Kim Ribbink

FRANCE Puts Health on the Map

France is renowned for the quality of its healthcare system, competitive R&D environment, and worldwide translational medicine centers of excellence in several disease states.

France is a leading light in the area of healthcare and pharmaceuticals.

Today, France is the second largest European country with 65 million people, just behind Germany with 80 million. However, the gap is closing and it is estimated that France will become the largest European country in the next few years as birth rates are higher and the death rates lower than in Germany, says Isabelle Genin, managing director of Chandler Chicco Companies, France.

France ranks first in the European Union for the manufacture of medicinal products, and is the second-most important market for medicinal products, says Stéphane Sclison, strategy director at IMS.

"The retail market in France was valued at €29.3 billion ($38.6 billion), behind Germany (€38.4 billions), but ahead of Italy (€16.3 billions)," he says. "Yet the French market has been battling with stagnant growth over the past year, even compared with other European markets."

France continues to be a preferred destination for medical research and manufacturing, says Alain Sarraf, president of PHCG Europe, who points to a 2009 survey conducted by AEC Partners on the attractiveness and competitiveness of France, commissioned by LEEM, the French pharmaceutical companies' association.

One of France's greatest strengths is the quality of its healthcare system and management of patients, Mr. Sclison says.

"France has a centralized social healthcare system called Sécurité Sociale, whereby most healthcare services and products are reimbursed and there are no direct costs for the patient," Ms. Genin says.

The combination of a social healthcare system and a growing population suggest that France will become the highest-level healthcare consumer in Europe in the not-so-distant future, she adds.

However, according to Isabelle Buckle, Ph.D., CEO of InGen BioSciences, only 4% of the public healthcare's R&D expenses are financed by private companies, with the majority supported by the public sector, raising the problem of financing innovation.

Pharma Attraction

The majority of major pharmaceutical companies have a direct presence in France, and according to Thierry Bernard, corporate VP, global commercial operations, of bioMérieux, the country's central geographical position in Europe makes it an ideal hub for southern or northern European operations.

Its central location, strong scientific and academic infrastructure, and commitment to building centers of excellence make France a competitive market for R&D.

> "France is a mature, regulated market, with a relatively steady market share between competitors."
>
> **THIERRY BERNARD** / bioMérieux

"A number of successful initiatives have been implemented in France to foster R&D activities, such as the creation of clusters, a public loan to finance investments in biomedical research institutes, mixed public/private funds for biotechs, and a tax refund for investment in R&D," says Claude Bertrand, executive VP, research and development, chief scientific officer, for Ipsen. "France has been a leader in a number of areas. For example, it has worldwide translational medicine centers of excellence in oncology, neurology, infectious diseases, and

> **“France has been Europe’s leading medicine producer for more than 15 years and continues to be the destination of choice for medical research and manufacturing.”**
>
> **ALAIN SARRAF** / PHCG Europe

> **“Patients in France trust their physicians to recommend the correct medication for their ailment or condition rather than relying on advertising to inform them about options.”**
>
> **JULIE ROSS** / PharmaNet/i3

rare diseases. There are also technology centers of excellence in bio-imaging, computer-assisted micro surgery, stem-cells, and bio-production. In addition, new initiatives are bridging hard sciences — physics, chemistry, and informatics — and biomedicine, including at the educational level.”

Mr. Sarraf says in order to be more competitive, France has decided to simplify, amplify, and secure the French research tax credit, known as the Credit Impôt Recherche (CIR).

“Thanks to this reform from 2008, a company can get back 30% of its R&D investment in tax credits and up to 60% when the R&D work is subcontracted to a public research laboratory,” he says. “And eligibility for the R&D credit can be secured before beginning work, within less than three months after the application has been made.”

Moreover, Dr. Buckle says R&D is supported by other French institutions, such as OSEO, a state company dedicated to selecting, accompanying, and financing promising innovative projects. For the coming year, the organization has loaned several billion euros to the healthcare industry for R&D.

