OVERVIEW

Population: 64,876,618
Life expectancy: 81
(male: 78, female: 85)
GDP Growth: 1.5 per cent
GNI per capita: $34,440
Health expenditure per capita: $4,798
Health expenditure of GDP: 11.7 per cent
(Source: World Bank, 2010 and 2009)
Capital: Paris
President: Nicolas Sarkozy
Minister of Labour, Employment and Health: Xavier Bertrand
Language: French
Currency: Euro

EXECUTIVE SUMMARY

France is one of the leading producers, and the largest consumer, of pharmaceuticals in Europe

Market strength, political stability and solid investment outweigh concerns such as heavy taxation, price controls and new regulations that limit profitability

Healthcare reforms aimed at extending universal service, patient choice and quality of care have led to increasing public expenditure

The healthcare system is dominated by state intervention and characterised by freedom of choice for patients and freedom of practice for doctors

A system of public insurance covers most of the population with generous co-payment and reimbursement policies

French health expenditure is around 12 per cent of GDP, according to World Bank figures and it remains attractive when compared to other countries in Europe. Rewarding innovation will still figure highly in the pricing system, particularly for unmet medical needs

The financial crisis marked the end of a decade of impressive pharma growth, with austerity measures now impacting on the pharmaceutical industry

Changes in reimbursement policy, prescription habits, patent expiries and shift of investment to emerging markets will lead to decreased profits for traditional pharma business models from the era of the blockbuster

According to LEEM, the industry association, the prescription drugs market lost momentum in 2010, achieving €27.3bn in revenues and a one per cent growth domestically

Hospital medicines, generics and the over-the-counter sectors offer great potential for growth

France aims to be a hotbed of innovation, investing in biotech through public/private partnerships, as the sector enjoys generous tax credits

The ‘Mediator scandal’ over the diabetes drug prescribed to suppress appetite and implicated in 500 to 2,000 deaths has impacted the image of the industry, regulatory agency and health authorities, leading to tighter regulations.
INTRODUCTION
France is the world’s fifth largest economy and second wealthiest country in Europe after Germany, its main ally and trading partner. It entered the 2008 recession late and it has weathered it better than others, despite stalled growth and a rise in unemployment, now at its highest level for over a decade. The country is undergoing a transition from state intervention and ownership to a more market-reliant economy. In recent years, many companies, banks and insurance firms have been privatised and stakes have been ceded in public giants such as Air France, France Telecom and Renault. The government has responded to the economic crisis with aggressive investment measures that have contributed to a sharp rise in budget deficit (up to seven per cent in 2010) and well above the European Union (EU) ceiling of three per cent. Increased financial woes are impacting healthcare budgets, already struggling to sustain a universal system where patients pay little and overprescription is rife. The budget draft for 2012 contains a new law on social security funding, with a maximum spending growth of 2.8 per cent per year on year and savings of €2.2bn in the healthcare sector as part of the strategy to bring public deficit down and a drive for structural reforms.

GOVERNMENT
The French government is a semi-presidential system determined by the constitution of the Fifth Republic. While president and prime minister share executive power, parliament – consisting of the National Assembly and Senate – comprises the legislative branch.

The latest polls suggest President Nicolas Sarkozy, in power since 2007, will lose next April’s re-election bid. The Eurozone financial meltdown has affected the popularity of most European leaders, but Sarkozy has suffered from overcentralising and shying away from the liberalising reforms he once campaigned for, according to The Economist (‘France’s beleaguered president: Can he recover?’, September 2011).

However, he faces no serious opposition for the centre-right or from the Socialist party, which could help him cling on to office. ‘If he merely tries to sell a lighter version of socialism, many French voters will prefer to go for the real thing instead. Moreover, his appeal has always been as a reformer,’ argued The Economist.

In healthcare, a Sarkozy government is likely to continue its pharmaceutical industry-friendly approach, even if a difficult economic backdrop means that more budget cuts will certainly be on the agenda and these will impact pharma.

Moderate Francois Hollande has been chosen as the Socialist Party candidate to run against Sarkozy. He has stated that, if he wins, health policy will change and he will put an end to the “politics of mistreatment and degradation of the sector”. He has been critical of the shift towards complementary health that he called “a tax on illness” (Le Monde, September 2011).

