France is the leading producer of pharmaceuticals in Europe and also the largest consumer of medicines. Policy and pricing reforms are being introduced by the government to reduce the healthcare budget deficit.
INTRODUCTION

France is the second highest population in Europe with 67.5 million people. In 2006, 20,000 people died aged 10 years, of which 3 per cent and 21 per cent respectively were due to heart disease and cancer. France had the highest mortality rate - 14 per 1,000 in 2005. The campaign against smoking in France was launched in 2005.

France had 4.1 per cent of its workforce working in the health sector. The French health care system is based on a three-tier system - primary, secondary, and tertiary care. The National Health Insurance (HNS) is responsible for providing free access to health care for all citizens.

France has the second highest consumer of drugs in Europe after the UK, with a 4 per cent increase in drug consumption between 2005 and 2006. France is the second highest consumer of antibiotics in Europe, with 8 per cent of the total consumption.

HEALTH

Generally speaking, the French are in good health. Life expectancy is 80 years for both men and women, which is the highest in Europe. In France, 44 per cent of people are overweight, and 11 per cent of adults (men and women) are classed as obese. Excess weight is also observed in children, with 14 per cent of children, especially those from low socio-economic classes, being overweight.

A report from the Ministry of Labour, Social Relations and Solidarity revealed that levels of premature death, and in particular, avoidable premature death, is one of the highest in Europe - notably within the male population where this is four times higher than in other countries. Accidents (5 per cent) are now the primary cause of death, followed by cardiovascular diseases (29 per cent) and cancer (30 per cent). It is estimated that 10 per cent of deaths are caused by accidents. In France, 75 per cent of deaths are caused by chronic diseases - diabetes, cancer, cardiovascular diseases, or myocardial infarction, which equates to 3,000–5,000 lives saved.

In France during 2007, nine therapeutic categories represented 33 per cent of drug consumption and 40 per cent of drug expenses. These were (in order): analgesics; oral anticoagulants; cardiovascular drugs; antihypertensive agents; protons pump inhibitors; non-narcotic analgesics; sedatives; antidepressants; and central nervous system agents.

France has the second highest population in Europe - 90 per cent of GP consultations are attended in France. This can be explained by the high prevalence of chronic diseases - diabetes, cancer, cardiovascular diseases, or myocardial infarction, which equates to 3,000–5,000 lives saved.

Health expenses in France are 8.4 per 1,000. Cancer is the primary cause of death in France, followed by cardiovascular diseases (29 per cent) and accidents (5 per cent).

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HEALTH INSURANCE

The Assurance Maladie, the French social security scheme covering primary care physicians (general practitioners), usually consists of three fundamental principles: access to healthcare, quality, and reimbursement. These three fundamental principles are also reflected in three additional principles: solidarity, equity, and financial sustainability. By subscribing to the Assurance Maladie, individuals can access healthcare, receive reimbursement for quality healthcare, and contribute financially to the healthcare system.

The Assurance Maladie comprises three main components:

- Régime Social des Indépendants (RSI) – a scheme for the self-employed which covers skilled workers, retailers and manufacturers.
- Mutualité Sociale Agricole (MSA) – an agricultural scheme, which covers farmers and farm employees.
- Régime Général de Sécurité Sociale (CNAM-TS) – a general health insurance scheme for salaried employees, which covers 75 per cent of medical expenses.

SUBSCRIBING TO THE ASSURANCE MALADIE IS COMPULSORY. INDIVIDUALS MAY SUBSCRIBE TO ANOTHER HEALTH INSURANCE SCHEME IN ADDITION TO THE ASSURANCE MALADIE. IN 2006, 84 PER CENT OF THE POPULATION NOW SUBSCRIBES TO ONE, BECAUSE OF THE INCREASED FINANCIAL RESPONSIBILITIES FOR HEALTHCARE.

The national union of health insurers (Union Nationale des Caisses d’Assurance Maladie – UNCAM) – determines the reimbursement rates for medical consultations. If needed, the industry will be forced to develop new healthcare products to ensure the population's health and financial sustainability.

FOCUS ON

PHARMACEUTICAL REIMBURSEMENT

The French national health insurance system is based on the principle of solidarity. The pricing policy is being tightened, and studies of the long-term impact on the healthcare system at the population level will be necessary. The use of the product. Price, volume and healthcare system at the population level.