“These incentives make possible the emergence of state-of-the-art collaborative projects that are partly financed by governmental offices,” she says.

Alliances between industry and academia are also growing, fostering the development of joint research units and partnerships.

In 2009, the CSIS (Conseil Stratégique des Industries de Santé or Strategic Council for Healthcare Industries), which includes authorities, public research bodies, and pharma companies, launched InnoBio, an investment fund to support the development of biotech companies. Pharma companies contributed €139 million ($182.9 million) to this fund, Mr. Sclison says.

“The alliance between the state or local authorities and many private companies has given birth to an aggressive technology cluster policy, in which Lyon and Grenoble play a role at the forefront in healthcare and biotech,” Mr. Bernard says.

Etienne Drouet, executive director, oncology Europe, at Premier Research Group, notes there are internationally recognized key opinion leaders and public research institutions in biomedicine, such as the French National Institute of Health and Medical Research (INSERM), the renowned cancer center Institut Curie, the internationally recognized infectious diseases center Institut Pasteur, and government-funded research organization the National Center for Scientific Research (CNRS).

The one area that has tended to be underdeveloped is the generics market. In 2011, generics made up 56% of the unprotected retail market value and 14% of total market value for prescribed products, Mr. Sclison says, adding that the generics market is based on the prescribing right of the pharmacist. The potential growth is clearly linked to the extension of the scope for generics, which will experience a dramatic change with loss of exclusivity for several major products this year.

“Interestingly, pharmacists in France, unlike other European countries, have the right to substitute a brand for a generic prescription,” Ms. Genin says. “And, patients have the right to reject being given a generic medicine should they wish to still have a branded medication.

France: Healthcare Reform Update

These healthcare reforms are a result of the French government’s review of the clinical research system.

- Partnering between academic research and industry in France is financially stimulated through the creation of competitiveness centers, the selection of university hospitals as excellence centers with investments from Innobio, a combination of public and private multinational laboratories funds. These centers concentrate the facilities, expertise, trained staff, and transfer of knowledge necessary for the development and use of new targeted investigational products derived from biotechnology. It facilitates translational research and investment in startups. This differentiates France from countries where sites are organized to run studies with traditional compounds requiring less technological investments.
- A new pricing system that rewards innovation and makes profitable research investments on innovative products.
- The collaboration procedures between industry and public organizations has been clarified through the creation of a unique interlocutor called l’Alliance, renamed recently Aviesan, which is in charge of the coordination, harmonization, and simplification of the procedures.
- A research tax credit has also been created to stimulate reinvestment of R&D costs, and to attract research to France. Up to 30% of research expenses can be recovered.

Source: Etienne Drouet, Executive Director, Oncology Europe, Premier Research Group

“With the Mediator crisis, French patients are more and more fearful of changing drugs to generic medicines and they tend to expect and rely on the drug they are most familiar with and have been taking long term,” she adds. “For this reason physicians are now writing ‘no substitutes’ on prescriptions and this is having an impact on the volume of generic medicines within the French market, which is lower than the U.K. or Germany.”

Mediator was developed for treating overweight diabetics and was taken off the market in November 2009.

Clinical Research and Patient Access

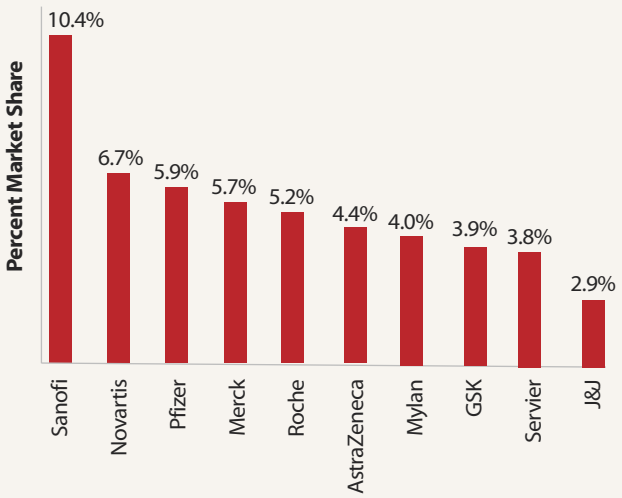
France is among the top European countries for Phase I or II clinical trials and is