HEALTHCARE & DISEASE PREVALENCE
France’s spending on healthcare was an estimated €234.1bn in 2010, according the French Institute of National Statistics, with public spending accounting for around three-quarters of the total or around 12 per cent of GDP, compared to 10.5 per cent in Germany and 8.7 per cent in the UK.

Considered by the World Health Organisation (WHO) as the best in the world in a one-off ranking study in 2000, the French healthcare system has universal coverage as its cornerstone in a mix of mainly public and some private providers and insurers.

The French enjoy good health, with a life expectancy of 81 years, and the country compares well with other developed nations in terms of cardiovascular diseases, despite a high rate of premature male mortality, due to accidents and lifestyle choices such as smoking, says the European Observatory of Health Systems and Policies. Its obesity rate is also rising, due to dietary changes, even though the French are among the slimmer Europeans. Almost 40 per cent are overweight, including 11.2 per cent categorised obese (Organisation for Economic Co-operation and Development, [OECD] report, 2010). Projections suggest that overweight rates will increase by a further 10 per cent within 10 years.

Cancer is the most common cause of death, followed by heart disease and stroke, and then external causes. Twenty-six per cent of the population smokes, a slight decrease from 30 per cent in 1980 (OECD). This affects mainly the male life expectancy rate, which lags behind that of women by seven years.

HEALTH SYSTEM REFORMS
The social security system, set up in 1945, included statutory health insurance and compulsory protection of employees. Coverage was first extended in the 1970s and then with the Juppé reforms in the late 1990s, which further increased the role of the state in controlling expenditure. The Universal Health Coverage Act came into force in 2000 and established residence in France as the main condition for access to an affordable health service based on patient choice.
2009 saw the implementation of the Hospital, Patients, Health and Territories Act (Law Bachelot), which changed the organisational structure and management of the healthcare system at the regional and local level, impacting mainly on hospitals. Despite this, the Ministry of Health maintained considerable centralised control.

The ‘Régime Général’ covers employees and their families, around 88 per cent of the population. This public health insurance fund is ‘Caisse nationale de l’assurance maladie des travailleurs salariés’ and is financed by both employees, proportionally to their income, and employer contributions, as well as taxes. Because ‘L’Assurance Maladie’ is the top buyer of medical services, it can keep doctors’ fees relatively low through agreements.

To consult a doctor costs around €23 with a social security registered practitioner and 70 per cent is refunded, so the patient pays less than €7. Major surgery at a public hospital is reimbursed at 95 per cent and pregnancy and childbirth at 100 per cent, although treatment, whether private or public, and medicines are not free at the point of delivery; they are paid by the patient and refunded later.

In most companies, employees must visit the doctor at least once a year for a check-up, which leads to early diagnosis of many conditions, such as diabetes. The diagnosis rate for diabetes in France is above average, with 85 per cent of the population aware of their disease compared to total European figure of 60 per cent.

There is also an agricultural scheme and an insurance for professional self-employed workers, as well as a safety net for those who are unemployed.

The government is keen to raise additional revenue for statutory health insurance and to increase the role of voluntary health insurance, but these measures remain highly controversial, especially near elections.

Complementary health insurance is taken out by around 90 per cent of the French and is supplied by private and not-for-profit organisations providing top-up reimbursement and expensive non-reimbursable services such as dentistry, ophthalmology, gynaecology and private hospital care. It represents one quarter of health spending and it is a competitive sector, often subsidised by employers.

Financial responsibility for healthcare in France is mainly borne by the state in its many guises in a complex and pluralistic web of agencies and insurers.

The French Ministry of Health is in charge of the Medicines Agency (AFSSAPS) – the body equivalent to the US Food and Drug Administration or the UK’s National Institute for Health and Clinical Excellence, responsible for market authorisation, pharmacovigilance and safety of drugs – and the Products Pricing Committee (CEPS) in charge of pricing and cost-containment. The independent High Authority of Health, created in 2004, evaluates medical benefits of pharmaceuticals through its Transparency Committee. Reimbursement is the responsibility of the National Union of Social Health Insurers (UNCAM), which is composed of the three main insurers.

The majority of French hospitals are public and the rest are run by private firms and the not-for-profit sector, such as foundations, religious groups and mutual-insurance associations linked to the state.

COST Containment

Cost containment policies have had some impact on both doctors and patients, as prescription freedom is now questioned in a country known for overprescription to eager ‘pill poppers’ as described in The Economist (‘French drug consumption, Pass the pills’, February 2011).

