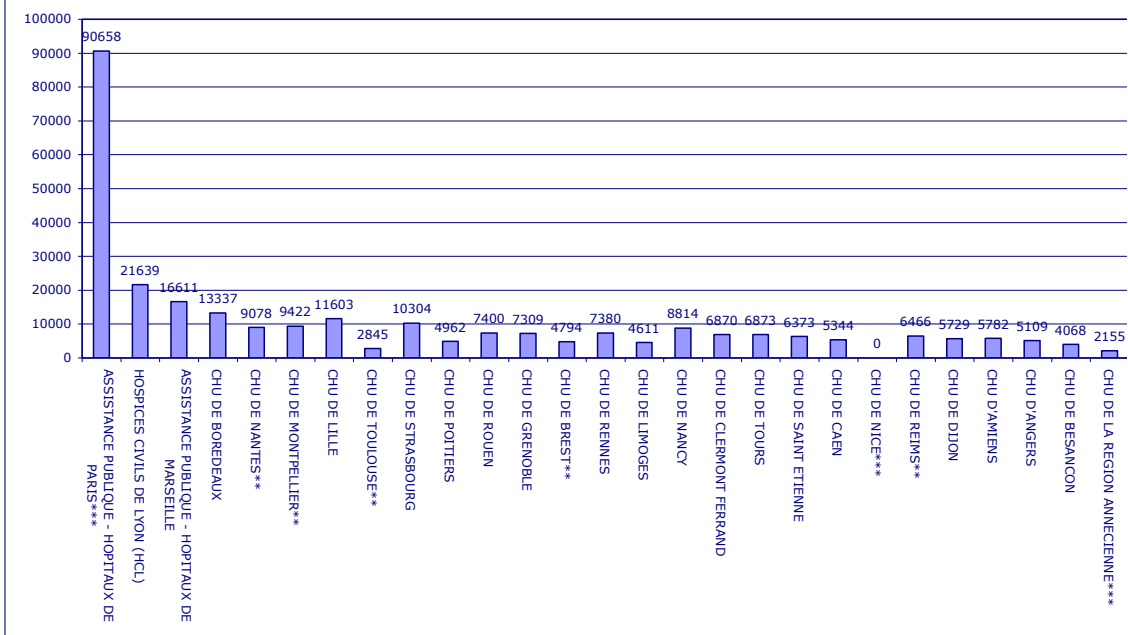
TOP 5 PUBLIC HOSPITALS RANKING BY NUMBER OF STAF IN 2010

TITRE	NUMBER OF STAFF
ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS*	84,257
HOSPICES CIVILS DE LYON (HCL)	21,724
ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	12,000
CHU DE BORDEAUX	13,493
CHU DE NANTES	10,577

*2008

Source: HALTYS

PUBLIC HOSPITALS RANKING BY NUMBER OF STAF IN 2003



N°	NAME	NUMBER OF STAFF
1	ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS***	90,658
2	HOSPICES CIVILS DE LYON (HCL)	21,639
3	ASSISTANCE PUBLIQUE – HOPITAUX DE MARSEILLE	16,611
4	CHU DE BORDEAUX	13,337
5	CHU DE NANTES**	9,078
6	CHU DE MONTPELLIER**	9,422
7	CHU DE LILLE	11,603
8	CHU DE TOULOUSE**	2,845
9	CHU DE STRASBOURG	10,304
10	CHU DE POITIERS	4,962
11	CHU DE ROUEN	7,400
12	CHU DE GRENOBLE	7,309
13	CHU DE BREST**	4,794
14	CHU DE RENNES	7,380
15	CHU DE LIMOGES	4,611
16	CHU DE NANCY	8,814
17	CHU DE CLERMONT-FERRAND	6,870
18	CHU DE TOURS	6,873
19	CHU DE SAINT-ETIENNE	6,373
20	CHU DE CAEN	5,344
21	CHU DE NICE***	ND
22	CHU DE REIMS**	6,466
23	CHU DE DIJON	5,729
24	CHU D’AMIENS	5,782
25	CHU D’ANGERS	5,109
26	CHU DE BESANÇON	4,068
27	CHU DE LA REGION ANNECIENNE***	2,155