> "France has expertise in specific areas, such as oncology, vaccines, cardiovascular, and metabolism diseases, which represent 75% of patients recruited for clinical studies in the country."
>
> **STÉPHANE SCLISON** / IMS Health

> "Over the years, France has been an active and influential member of the European regulatory system."
>
> **CLAUDE BERTRAND** / Ipsen

> "In France, the scales seem to tip more toward challenges than opportunities for the marketing of healthcare products."
>
> **ISABELLE BUCKLE** / InGen BioSciences

Top 10 Pharma Companies in France



Source: IMS Health, MIDAS, MAT September 2011.
For more information, visit imshealth.com.

highly competitive in therapeutic areas requiring complex organization of care, for example, oncology, orphan diseases, inflammatory diseases, and CNS, Mr. Sarraf says.

"In conjunction with the pharmaceutical industry, the French government has initiated an encouraging reform of the clinical research system, adapting the process for a new generation of pharmaceutical products," Mr. Drouet says. "The goal is to reverse the 40% decline in the number of clinical trials initiated in France between 1998 and 2010."

But Mr. Drouet says the cultural perception of clinical studies also needs to be improved through better communication of results and potential benefits to the patients accessing new treatments options.

"The patient recruitment rate per site is 20% lower than the average rate in Europe," he explains. "This can be explained by the dispersion of hospital centers, which reduce the access to a sufficient pool of patients in certain indications, compared with countries that have more centralized healthcare centers, such as Belgium or Holland. Another factor is the lack of patient databases, such as ones in the United States, the U.K., Canada, or Scandinavia. In the recent past, a lot of activities have moved to Eastern Europe and to Asia."

Efforts to improve patient enrollment and the quality of data generated have been led by an organization called Centre National de Gestion des Essais de Produits de Santé (CeNGEPS), which was created in 2007.

To date, Mr. Drouet says the organization has augmented site support in terms of providing resources, equipment, funding, training, and improving processes; standardizing procedures at a national level to reduce delays in site activation; facilitating the information exchange between sponsors and investigators on recruitment potential, access to patients, site maps, and existing investigational networks; and improving patient communication to overcome their reluctance to participate in clinical trials.

Julie Ross, senior VP, global strategic services, at PharmaNet/i3, says unfortunately, the majority of physicians are not experienced in clinical trials and how to incorporate these services into their working practices.

"The potential to increase revenue drives physician interest in participation in clinical trials, and while many want to participate, they frequently lack the infrastructure, resources, and time needed to effectively conduct the studies," she says.

Dr. Buckle says as in other developed countries, there is a focus on the development of personalized medicine, moving toward giving the right treatment to the right person at the right time, and away from a one-size-fits-all strategy.

"This trend is characterized by an acceleration of collaborations between biotech companies, academia, and pharma, she says. "Thus, personalized medicine is closely related to new biomarkers emerging in the areas of oncology, cardiovascular diseases, immunology, neurology, and infection."

Marketing and Communications

As with other European markets, direct communication to patients is forbidden, with a few exceptions: over-the-counter products or when companies have crucial information such as new indications, their label has been restricted to a specific patient population, or there has been a default with production, Ms. Genin notes. She adds that working with patients and patient advocacy groups has become more limited due to the ethical codes that govern commercial practices within the French market.

"The industry can promote disease awareness campaigns — via communications activities, Internet sites, etc. — or work in partnership with patient advocacy groups on initiatives to help improve awareness and education for specific patient populations," she says. "However, patient organizations are leery

of being seen to have been bought by the pharma industry, and any partnership initiatives need to be publicly declared and within the code of ethical conduct."

Patient education is largely provided by the primary care physician; patients are also turning to the Internet for information or clinical trial opportunities, Ms. Ross says.