Consumption of pharmaceuticals per head was an estimated €585 in 2010 – one of the highest in the world – and, according to the Institute for Research and Information in Health (IRDES) based in Paris, 90 per cent of medical consultations result in prescriptions (Drug price-setting and regulation in France, 2008).

Limits on the numbers of doctors graduating, prescription ceilings, delisting of reimbursable drugs and price controls for medicines have been considered pure interference in the way medicine is practised. Many doctors are self-employed and retain considerable freedom within practice guidelines, despite being dependent on agreements with social security.

Reducing the healthcare budget has been a priority of President Sarkozy’s government. Last year, the prime minister, François Fillon, stated that major changes had to be made to achieve budget control, but no further profound restructuring of the system is expected in the

### CONFLICTING INTERESTS

At its heart, the French system is a contradictory one, with universal coverage as a foundation and deficit reduction as an economic imperative, which results in a conflict between medical unions, health insurance funds and state authorities.

Costs are rising due to an ageing population, growing unemployment and illnesses requiring ever more expensive treatments. The system is under financial pressure, with a shortage of staff in many regions and patients’ out-of-pocket payments increasing.

#### EVOLUTION OF PHARMACEUTICAL CONSUMPTION IN FRANCE

<table>
<thead>
<tr>
<th>Year</th>
<th>€ (m)</th>
<th>€ per person</th>
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<tbody>
<tr>
<td>1980</td>
<td>5,136</td>
<td>95</td>
</tr>
<tr>
<td>1990</td>
<td>14,654</td>
<td>258</td>
</tr>
<tr>
<td>2000</td>
<td>25,069</td>
<td>414</td>
</tr>
<tr>
<td>2009</td>
<td>35,383</td>
<td>547</td>
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Source: LEEM and INSEE, National Institute of Statistics and Economic Studies
In the last few years, patient associations campaigning for state-funded treatments, choice and drug safety have been strengthened through the creation of a Patients’ Federation (CISS – Collective Inter-Association for Health). Opinion polls carried out by the Patients’ Federation in 2010 on the public’s feelings towards healthcare reforms in France revealed that more than half believed that the priority should be to maintain high levels of reimbursement. Eighty-five per cent wanted to keep social security in charge of managing health expenditure and almost 70 per cent preferred to pay more taxes than endure cuts or a shift to private providers. Around 47 per cent also felt strongly about socioeconomic disparities and geographic inequality, citing the abolition of ‘medical deserts’ as an absolute priority for reform. Only 27 per cent of patients considered healthcare deficit reduction to be an issue.

Eight million patients with chronic conditions still receive 100 per cent coverage not only for their illness but for any other medical complaints, which accounts for 60-70 per cent of health spending. When the Sarkozy government suggested restricting coverage to the patient’s chronic disease, there was such a negative response from the public that the proposal was quickly abandoned.

Reforms to reduce state healthcare costs are extremely unpopular, as access to free health is enshrined in the constitution as a right. Consequently, the government opted for mere “emergency short-term measures” in the president’s first term, Anne-Charlotte Honoré, pharma analyst at IHS Global Insight told PME. However, “a structural reform of the drug regulatory system is underway that is expected to render access to reimbursement more difficult. The inclusion of new medicines to the reimbursement list will be conditioned to the manufacturer’s ability to provide comparative clinical trials against the standard of care ... it is by far one of the strictest measures,” she added.

Pharmaceuticals will be affected by the Law Project on Social Security Financing (PLFSS) 2012, underlining the state’s commitment to reduce its healthcare deficit. Additional measures will include a decrease in wholesalers’ margins, an increase in contribution from pharmaceutical companies’ turnover to 1.6 per cent and an improvement in hospitals’ performance.

Increases in co-payments, generic promotion, higher taxes for private supplementary health insurance funds and a rise of €1 per day in hospital stays have already been introduced to curb spending. Since the first cost-containment measures were introduced, only minor savings have been achieved as the system has expanded.

Recently, Sarkozy’s government focused on cutting the budgets of public hospitals by improving management practices and increasing efficiency, which led to a protest by doctors fearing the demise of public healthcare and accusing the government of pursuing profits.

Patients are required to register with a GP or ‘médecin traitant’ to act as a gatekeeper to oversee treatments and guide patients, who face lower reimbursement if they wish to keep absolute control over the process. This last move aims to avoid what the French call ‘nomadisme médical’ or the habit of seeing several doctors for the same condition to compare opinions. The co-ordinated care journey set up in 2004 allows higher co-payments for patients taking this route.