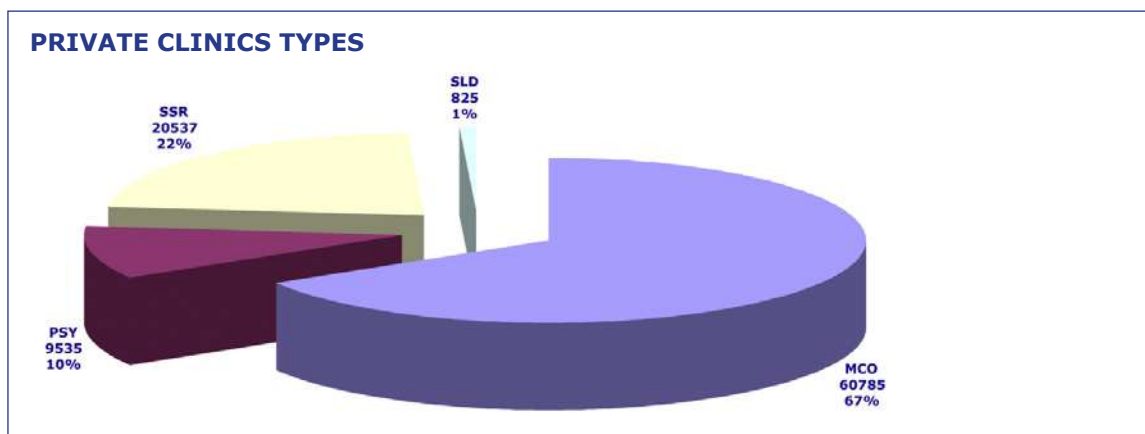
***2001 **2002

Source: MSI

→ **AP-HP has 32% of hospitals staff in France.**

16.2 Private clinics

16.2.1 Type of establishment (number of beds)

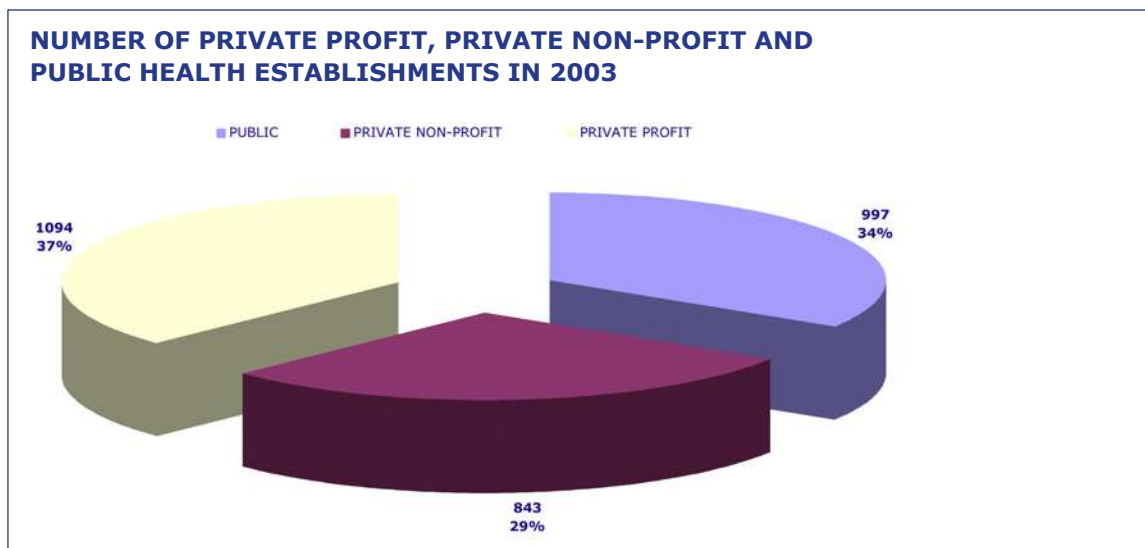


MAJOR CATEGORIES PRIVATE CLINICS IN France

	NUMBER OF BEDS AND PLACES	%
MCO: Medicine, Surgery, Obstetrics	60,785	66.30%
PSY: mental health, psychiatry, addictions	9,535	10.40%
SSR: follow-up care, rehabilitation	20,537	22.40%
SLD: long-term care	8,25	0.90%
TOTAL	91,682	100.00%

