FRANCE

PHARMACEUTICAL PRICING AND REIMBURSEMENT

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1. Overview of the health care system

The French population is almost universally covered (99% of the population) by statutory health insurance (Assurance-maladie), a branch of the social security system (Sécurité Sociale). Affiliation to Assurance-maladie is by means of different schemes, determined by the individual's social and/or professional category. The main scheme, the Regime General, covers employees and pensioners from trade and industry sectors, as well as their families and, thus, accounts for 80% of the French population. The Regime General is financed mainly by payroll contributions made by both employers (12.8% of gross salaries) and employees (6.8% of gross salaries). In addition to the statutory health insurance scheme, 87% of the population are members of voluntary, supplementary sickness funds (mutuelles), or purchase private insurance, which serves to complement the statutory health insurance and covers [some of] the charges, and services that the latter does not reimburse.

Within the system of Assurance-maladie, patients have freedom of choice and can consult any doctor at any time and also have direct access to specialists — although currently implemented policies aim at giving general practitioners a ‘gatekeeper’ role. Doctors are predominantly in private practice and are paid on a fee-for-service basis, according to a negotiated fee schedule. Approximately 30% of these doctors (Secteur 2) can exceed these fees. Patients are also free to choose between state and private establishments of secondary care; sickness funds cover at least the treatment costs in both cases, and the balance is paid through supplementary insurance. Initially, patients pay the provider directly and are reimbursed later, subject to a cost-sharing scheme (ticket-moderateur). Co-payments vary depending on the nature of the service provided and the type of patients' needs.
2. Pricing of pharmaceuticals

A pharmaceutical company may set its own price for a drug that has received marketing authorisation. For this to be reimbursed by the national health insurance fund, i.e. Caisse Nationale d’Assurance Maladie (CNAM), reimbursement status must be granted by Commission de Transparence (Transparency Commission), and a reimbursement price negotiated with Comité Economique du Médicament (CEM) All registered pharmaceuticals are subjected to Evaluation of Therapeutic Benefit (Amélioration du Service Medical Rendu, or ASMR), that is expressed as a classification between 1 & 6, as follows:

1 = innovative product of significant therapeutic benefit
2 = product of therapeutic benefit, in terms of efficacy and/or reduction in side effect profile
3 = already existing product, where equivalent pharmaceuticals exist; moderate improvement in terms of efficacy and/or reduction in side effect profile
4 = minor improvement in terms of efficacy and/or utility
5 = no improvement but still granted recommendations to be listed
6 = Negative opinion regarding inclusion on the reimbursement list

The ASMR evaluation is based on the expert judgement of the Transparency Commission of the Pharmaceutical Agency (Agence du Medicament). In France, medicines may only be sold at one price; when reimbursement status is obtained and accepted, the price negotiated with CEM becomes the price at which the drug is sold throughout the country, even for private prescriptions.

2.1. The Framework Agreement (Accord Cadre)

As a rule, the prices of reimbursable pharmaceuticals are fixed by the state; over the past three years, however, price fixing has been determined to a great extent by negotiations. The prices of reimbursable pharmaceuticals are determined by the interministerial Economic Pharmaceutical Committee (CEM) after negotiations with the manufacturers and can be fixed in contracts between the CEM and the pharmaceutical company in question. The price depends on
• the ASMR evaluation
• the relevance of the respective pharmaceutical in the market (valuated by the number of packs sold)
• the research expenditure, and
• the advertising costs of the manufacturer

Pharmaceutical companies requesting a reimbursement price for a new drug are requested to provide the prices of that drug in other EU member states. There is no formal mechanism of setting the price of a drug in France on the basis of its price in other European countries. However, CEM is sensitive to accusations that prices in France are low compared to those elsewhere in Europe, and is prepared to bring launch prices closer to the European average.

The system of price determination is based on a framework agreement (accord cadre) between the State and the pharmaceutical industry, which in 1994 replaced the price regulation by the State (which had been in use for 25 years). In the accord cadre, manufacturers committed themselves to limiting their advertising expenditures and to inform doctors on a "rational use" of the pharmaceutical in question. This voluntary restriction by the pharmaceutical industry is a pre-requisite for higher selling prices. Any violation by manufacturers of these principles results in the State setting a price as before 1994, i.e. reverting to price regulation, with the price level being lower than before. Prices of reimbursed drugs may not be changed without the authorisation of CEM. Price reductions can be imposed if the sales of a medicine surpass the volumes set out in a price–volume agreement. There are limitations on the industry's promotional expenditure.

For non-reimbursable and hospital-exclusive pharmaceuticals the price regulation by the State was abolished in 1987. For pharmaceuticals in the hospital sector, manufacturers may submit a tender to hospitals, taking into consideration volume variations.
The 1998-99 social security financing bill, has several important implications for pharmaceuticals. The bill focuses on promoting generics and generic substitution from January 1999, and rationalising the reimbursement system. Reimbursement will be focused on "products whose medical efficacy is proven", and the criteria for reimbursement will be reviewed to take account of the seriousness of the disease and the medical advantages of the product. The government is also poised to pursue an active price policy for innovative medicines, in order to encourage research by French pharmaceutical companies. In particular, the following are being implemented:

Firstly, article 24 of the bill says that the price committee is to monitor pharmaceutical spending on a continual basis to ensure that it is in line with the annual target for national health insurance spending. This would involve at least two annual evaluations of spending trends, after the fourth and eighth months. If these checks showed pharmaceutical spending to be out of line with the overall spending target, the committee would decide what steps to take. It could, for example, tell a company to cut the prices of its reimbursed products (as set under its pricing contract) and publish the new prices in an annex to the contract. If the company refused, the contract could be rescinded, the bill says. This represents a radical departure from the spirit of the pricing system as originally envisaged, which was to have a collaborative price negotiation scheme giving companies a long-term stable framework within which to operate.