"However, in some key therapeutic areas, specialty hospitals and/or centers of excellence offer education sessions for patients," she adds. "We have found that these sessions are an optimal way to educate patients about clinical studies. For example, we experienced favorable participant results from a diabetes education session, which focused on the value of various medical options."

As in other European markets, the pharmaceutical industry cannot leverage celebrity testimonials or experiences to help raise awareness of a disease. Nor is it permissible for physicians to drive any publicity for their healthcare practice, and therefore if a physician received specific training on a drug/device, he or she cannot then leverage this promotionally to drive patients to the practice, Ms. Genin notes.

There are also strict rules in terms of product promotion to healthcare professionals, and this can only be done with strict respect of the indication and labeling granted for the specific therapy, she says. All statements should be informative only and have to be strictly related to a Lecture Committee publication. In other words, no posters or abstracts older than a year, and no data on file can be used.

"The French government just voted in a new law stating that all promotional documents have to be addressed to health authorities for verification before they are disseminated to physicians," she says. "As a result of growing constraints added to a poverty of pipelines, salesforces are decreasing, traditional brand promotion and advertising has been reinvented, and the medical media continue to struggle in an environment that has become increasingly dominated by the Internet, public relations, and medical educational initiatives."

"France is a unique market, with several differences from other European markets, including the fact that the French consumer does not pay for healthcare."

ISABELLE GENIN / Chandler Chicco Companies

"The French government has initiated a very encouraging reform of the clinical research systems adapting the process for a new generation of pharmaceutical products."

ETIENNE DROUET / Premier Research Group

Mr. Sarraf says the forthcoming overhaul of the drug regulatory system will significantly change relations between pharmaceutical companies, healthcare professionals, patient associations, and physician associations. The Reforme du Medicament legislation aims to crack down on health practitioner conflicts of interest, restructure the country's drug regulator, and tighten the process for licensing drugs and for monitoring their effects once in use.

"The proposed bill creates compliance requirements that far outstrip the U.K. anti-bribery laws and includes a number of significant changes that will directly affect the way pharmaceutical companies interact with opinion leaders across the French health service," he says.

In terms of medical education, France has been moving toward stricter rules in engaging with physicians, Mr. Sarraf says.

"Currently, certified medical education cannot be directly sponsored by pharmaceutical companies," he says." However, CME is becoming more important for physicians since it is now a criterion that will be used within the evaluation process." PV

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Bringing Drugs to Market in France

In the French market, reimbursed branded drugs account for 72% of pharma industry revenue, making these drugs key for physicians and the healthcare consumer. However, receiving reimbursement by the French government is challenging due to the strict regulatory environment within which the French market operates, says Isabelle Genin, managing director, Chandler Chicco Companies, France.

The reimbursement system in France is implemented at the national level by governmental bodies. The International Society for Pharmacoeconomics and Outcomes Research notes that when marketing authorization for a product is granted — either by the European Medicines Agency (EMA) or the French authority, AFSSAPS (Agence Françaisede Sécurité Sanitaire des Produits de Santé) — the company has to apply for reimbursement on positive lists to obtain funding by the mandatory health insurance fund (assurance maladie obligatoire). There are two lists: one for reimbursable drugs dispensed by retail pharmacies (Liste des Spécialités remboursables aux Assurés Sociaux) and one for hospital drugs (Liste des Spécialités agréées aux collectivités). A pharmaceutical product can be on both lists.

While the manufacturer of a new drug that has obtained marketing authorization can set the price of the new drug, for it to receive reimbursement by the national health insurance fund, i.e. Caisse Nationale d' Assurance Maladie (CNAM), it must achieve reimbursement status from the Transparency Commission (Commission de Transparence).

Reimbursement can range from 15% to 65% and is studied by a transparency commission, known as the Haute Autorité de Santé, or HAS. The HAS commission sets the reimbursement in partnership with Comité Economique des Produits de Santé (CEPS), and Unions régionales des caisses d'Assurance Maladie (URCAM) Union, Ms. Genin says. She notes that drug approvals can take two years or longer.