### LEADING PHARMACEUTICAL COMPANY SALES IN FRANCE ($M) IN 2010

![Graph showing leading pharmaceutical company sales in France in 2010](source: IMS Health 2010)
a drop in the price of medicines, policies to promote generics, changes in the evaluation criteria by the Transparency Commission and in hospital prescriptions management.

“The pharmaceutical industry is part of the activities that make France a major world industrial power. As France’s second exporting industry and fourth contributor to the country’s trade balance, it’s establishing itself as a real growth engine for recovery,” LEEM’s chairman Christian Lajoux told PME.

Analysis from IHS Global Insight shows that growth was driven by ‘a very healthy hospital market’, where expenditure on drugs was up by 4.2 per cent. This market has been much more dynamic, but tighter regulation and efficiency-driven restructuring will take their toll. French pharma had to go abroad to find growth, with exports, primarily to Europe, rising to €24.1bn in 2010, a growth rate of 4.5 per cent.

The reimbursable drug market grew just 0.3 per cent during 2010. Price cuts of about €670m are planned for 2012, while reimbursement cuts will affect a total of 64 drugs over the period, stated IHS Global Insight.

LEEM described the budget cuts and added levies on the industry as ‘unfair, incomprehensible and short-term measures’. Mr Lajoux commented: “These are anti-manufacturing measures. They will weaken a strategic business sector for our country and hinder France in the field of international competition. They contradict the ambitions stated for many years, namely to make France one of the great countries for life sciences.”

Best-selling reimbursed drugs, such as Pfizer’s Lipitor and AstraZeneca’s anti-ulcerant Inexium are reaching patent expiration, with generic versions of the two drugs entering the market and bringing healthcare budget savings of between €130m and €170m, respectively. Sanofi has reached a deal with Pfizer to sell Lipitor’s generic version domestically as part of its general strategy to weaken its dependency on patents. Its sales of generic products increased by 41.5 per cent in 2010 to €1.5bn.

The deal gives the original manufacturer a tax break if it allows a generic company to produce and sell copies as the branded drug’s patent expires, and is designed to keep production sites and employment in France.

Sanofi continues to dominate the French market, accounting for 13 per cent of pharmaceutical sales there in 2009. Other big pharma firms, such as Novartis, Roche, GlaxoSmithKline (GSK) and Pfizer had market shares below six per cent.

The French pharma giant remains in fourth place in world rankings, with revenues of €30.4bn in 2010, with vaccines, generics and consumer health described as its strongest sectors and a crucial part of its diversification strategy. According to the company’s projections, around 40 per cent of its profits by 2015 could come from ‘pharmerging’ as conditions worsen in Europe and the US. Having lost the patent on bestseller Plavix, Sanofi intensified its acquisitions, buying Genzyme, a US biotech company specialising in rare diseases, for $20bn in February 2011. It also completed the acquisition of BMP Sunstone, a manufacturer of paediatric and women’s health products in China. In 2009 it had bought Zentiva – a generic producer in the Czech Republic, Kendrick – a Mexican generics company, and Medley – Brazil’s leading generics firm.

Some analysts believe that Sanofi is being over-optimistic about emerging markets, particularly in Turkey, with its price decreases, and in eastern European markets because of the economic crisis.

### PRICING AND REIMBURSEMENT

The French pricing system, controlled by CEPS, the pricing committee, aims to be fair and reward R&D. There is a European reference pricing in place, but negotiations between the committee and the industry focus on volumes and conditions. Over-the-counter (OTC) products and some hospital drugs face no restrictions on pricing. Price-setting is mainly determined by clinical benefit or added value of the medicine, prices of similar products, European prices, sales forecasts and size of the target consumer market.

There is also a system of industry paybacks, where companies are ‘taxed’ when their sales growth target is exceeded, although some exemptions are allowed for generics, orphan drugs and medicines with high clinical benefit for agreed periods of time.

In France, prices have stayed low in comparison with other European countries (14 per cent lower than the EU average) due to state control mechanisms and VAT for prescribed medicines is only 2.1 per cent, compared to 19 per cent in Germany (according to EU and European Federation of Pharmaceutical Industries and Association figures).

Market access is still slow, although there is a system of Temporary Authorised Use (ATU) that allows for the launch of innovative, life-saving drugs in hospitals even before registration and is free to the developer of the drug. This is the case with oncology treatments as part of a national cancer care plan that includes fast access to new therapies.