Source: DREES, SAE 2003, données au 31 Décembre (France Métropolitaine)

16.2.2 Number of establishment evolution

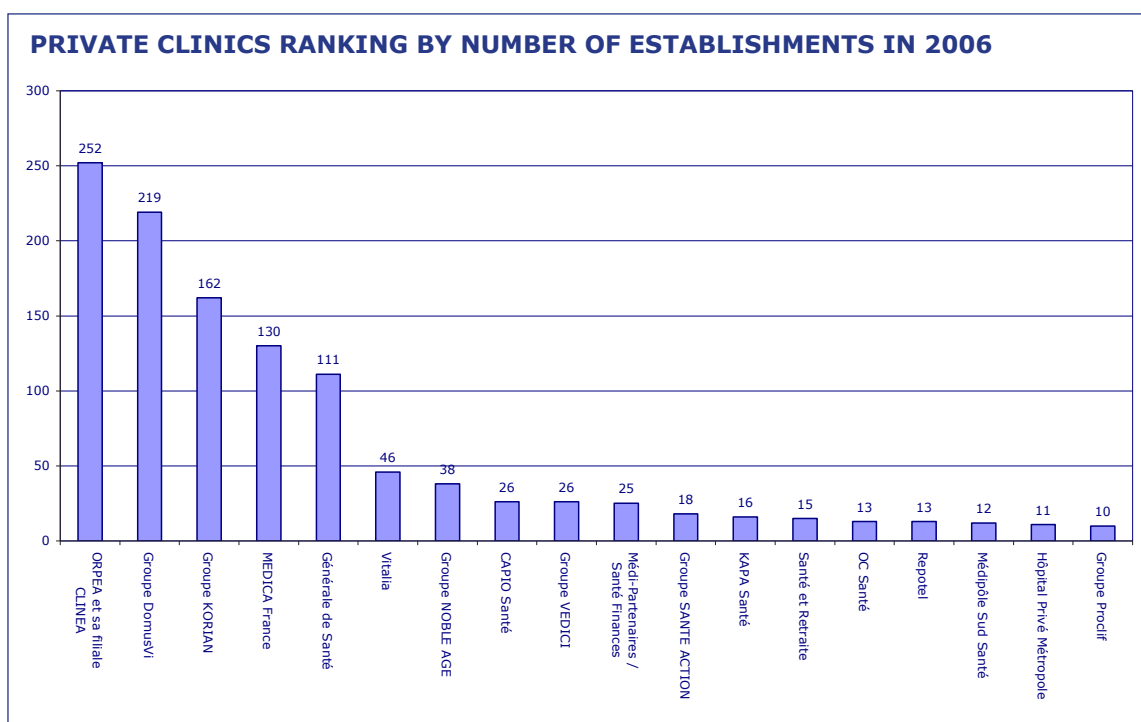


EVOLUTION OF PRIVATE PROFIT, PRIVATE NON-PROFIT AND PUBLIC HEALTH ESTABLISHMENTS BETWEEN 1992 AND 2003

	1992	2003
PUBLIC	1,057	997
PRIVATE NON-PROFIT	912	843
PRIVATE PROFIT	1,426	1,094

Source: DREES, SAE 1992-2003, données au 31 Décembre (France Métropolitaine)