On top of this, HAS carries out drug re-evaluations and can decide to narrow a drug's indication, decrease its price, and/or decrease its reimbursement level.

Decision-Makers and Influencers in French Healthcare

- AFSSAPS (Agence Française de Securité Sanitaire des Produits de Santé): On July 1, 1998, the French Health Products Safety Agency was created within a global context of reinforcing health monitoring and control of all products for human use. Therefore, AFSSAPS is the competent authority for all safety decisions taken concerning health products from their manufacturing to their marketing. AFSSAPS carries out three core missions: scientific and medico-economic evaluation; laboratory control and advertising control; and inspection of industrial sites. The agency also coordinates vigilance activities relating to all products for which it is relevant.
- CEPS (Comité Economique des Produits de Santé): The Economic Committee on Health Care Products fixes the medicine price after negotiation with the medicine company.
- Commission d'Evaluation des Médicaments: The purpose of the Commission d'Evaluation des Médicaments is to provide scientific advice concerning the usefulness, interest, and good use of drugs. The opinion of the French Transparency Commission is used to assess the medical service provided by a new drug and the improvement of this medical service subsequent to its use. This opinion is taken into consideration for establishing the reimbursement rate applied by the social security organizations and the selling price set by the administration. The expert opinions and recommendations established by the Commission d'Evaluation des Médicaments participate in implementing good use of drugs.
- HAS (Haute Autorité de Santé): The French National Authority for Health was set up by the French government in August 2004 to bring together under a single roof a number of activities designed to improve the quality of patient care and to guarantee equity within the healthcare system. HAS activities are diverse. They range from assessment of drugs, medical devices, and procedures to publication of guidelines to accreditation of healthcare organizations and certification of doctors. All are based on rigorously acquired scientific expertise. Training in quality issues and information provision are also key components of its work program. HAS is not a government body; it is an independent public body with financial autonomy. It is mandated by law to carry out specific missions on which it reports to government and parliament. It liaises closely with government health agencies, national health insurance funds, research organisms, unions of healthcare professionals, and patients' representatives.
- Health Ministry: The Health Minister determines if a medicine will be registered on the refundable list, and the UNCAM decides the reimbursement rate.
- UNCAM (Union Nationale des Caisses d'Assurance Maladie): The UNCAM is a new public healthcare organizational system following the reform law of Aug. 12, 2004. Its first purpose is the coordination of the three mandatory sickness funds, links with complementary scheme and with healthcare professionals, to obtain a better health insurance management. Its second purpose is the intervention in negotiation of agreements with medical professionals in decisions concerning prescription drug and healthcare reimbursement procedures.

Source: International Society for Pharmacoeconomics and Outcomes Research. For more information, visit ispor.org/htaroadmaps/france.asp.

"For example, this was seen with Multaq — an antiarrhythmic drug indicated to reduce the risk of hospitalization for atrial fibrillation (AFib) in patients in sinus rhythm with a history of paroxysmal or persistent AFib — which now as a result is indicated for a specific segmented patient population and prescribers can only be cardiologists," she says.

One thing that sets the French market apart is the exclusive drug distribution channel of pharmacies.

"The pharma industry mainly sells to wholesalers that are selling to 22,000 privately owned pharmacies," Ms. Genin says.

According to Claude Bertrand, executive VP, research and development, chief scientific officer, Ipsen, there was a significant level of price cuts and delisting of drugs last year, which is expected to result in a decline in drug sales in 2012 by 1% to 2%.

But while reimbursement challenges exist, Stéphane Sclison, strategy director at IMS, says those companies that are able to develop real-world evidence to demonstrate the value of their products will enjoy a fair reimbursement status and price for innovations, to the detriment of other products, from the French authorities.

Isabelle Buckle, Ph.D., CEO of InGen BioSciences, says given the high costs to the healthcare system, the government is focused on reducing expenses.

"At the M.D. level, there are efforts to foster the prescribing of generics, at the level of laboratory medicine, there are efforts to encourage consolidation among laboratories from 4,000 to around 1,000, and at the pharma level, stricter criteria to make medicine eligible for reimbursement are being introduced," she says.