The proportion of people choosing to fund such studies, as happened with growth hormones and Cox-2 inhibitors. If needed, the industry will be forced to develop new healthcare products to ensure the population's health and financial sustainability.
BUDGET REFORMS

France's budget deficit, similarly to other countries, reached €23bn at the end of February 2008 for the first time since 1998. Furthermore, the deficit is growing at a rate similar to that of other western countries. France is aiming at saving €10bn per year in public spending between 2008 and 2011 in order to balance public finance by 2012. Of course, more public spending can be expected in 2009 and 2010 due to the French social security will have to contribute to this by saving up to €5bn per year. Earlier this year Woerth had mentioned plans to achieve this by creating new taxes, and by increasing the existing contributions.

Eric Woerth, the minister of budget and public accounts announced that already contributing through specific taxes that are not applied to other industry sectors (tax on advertising, tax on revenues, exceptional contribution on revenues of fast moving consumer goods, etc.). Such taxes have represented 4.9% of sales in 2005 and affects the profitability of the French pharmaceutical industry, which is already lower than in other major European countries.

FRANCEFOCUS ON

FRANCE

RENDERED MEDICAL SERVICE (SMR)

TABLE 1. TRANSPARENCY COMMISSION'S EVALUATION CRITERIA

<table>
<thead>
<tr>
<th>Classification</th>
<th>Reimbursement</th>
<th>ASMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>I  Major innovation</td>
<td>&gt;75% co-payment</td>
<td>-</td>
</tr>
<tr>
<td>II Important improvement</td>
<td>&gt;50% co-payment</td>
<td>-</td>
</tr>
<tr>
<td>III Moderate</td>
<td>&gt;25% co-payment</td>
<td>-</td>
</tr>
<tr>
<td>IV Minor</td>
<td>&gt;10% co-payment</td>
<td>-</td>
</tr>
<tr>
<td>V No improvement</td>
<td>0% co-payment</td>
<td>-</td>
</tr>
</tbody>
</table>

Based on:
• Direct/indirect comparative studies versus reference products
• Most sold, most recent or most expensive
• Sub-population targeted
• Indication
• Indication of the occurrence of a disease
• Sub-population targeted
• Efficacy/tolerance
• Efficacy and disease severity account for 90 per cent of the financial burden that reimbursement represents for the public healthcare budget.

Expenses linked to the organisation and the management of the healthcare delivery (over 3-5 years) is growing more slowly in value compared to the industry's turnover. Drug price cuts (introduction of a reference pricing in 2005) and a decrease in the allowed volume (but probably not the number) of products approved by the HAS (up of the early 2000s) and the prospect of a new mechanism to increase or decrease the reimbursement of healthcare products (introduction of the Conjonctivé, the Évaluation des médicaments, the Évaluation des technologies de santé).

Increasing pressure for the industry to invest in bigger and longer phase IV studies to judge the drug's performance in real life. More recently, initiatives to agree on precise, quantitative criteria to referencepricing gap (ASMR) and a decrease in the allowed volume (but probably not the number) of products approved by the HAS (up of the early 2000s) and the prospect of a new mechanism to increase or decrease the reimbursement of healthcare products (introduction of the Conjonctivé, the Évaluation des médicaments, the Évaluation des technologies de santé).

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Pharma is facing the lead taken by NICE. The public healthcare budget had a deficit of €8bn in 2007 but still a significantly lower than expected at the end of February 2008. Therefore, more public spending can be expected in 2009 and 2010 due to the French social security will have to contribute to this by saving up to €5bn per year. Earlier this year Woerth had mentioned plans to achieve this by creating new taxes, and by increasing the existing contributions.

The government plans to reduce the ASMR (Assurance Maladie) gap in 2008 by reducing the number of products reimbursed. The strategy is aimed at cutting costs will no doubt lead to removing more products from the list of reimbursed medications, which means that patients will have to pay more for the drugs they need.