All registered pharmaceuticals are subjected to evaluation of therapeutic benefit (Service Médical Rendu) by the Transparency Committee and then reimbursable status can be applied for, as the

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**ECONOMIC FORECASTS FOR PHARMACEUTICAL COMPANIES IN FRANCE 2011-2012**

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<tr>
<td>Revenue France</td>
<td>27,334</td>
<td>+0.7%</td>
<td>+0.4%</td>
<td>+0.5%</td>
</tr>
<tr>
<td>Pharmacy revenue</td>
<td>21,524</td>
<td>+0.3%</td>
<td>+0%</td>
<td>+0.1%</td>
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<tr>
<td>Reimbursable pharmaceuticals</td>
<td>19,625</td>
<td>+0.4%</td>
<td>+0%</td>
<td>+0%</td>
</tr>
<tr>
<td>Non-reimbursable pharmaceuticals</td>
<td>1,899</td>
<td>-0.8%</td>
<td>+0%</td>
<td>+1%</td>
</tr>
<tr>
<td>Hospital revenue</td>
<td>5,810</td>
<td>+2.0%</td>
<td>+2%</td>
<td>+2%</td>
</tr>
<tr>
<td>Export revenue</td>
<td>24,137</td>
<td>+4.5%</td>
<td>+3%</td>
<td>+5%</td>
</tr>
<tr>
<td>Total revenue</td>
<td>51,471</td>
<td>+2.4%</td>
<td>+1.6%</td>
<td>+2.6%</td>
</tr>
</tbody>
</table>

Source: LEEM, industry association, 2011
current policy stipulates that patients should have access to innovative medicines. However, to keep costs down, other products considered of low or moderate value will see their reimbursement rate cut or even be removed from the list.

Once approved for reimbursement, a medicine will be on the positive list for five years, when it will be evaluated and have its price reviewed.

Most pharmaceuticals are covered at a rate of 65 per cent, but this varies from 100 per cent for non-substitutable or expensive drugs with high innovation to 15 per cent for drugs considered of low medical benefit. An IRDES study found pharmaceutical expenditure grew 12.3 per cent from 2005 to 2010 and that 24 per cent of medicines remained reimbursable at 15 per cent, even with low clinical benefit. Changes occurred in 2010, when 150 medicines saw their reimbursable rate lowered to 15 per cent, and in 2011, hundreds considered of inefficient value were delisted.

In 2011, price cuts on medicines agreed with CEPS amounted to €500m and reimbursement levels dropped to bring France in line with other EU countries.

### GENERICS AND OTC

With patent cliffs dominating the landscape in France and cost-containment a growing concern, generics are moving centre-stage.

The generics market was introduced late and patent protection was extended in the 1990s, with generics not being clearly defined and reimbursable until 1997. Only when pharmacists were allowed to substitute did generics take off in 1999. Substitution is voluntary but encouraged and compensated, since pharmacists have a dispensing margin to match branded products.

However, doctors have been unenthusiastic, since generics are seen as a means of interfering with prescribing freedom. Financial incentives are also given to medical practitioners who prescribe by active ingredient or generic brand, which, combined with pharmacy-subsidised margins, eat into generics’ expansion and the public savings that could be made.

R&D firms have responded by cutting prices, giving discounts to distributors and introducing their own generic versions ahead of patent expiration.

Generic drugs represent only 12 per cent of the market (worth €2.6bn) compared to 31 per cent in Germany and 33 per cent in the UK. The generics association, GEMME, said that €1.7bn in savings were secured in 2010 through generic use. However, there is a tendency for sales to drop when a generic version is introduced, with transfer of prescriptions not to the generic but to products which are still patented. A similar trend occurs when any branded products are delisted and doctors prescribe others on the positive list.

In France, generics are four per cent cheaper than the European average, yet France is in fifteenth place in terms of generics consumption. The substitution list, containing medicines eligible for substitution, covers only 22 per cent of the market volume and GEMME wants to grow it to 30 per cent. According to GEMME, the authorities have an interest in making this a reality to keep the universal healthcare system sustainable. Catherine Bauriennne-Bautista, president of GEMME, told PME: “To truly develop the generics market, there has to be a combined effort of all actors involved. We are currently lobbying for a broad institutional campaign.”