Regulatory

Mr. Bertrand says France has been an active and influential member of the European regulatory system, and the French regulatory agency has taken the lead in the evaluation of many of the important new drugs of the past two decades.

"French regulators have sustained a strong reputation of scientific excellence, and the agency has been open to dialogues with the industry to collaborate on all phases of drug development and commercialization," he says.

France: Two Major Factors for Success

Now, more than ever, there is greater emphasis on innovative technology and renewed partnerships. Seeking product approval in France creates many questions. Among them are: Is France an attractive investment option for the international managers of pharmaceutical companies? On what basis? What concrete measures will enable France to reindustrialize and remain a major country in pharmaceuticals over the next 10 years?

To provide objective answers to these questions, particularly in the framework of the CSIS (Strategic Council for Healthcare Industries), in 2009 the French Pharmaceutical Companies Association (LEEM) commissioned AEC Partners to conduct a study, the first in France, among major pharmaceutical groups. This qualitative study was based on interviews with 73 international managers of pharmaceutical companies on several continents to find out their views of France as an investment destination. The interviewees represented 19 major pharmaceutical companies accounting for more than two-thirds of the French market.

The qualitative results paint an encouraging picture and reveal the challenges to be met.

» First lesson of the study: France remains a relatively attractive and eligible market undergoing restructuring. By size, it is one of two large European markets and the fourth global market behind the United States, Japan, and Germany. As with other Western countries, however, it is trapped between two very attractive geo-economic forces — the United States and emerging countries.

» Second lesson: France has an excellent industrial tradition, yet whose social environment prompts mixed reactions and which must place greater emphasis on innovative technology. The position of a leading country for the production and export of pharmaceuticals in Europe, if not the world, can be explained by the French industrial environment: quality of the engineers and technicians, transport and telecommunications infrastructure, strong industrial tradition in the pharmaceutical sector, and quality of the pharmaceutical distribution system.

However, the social environment is viewed much less positively due to two main factors: organization of working time and labor relations, particularly in public transport and the civil service.

Yet this view is nuanced by industrialists who have a more intimate knowledge of France, who point out the difference between perception and reality. In particular, they stress the high productivity of the French workforce and the reforms undertaken, and note that other countries also have a complex and restrictive working environment.

» Third lesson: France has a highly competitive academic R&D environment, with underexploited potential, where cooperation and partnerships are required. France has significant strengths to be a competitive global player in R&D: strong public research in the biomedical sector; excellence in the areas of engineering, mathematics, physics; quality of the healthcare system and skilled clinicians; and opinion leaders with international reputations in several therapeutic areas.

In the eyes of international managers, France, however, is unlike other countries, is unable to turn its strengths into competitive advantages through lack of a strong investment policy for life science research, the fragmentation of public research, the relative dispersion of public investment and the shortage of public-private partnerships.

» Fourth lesson: There is a positive perception of a political environment that has incorporated dialogue and consultation.

France stands apart from the rest of Europe with a clear political will to consider healthcare industries as a strategic sector, with a range of concrete measures, and initiatives over the last three years. CSIS, R&D Dating meetings, General State of Industry meetings, Great Loan, implementation of Aviesan (French National Alliance for Life and Health Sciences) in 2009, and reform of the Research Tax Credit in 2008. These structural developments are viewed positively by economic decision-makers.

Regulations continue to evolve. For example, the European directive that covers IVD (in vitro diagnostics) as medical devices will soon have a new version, after which each country will either have to apply it or transcribe this new version in their national laws, says Andrew Sette, VP, global regulatory affairs, for bioMérieux.

"It is very likely that the new version will require more stringent controls before placing a new IVD product in the market, which will likely mean that the overview from the authorities in France will increase," Mr. Sette says. "For well-established companies with the experience of stringent international regulations and solid quality systems, this could become a strategic advantage while smaller companies and start-ups could have more difficulties." PV

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