16.2.3 Groups ranking



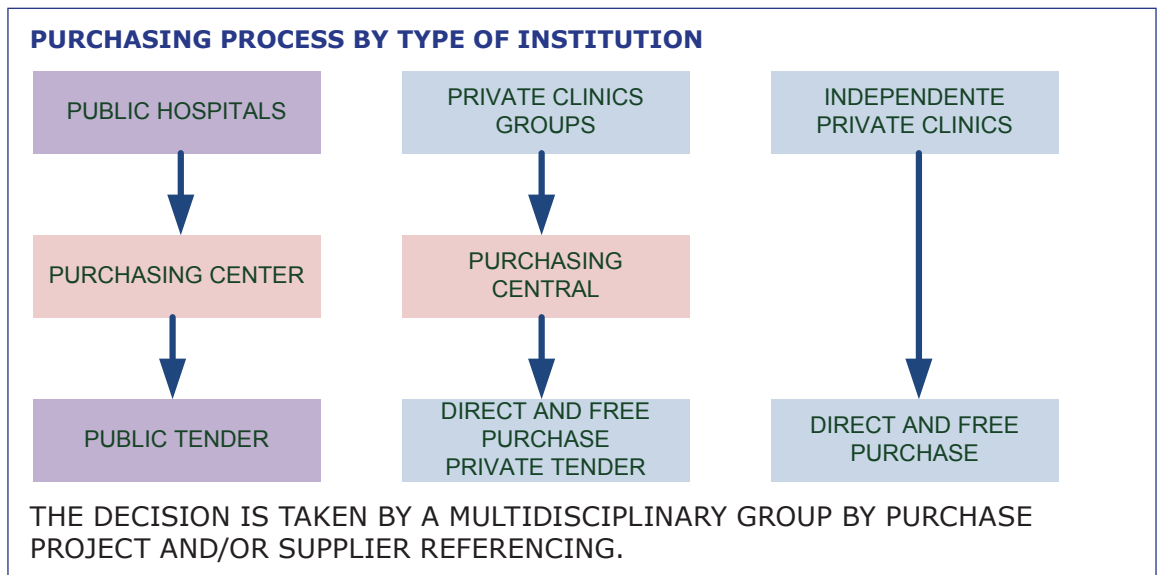
→ Not considered the redemption between the groups after 2006

NAME	NUMBER OF ESTABLISHMENTS
ORPEA et sa filiale CLINEA	252
Groupe DomusVi	219
Groupe KORIAN	162
MEDICA France	130
Générale de Santé	111
Vitalia	46
Groupe NOBLE AGE	38
CAPIO Santé	26
Groupe VEDICI	26
Médi-Partenaires / Santé Finances	25
Groupe SANTE ACTION	18
KAPA Santé	16
Santé et Retraite	15
OC Santé	13
Repotel	13
Médipôle Sud Santé	12
Hôpital Privé Métropole	11
Groupe Proclif	10

16.3 Health and Care services establishments

18,870	Public Health and Care establishments
28,458	Hospital Care services par specialties
7,294	Administrative services
10,431	Private or Organized cares establishment
11,230	Hospital Care services par specialties
6,428	Administrative services
18,856	Public or Private Health establishments (research, worklabour medicine, laboratories...)
904	Health administration establishments
2,784	Vetenary clinics
11,707	Optician shops

17 Decision makers, Purchases and Purchasing process



The role of most of health actors is limited by law.

The role of the doctor/surgeon is to provide health acts in hospitals, clinical and Liberal cabinets, he can participate in the process of accreditation of health facilities, purchasing and defining the role of MD in therapeutic strategy...

The administration is responsible for financial, administrative and human management; It must meet the budgets and achieve the goals set in the CPOM.

The purchasing department ensures the accreditation of suppliers and their periodic evaluations; the pricing is already fixed by law in the CEPS procedure.

18 Competitiveness Clusters

18.1 What is a Competitiveness Cluster?

A joint theme-based initiative for a given geographic area.

A competitiveness clusters is an initiative that brings together companies, research centers and educational institutions in order to develop synergies and cooperative efforts.

Other cluster partners may include local and national authorities and services catering to cluster members.

A chance to become a leader

Clusters use synergies and innovative joint projects to give their member companies a chance to be national and international leaders in their fields.