Most prescribed medicines, such as antibiotics, antidepressants, anti-ulcerants, antihypertensives and statins, now have generic versions on the reimbursable list and their reach has extended in recent years. Companies active in this market include Ranbaxy, Teva, Ratiopharm and Biogaran.

Many R&D firms are also taking advantage of growth by anticipating patent loss with investments in generics and the OTC market. Since 2008, pharmacies have been allowed to have an OTC counter as a distinct space and, in 2009, the official OTC list contained 302 medicines, mainly painkillers, dermatological and anti-smoking products. The self-medication market was not encouraged until recently, but is now seen as way of getting patients to pay for themselves. According to a 2007 study by the High Authority for Health and the AFSSAPS, the market had not changed since 2001 and needed a boost. Self-medication in France was €27 per person per year, compared to €60 in Germany and €40 in the UK.

It is a growing market, where the government can make savings and price competition is permitted. Again, GPs were mainly opposed to the opening up of the OTC market, citing a threat to patients’ safety. The OTC market is worth €1.9bn, or 6.4 per cent of the whole pharmaceutical market, according to AFIPA, the association of OTC companies. The largest OTC players are Sanofi, with 11 per cent of the market, followed by UPSA Total and MC Neil Santé GP.

### BIOTECH AND INNOVATION

Mr Sarkozy has declared that the health industry is of premier strategic importance to France and funding and research incentives have grown, particularly for biotech projects, in recent years.

Breakthrough measures include the creation of InnoBio, a €130m biotechnology venture combining France’s sovereign wealth funds and financial contributions from multinational pharma companies such as Sanofi, GSK, Pfizer, Roche, Ipsen, Lilly and Novartis. Most biotechs in France are too small and suffer from chronic under-funding and lack of capacity, so this is a much-needed boost.

A France Biotech (the French association of life science companies) survey found that funding increased 56 per cent in 2010. Such tax breaks allowed two-thirds of the companies to have at least one therapeutic product in development or on the market.

The National Institute of Health & Medical Research (INSERM), a biomedic and public health research institution, though created in 1964, has a new role as a funding agency. Seventy-two per cent of its €773m budget comes from the state and is currently supporting over 600 R&D projects.

France had been lagging behind Germany and the UK in terms of infrastructure, production and research, although it is still the third largest biotech market in Europe. It had also been a pioneer in the sector, particularly in vaccines and the creation of the internationally renowned Institute Pasteur in the 19th century. A not-for-profit organisation, it carries out research for the pharma industry and acts as an incubator of biotechs.

In 2005, France also launched the Pôles de Compétitivité initiative to support competitiveness in a number of industries. Seven pharmaceutical/healthcare poles were established, focusing on different areas. Lyonbiopôle, for example, focuses on vaccines, immunology, infectious diseases and is a public/private partnership of academic research at Lyon University, start-ups and big pharma (BioMérieux, Sanofi Pasteur, Merial, Becton Dickinson).

Another issue affecting innovation has been a lack of co-ordination and fragmentation of agencies, organisations and institutes. In 2009, the government set up the strategic alliance of Life Science and Health to group stakeholders in the sector, strengthen co-operation between them and foster relationships between academic research and the business world through technology transfer.

### MEDIATOR & REGULATORY REFORMS

Servier’s diabetes drug Mediator, was being prescribed as an appetite suppressant for decades when it was taken off the
market over safety concerns in 2009. It was revealed that it caused heart damage in patients who could have resulted in between 500 and 2,000 deaths and 3,500 hospitalisations, subsequent studies concluded. An estimated five million people took Mediator in France and it was reimbursed at 65 per cent.

Safety concerns had long led to its withdrawal from the market in other European countries, such as Italy and Spain in 2003.

Servier, the regulatory agency and the medical community were left with a tarnished reputation. The industry association suspended Servier’s membership and tried to distance itself from the affair, which it described as ‘an isolated case’ and the head of the medicines regulator AFSSAPS, Jean Marimbert, resigned in 2011, to be replaced by Francois Hebert.

Health minister Xavier Bertrand promised a ‘radical reform’, with new regulation to improve pharmacovigilance and increase transparency. Pharma companies will be banned from funding professional development of health staff and fined if they fail to disclose conflicts of interest. The medical and pharmaceutical press will also have to declare industry funding.

The AFSSAPS is soon to be renamed National Agency for the Safety of Medicines (ANSM) and it stated that it needs a 20 per cent increase in its €115m budget to implement the reforms.