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advisers undermined and 68 per cent fear that this new mode 'bad' or 'very bad'. Pharmacists see their role as
Pharmagora-Wolters Kluwer – showed that 84 per cent consider
201 pharmacists in February this year – conducted by Ipsos-
be made available on general sale in pharmacies in order to
January 2008, the minister for health, Roselyne Bachelot,
French people currently have low purchasing power and in

INDUSTRY OVERVIEW
The French pharmaceutical industry is worth €42.4bn – 43 per cent of this is from exports. France's share of the global market is 5.6 per cent, placing it third. GlaxoSmithKline leads the 23,000
5,100 products are available for 10,000 conditions and diseases. There are an estimated 22,600 drug stores.
84 per cent consider the future of the country, placing it third. France has the top 500
every year is estimated at €3bn. Mylan, GSK, AstraZeneca and Bristol
Sanofi-Aventis leads with 15 per cent market share. Other companies such as Pfizer,

Distribution
Generics
Hospitals
Consumption of medications per head in 2005 was valued at €500. In 2006,
turnover. Generics are worth 8.6 per cent, and cancer 6.7 per cent.
8.6 per cent, and for cardiovascular conditions 21.3 per cent. Generics make up
15.5 per cent and digestive conditions 13.7 per cent. Anti-infectives make up
5.6 per cent, and neurological conditions 8.2 per cent.

Table 2: Top 10 Primary Care Drugs in France

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plavix</td>
<td>Platelet aggregation inhibitor</td>
</tr>
<tr>
<td>Tahor</td>
<td>Cholesterol-lowering agent</td>
</tr>
<tr>
<td>Arétide</td>
<td>Asthma and COPD therapy</td>
</tr>
<tr>
<td>Lyum</td>
<td>Protein kinase inhibitor</td>
</tr>
<tr>
<td>Aricept</td>
<td>Alzheimer's disease therapy</td>
</tr>
<tr>
<td>Symbicort</td>
<td>Asthma therapy</td>
</tr>
<tr>
<td>Glivec</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Elixis</td>
<td>Cholesterol-lowering agent</td>
</tr>
<tr>
<td>Enbrel</td>
<td>Rheumatoid arthritis therapy</td>
</tr>
</tbody>
</table>
### SUMMARY OF REFORM INITIATIVES

The government's priorities include:

- Increasing the roles of individual responsibility;
- Making provision of healthcare more efficient and uniform across the country;
- Easing access to innovation in oncology, Alzheimer's disease and palliative care.

#### Primary care

- Patients get less reimbursement for consultations with specialists if they bypass the 'médecin traitant' system and 80% of French people have now chosen their GP for this role.
- Generic penetration was 17% by volume in 2006, which is low compared to 60–80% in some EU countries. The campaign to raise generic prescribing initially focused on antibiotics and statins, followed by proton pump inhibitors and now anti-hypertensives. Future contracts for GPs will contain incentives to prescribe generically.

- An electronic patient records system is expected to be initiated soon with the aim of improving coordination and efficiency of care.
- Promotion of GP group practices and moves for more uniform healthcare country-wide is also underway.

- **Patient co-payments.**
  - Most patients pay €1 per medical procedure and, since January 2008, €0.50 per box of prescription medicine up to a cap of €50 annually. These measures have been criticized for penalizing the less well off and may lead to poor health outcomes.

- Other initiatives discussed, but politically sensitive and unlikely to happen in the near future, include:
  - The creation of a healthcare shield to allow automatic public reimbursement when the patient has reached a certain level of out-of-pocket expenses;
  - Reduced reimbursement level for chronic diseases – currently capped at 100%.

#### Hospitals

- The shift towards funding based on level of service provision and tariffs for diagnosis-related groups should be fully implemented within a few years. The system has flexibility to allow funding of expensive, innovative drugs.

- New regional agencies (Agences Régionales de Santé) will likely transpose the central governance model, aiming for more effective management and control of hospital prescribing, rather than devolving funding to the regional level.

#### Cost-effectiveness

- The approach of the Haute Autorité de la Santé (HAS) is expected to evolve to a position closer to that of the German IQWiG (rather than the UK's NICE) – using cost-effectiveness analysis but without absolute thresholds to award funding.

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**TABLE 3. TOP 10 DRUGS IN HOSPITALS**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herceptin</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Taxotère</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Mabthéra</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Rémicade</td>
<td>Immunosuppressive agent</td>
</tr>
<tr>
<td>Avastin</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Erbitux</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Eloxatine</td>
<td>Cancer therapy</td>
</tr>
<tr>
<td>Advate</td>
<td>Haemophilia A therapy</td>
</tr>
<tr>
<td>Tegeline</td>
<td>Immunoglobulin, immunomodulator</td>
</tr>
<tr>
<td>Campto</td>
<td>Cancer therapy</td>
</tr>
</tbody>
</table>

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**Author:**

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