18.2 Strategy

Each competitiveness cluster draws up a five-year plan, based on a vision shared by the various stakeholders. With the plan, the cluster can:

- Develop partnerships between the various stakeholders, based on their complementary skills
- Construct shared strategic R&D projects that can benefit from public funding, particularly the Interministerial Fund (FUI)
- Promote an overall environment favourable to innovation and the cluster's stakeholders via presentations, knowledge-sharing and mutual support among cluster members on topics such as training and human resources, intellectual property, private-sector financing, international development

18.3 Goals

To strengthen the competitiveness of the French economy and develop both growth and jobs in key markets:

- Through increased innovation
- By encouraging high-value-added technological and creative
- Activities, principally industrial, at a regional level
- By attracting business to France thanks to a higher international profile

18.4 Public Support for Clusters

The French Government is particularly interested in promoting an overall environment favourable to enterprise and innovation, and in supporting R&D efforts within competitiveness clusters. It accompanies cluster development at both local and national levels in the following ways:

- By allocating, through the Single Interministerial Fund, financial support for the best R&D and innovation platform initiatives via calls for projects Partial financing for cluster governance structures, alongside local authorities and companies Financial support for theme-based collective actions initiated by clusters in a wide range of areas, via the various Regional Directorates for Industry, Research and the Environment.
- By involving various partners, such as the Caisse des Dépôts, or the French National Research Agency (ANR) and OSEO both of which finance R&D projects led by cluster stakeholders.
- By bringing new means from public research centres Finally, by seeking assistance from local authorities, who can also provide financial support for cluster projects (R&D, innovation platforms).

18.5 Few figures

18.5.1 Who are the clusters?

71 competitiveness clusters have been labelled
5,000 companies were cluster members in 2007
80% of these were SMEs

18.5.2 What sort of aid do clusters receive?

- 554 R&D projects have received public funding since 2005
- € 1,1 billion has been spent on R&D projects since 2005, including 729 million from the Government
- R&D projects represent a total of € 3.6 billion
- 12,000 researchers take part in funded R&D projects
- 54% of funding goes to cluster SMEs, within the framework of the Interministerial Fund and Oséo (not including support for laboratories)
- 1,343 R&D projects received agency support (ANR and Oséo) in 2006 and 2007
- € 4 million in funding came from the DGE in 2006 and 2007 to support international development

18.5.3 Focus on the BIOTECHNOLOGY AND HEALTH Clusters

→ **Non-invasive surgery: new tools and high-tech training**

The Anubis project is developing a surgical model in which organ surgery is carried out via the body's natural pathways. The patient is left without a visible scar, and both pain and post-operative complications are reduced. The project aims to create new surgical tools as well as the training needed to learn this new operating technique. It has been approved by the Therapeutic Innovations competitiveness cluster.

→ **A new system for intradermal injection (Lyonbiopôle cluster)**

MicroVax is a new vaccination system. The project aims to develop and market a micro-injection vaccination system capable of delivering micro-quantities of vaccine, while maintaining or improving the vaccination's efficiency.

Ministry of Economy, Finance and Industry – Ministère de l'économie, des finances et de l'Industrie

Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF)
Sous-direction E – Bureau E 1
59, boulevard Vincent Auriol
Télédoc 241
75703 PARIS Cedex 13
Tél. +33 (0) 1 44 97 23 61 – Fax +33 (0) 1 55 87 23 30
<http://www.economie.gouv.fr/>

The national association of the medical technology industry in France – Syndicat National de l'Industrie des Technologies Médicales

39–41, rue Louis Blanc
92038 PARIS-LA-DEFENCE – Cedex 72
Tél. +33 (0) 1 47 17 63 88 – Fax +33 (0) 1 47 17 63 89
<http://www.snitem.fr/>

AFNOR French Association for Standardization – Association Française de Normalisation

11, Avenue Francis de Pressensé
93571 SAINT-DENIS LA PLAINE Cedex
Tél. +33 (0) 1 41 62 88 27 – Fax +33 (0) 1 40 93 89 24
<http://www.afnor.org/>

19.2 Medical companies and Industry Associations

SNITEM – The national association of the medical technology industry in France – Syndicat National de l'Industrie des Technologies Médicales

SNITEM is the most important trade association; it represents more than 230 member companies from France's medical technologies sector.