Servier’s chief executive, Jacques Servier, was awarded the French Legion of Honour in 2009 by President Sarkozy, who had worked as a legal adviser to Servier’s businesses in the 1980s and 1990s, according to French media reports. The scandal involves prominent politicians of both main parties who were allegedly not informed of any issues regarding Mediator. In the aftermath of the Mediator affair, many other drugs are being re-evaluated in terms of proven efficiency over other drugs already on the market and more than 50 were put on a list for reinforced pharmacovigilance.

The French reform may have wider regulatory implications, with other countries looking into enforcing a system where each drug has to prove its added value against pre-existing medicines.

The medical community is also under tighter scrutiny over Mediator, because the scandal lifted the veil over prescription and misprescription as well as accusations levelled at the medical community and the pharmaceutical industry for having too close a relationship.

LEEM’s chairman told PME that the industry wholeheartedly supported measures regarding patient safety. However, Lajoux thought that the changes went too far and would harm business: “LEEM denounces the implementation of procedures intended to slow patient access to new medicines and the processes by the Transparency Committee, as well as the ban on individual visits by medical sales reps to hospitals, a move that will directly threaten the jobs of thousands of people. We are alarmed by a policy that is systematically burdening the medicine industry with additional constraints, while overturning the legal framework of its activity.”

**MARKETING RESTRICTIONS**

Tighter regulations, price cuts to avoid delisting and severe restrictions on promotional expenditure are key features of the current French pharma market. The promotional expenditure of pharmaceutical companies is taxed highly to limit such spending and subsequently reduce the strain on the public healthcare system. Some exemptions apply to orphan drugs and generics, but the Promotion Tax is between 19 and 39 per cent of the total spent.

Advertising of medicinal products is regulated by the French Public Health Code and guidelines of AFSSAPS and complies with EU law. Prescription-only products cannot be advertised directly to the public, with the exception of vaccines and anti-smoking products. Non-prescription products can be advertised if they are not reimbursable and their market authorisation allows it.

The Promotion Tax is controversial, as the industry already pays tax on direct sales (19 per cent), reimbursable products, annual increase of sales and market authorisations, but an increase in pharma taxes is likely, according to Salans, a multinational law firm.

**TRENDS AND OUTLOOK**

The industry forecasts for 2012 suggest zero growth in prescription products due to the strict regulation of healthcare expenditure.

A Sarkozy second term is bound to press on with an overhaul of the healthcare system, this time focusing on primary care (médecine de proximité). Here, reimbursement levels are due to drop and reclassification of drugs is likely. If a drug is reclassified as having fewer medical benefits, labelled ‘lifestyle’ or is unable to prove its added value, it will be delisted.

Pharmacovigilance will increase with tighter regulations and revamped medicines agencies as a response to the Mediator case. Pharma companies will be obliged to prove the clinical efficiency and added value of new drugs against pre-existing ones.

The R&D pharmaceutical industry will make a further contribution of £290m as a result of the recent cuts in the annual target rate for growth in healthcare expenditure over the coming years. This new penalty would come on top of a recent series of what LEEM calls ‘extremely damaging measures for the activities and development of companies in the sector’ such as price cuts of around £620m announced as part of the 2012 social security draft finance law, the creation of an additional £150m tax in order to finance the continuing education of physicians, an additional £40m contribution to the budget of the revamped medicines agency, as well as a new wave of delisting, totalling £40m. "In all, the additional levies on the pharmaceutical industry will amount to £700m in 2012, an unprecedented level,” LEEM told PME.

The culture of overprescription and overconsumption of medicines will not change overnight, but pressure is mounting for a more rational use of resources while maintaining a system that is viewed as outstanding in terms of universality and quality, and holds high levels of patient satisfaction. However, out-of-pocket co-payments will increase, as will the role of private insurers.

Patent expiries restrict areas of potential growth to hospital drugs (with high demand and high levels of innovation) and to generics and OTC drugs, reflecting the need to curb spending.

The biotech sector will continue to receive tax breaks and funding as a strategic industry for maintaining France’s pole position in Europe and incubate further co-operation between the private and public sectors.

Sanofi is expected to take the top spot among the world’s pharmaceutical manufacturers in 2012 and hold it through to 2016, according to a report by life sciences analyst EvaluatePharma. In France, the company is focusing on biotechnology with a €50bn public-private research partnership, as well as generics and OTC, while it continues to count on emerging markets growth.

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