SNITEM SCOPE:

ACTIVE IMPLANTABLE MEDICAL DEVICE

- Cardiology
- Orthopedics
- Ophthalmology
- Other internal prosthesis

MEDICAL DEVICE

- Audiology
- Orthotics

OPERATING ROOM MATERIALS, MEDICAL AND SURGICAL INSTRUMENTS

- Endoscopy
- Scalpels and ultrasound machines

CONSUMABLES

IMAGING

DIALYSIS

ANAESTHESIA, RESUSCITATION

ORTHOPEDIC REHABILITATION AND REPLACEMENT

INFORMATION TECHNOLOGY AND COMMUNICATIONS EQUIPMENT

MISCELLANEOUS

French Society of Cardiology – Société Française de Cardiologie

<http://www.sfcardio.fr>

French Societies of Orthopedics – Société Française d'orthopédie

French Society of Orthopaedic Surgery and Traumatology –
Société Française de Chirurgie Orthopédique et Traumatologique

<http://www.sofcot.fr>

French Society of Dento-Facial Orthopaedics – La Société Française d'Orthopédie Dento-Faciale

<http://sfodf.org>

French Society of Pediatric Orthopaedics – La Société Française d'Orthopédie pédiatrique

<http://www.sofop.org/>

**COMMIDENT – The Union of Industries of the Dental World –
L'Union des Industries du Monde Dentaire**
<http://www.comident.asso.fr/>

**Group of industrialists and manufacturers of optical –
Groupement des industriels et fabricants d'optique**
<http://www.gifo.org/>

**Industry Union of Medical Care Devices –
Syndicat de l'industrie de l'industrie des Dispositifs des Soins Médicaux**
<http://www.appamed.org/>

**Union of manufacturers and suppliers of contact lenses –
syndicat des fabricants et des fournisseurs des lentilles de contacts**
<http://www.syffoc.org/Accueil/>

Industry union of in vitro diagnostics – syndicat de l'industrie du diagnostic in vitro
<http://www.sfrl.fr>

French Society for Optical
<http://www.sfoptique.org/>

French Society of Radiology
<http://www.sfrnet.org/>

19.3 MD French exhibitions

MEDTEC France

Date: 4-APR-2012 to 5-APR-2012

Eurexpo, Lyon, France

MEDTEC France will put you in touch with thousands of French and French speaking medical device manufacturers that do not attend any other medical device technology exhibition in Europe. In 2007, 2,500 French medical manufacturers employing 40,000 people designed and produced € 11 billion in medical products. Spurred by the increasing healthcare demands of an aging population, the French medical device market continues to expand at nearly 7% every year.

ESC CONGRESS OF CARDIOLOGY 2011 – EUROPEAN SOCIETY OF CARDIOLOGY

Date: 27-AUG-2011 to 31-AUG-2011 in Paris – France

The European Society of Cardiology (ESC) represents more than 70,000 cardiology professionals across Europe and the Mediterranean.

The ESC comprises: 5 Associations, 5 Councils, 19 Working Groups, 54 National Cardiac Societies and The distinguished community of ESC Fellows and Nurse Fellows

BIOMEDevice Europe

Date: 15-FEB-12 to 16-FEB-12

BIOMEDevice Europe is the first European event to focus on the development of the next generation of combination products. As drug delivery systems continue to evolve and the medical device, bio pharmaceutical and pharmaceutical industries converge, BIOMEDevice is dedicated to key executives, engineers and researchers looking for new partnering opportunities and enabling technologies.

Venue: Grande Halle de La Villette, Paris, Ile-de-France, France

Foire De Nice

Date: 14-APR-12 to 22-APR-12

Organized by Nicexpo, Foire De Nice is acknowledged as leading trade fair for health and wellness sector, the fair encompasses of worldwide opportunities for sourcing and manufacturing in Medical & Pharmaceutical industry. Held at Nice Palais des Expositions, France, the fair becomes hub of major exhibitors from different parts of the world.

Venue: Nice Palais des Expositions, Nice, Alpes-Maritimes, France

EuroMedtech

Date: 31-MAY-12 to 01-JUN-12

EuroMedtech will be one of the most famous events related to medical technology industry. The event is designed as a fabulous consumer fair and which offers its exhibitors best selling opportunity and its visitor's best purchasing activity.

EuroMedtech will conduct with many sessions and companies presentation which will catch the attention of the participants. Professionals will be participating in the event from various countries like Sweden; Italy; Switzerland; Denmark; Italy; Germany; United Kingdom and many more. The event will be combined with conference; the conference will have discussion about various topics like The Emergence of a Health Outcomes Ecosystem the Commercialization of Telehealthcare Technologies and many more.
Venue: World Trade Center-Grenoble, Grenoble, Rhône-Alpes, France

AUTONOMIC PARIS

Date: 13-JUN-12 to 15-JUN-12

AUTONOMIC PARIS is the major meeting-point where all those involved in the disability and dependence sector converge to offer a better autonomy at home and in institutions.

Venue: Paris Expo Porte de Versailles, Paris, Ile-de-France, France

Cardiostim

Date: 13-JUN-12 to 16-JUN-12

Cardiostim offers the attendees the best possibilities to learn more about the latest developments and products in the field of cardiac pacing and electrophysiology.

Venue: Nice Acropolis, Nice, Alpes-Maritimes, France

CIAMED

Date: 23-OCT-12 to 24-OCT-12

CIAMED is the exhibition for Medical Hardware & Equipment Industry in France. This is one of the leading trade fair in France which will be held between 23-24 Oct 2012 at Espace Lyon. The event is being organized by Abe-advanced business events. This is the 4th Edition of the event.

Venue: Lyon Espace, Lyon, Rhône-Alpes, France

OTHER MEDICAL CONGRES

Microscopic and Endoscopic Approaches to the Skull Base
25-JAN-2012 in Strasbourg – France

IMCAS Annual Meeting 2012
26-JAN-2012 in Paris – France

23rd International Congress on Anti-Cancer Treatment
31-JAN-2012 in Paris – France

2nd International Congress of Breast Disease Centers
09-FEB-2012 in Paris – France

CONGRES INTERNATIONAL PATHOLOGIES MENINGEES ET SACREES
02 MAY 2012 in Vichy – France

Microscopic and Endoscopic Approaches to the Skull Base
20-JUN-2012 in Strasbourg – France

6^{ème} Congrès de la Médecine Générale France
21-JUN-2012 in Nice – France

18^{ème} Congrès de la SFAP
28-JUN-2012 in Strasbourg – France

Améliorer l'efficacité des traitements contre le cancer
08-NOV-2012 in Paris – France

THE LYON'S HIP MEETING
30-NOV-2012 in Lyon – France

19.4 Publications, Press

<http://www.devicemed.fr>

<http://www.revue-hospitaliere.fr/>

<http://www.techniques-hospitalieres.fr>

<http://www.hospitalia.fr>

<http://www.emdt.co.uk/>

20 Sources

AFSSAPS

<http://www.afssaps.fr/>

note: AFSSAPS is becoming ANSM – Agence Nationale de Sécurité des Médicaments et des Produits de Santé starting from the 1st of May 2012

www.anism.sante.fr

AVICENNE DEVELOPPEMENT

<http://www.avicenne.com/>

CIA – World fact book

<https://www.cia.gov>

COMMIDENT

<http://www.comident.asso.fr/>

Drees, Comptes nationaux de la santé

<http://www.sante.gouv.fr/direction-de-la-recherche-des-etudes-de-l-evaluation-et-des-statistiques-drees,5876.html>

HAS

<http://www.has-sante.fr>

Institut National d'études démographiques

<http://www.ined.fr/>

Institut Polanyi Franc

<http://www.institutpolanyi.fr/>

Kwintessential Ltd

<http://www.kwintessential.co.uk/>

L'Express

<http://www.lexpress.fr/>

Ministère de l'économie, des Finances et de l'industrie

<http://www.economie.gouv.fr/>

MSI

<http://www.msi-reports.com>

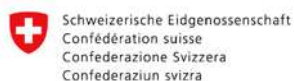
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