Secondly, the bill sets that contracts will be for a maximum of four years, and will cover the price of a company's products and, where applicable, fluctuations in these prices, particularly in terms of commitments on volume sales. It will also cover any rebates payable on excess volumes, and includes commitments on curbing promotional spending in order to ensure the proper use of medicines and meet volume sales commitments.

Thirdly, price-setting will be based on the product's medical value, the prices of comparable medicines, sales volume commitments, and the conditions in which the product is used. Initially, the bill also provided for a payback mechanism on any sales over the annual target which would apply to companies that had not signed contracts (Scrip No 2374, p 3). However, the French Parliament adopted an amendment making
all companies subject to the spending payback clause. Adopting the bill at first reading on October 30th 1998, the Assembly took on board an amendment by the social affairs committee under which companies that have signed pricing contracts will no longer be exempt from the payback clause. This means that companies must pay back a proportion of their annual sales and sales growth whenever health care spending is over target. Companies will therefore need to weigh up the drawbacks of signing a contract against the possibility of having to pay back a proportion of their sales each year if spending is over target.

Fourthly, article 26, suggests that the industry would make the 1998 financial contribution to the social security by way of a one-off payment. The payment was based on three factors: industry's French sales of reimbursed products in 1998; any increase (over 2.3%) in these sales compared with 1997; and promotional spending. The payment is due by August 31st 1999.

The new pharmaceutical pricing system places more emphasis on the real therapeutic value of products and far less on price/volume trade-offs as a way of restraining prices. In a firm break with the past, the pricing system no longer includes commitments on overall sales, nor is the use of price/volume contracts anywhere as systematic. Such contracts, where companies agree to price cuts when volume sales forecasts are exceeded, will be used only exceptionally. They could, for example, be used for products whose consumption was expected to be very high or which risked being used for un-approved indications - if this happened their price would be cut. Where companies claim higher prices for "innovative" products, the pricing committee will be looking for evidence that this translates into clear clinical improvements over existing products judged to be similar. The product will then get a price that reflects those of similar products in other countries in Europe. Assessing NCEs where no similar products are marketed elsewhere in Europe will be more difficult. For this reason, a group of pharmacoeconomics experts is being set up to look at the possibility of using such studies as a pricing criterion. The new group, which will be independent of the Transparency Commission, is needed because the pricing committee has little experience of such studies. Initially it will only look at the possible use of pharmacoeconomic studies for pricing purposes, but later it may also
be able to offer advice to companies wishing to use such studies as a support in their pricing talks.

The committee will be reviewing reimbursement with three criteria in mind:

1) Should the products still be reimbursed?
2) If so, at what level? and
3) Are the products' prices still justified in view of therapeutic progress?

The committee will be taking a much stricter approach to the reimbursement of pharmaceutical products in general, and the scale on which therapeutic progress is assessed (the ASMR rating) will be tougher. The national health insurance agency, the CNAM, will have a seat on the committee. As an "informed purchaser", the CNAM is expected to be tough on pricing and reimbursement issues.

2.3. Prices of generics

In November 1998, the government imposed sharp price cuts of almost 50% on some generic products, after the manufacturers failed to reach agreement on the cuts with the pricing committee by the 30th September 1998 deadline. The government issued a decree cutting the prices of 37 generic products. Generics companies had until the end of September 1998 to cut prices to 30% below those of the original, as set out in relevant legislation, or have the cuts imposed.

Some manufacturers have 'voluntarily' reduced the prices of a number of other products (published in the Economy Ministry's official bulletin). All 459 generic products on the most recent generics' list published by the Medicines Agency in July 1998 are now priced at least 30% below the original.

Separately, the two pharmacists' associations have drawn up proposals on remuneration to try to ensure, among other things, that they do not lose out financially when dispensing generics. The problem lies in the fact that, under the present margin system, pharmacists are discouraged from substituting generics for the original
because the mark-up is lower for generics. One proposal is that pharmacists would apply the same absolute (i.e. financial) mark-up on the generic as on the original.

2.4. Price revisions for generics

The government issued a decree in October 1998 cutting the prices of 37 generic products after the manufacturers concerned failed to reach agreement on cuts with the pricing committee. In July 1998, the Solidarity Ministry gave companies marketing generics until September 30th 1998 to cut their prices to 30% below those of the original products, as required by current legislation, or have the cuts imposed. Under current legislation, all versions of out-of-patent original products must now be marketed either with the INN plus the company name or with the suffix "Ge" added after the fantasy name.

2.5. Pricing of Hospital pharmaceuticals

A pharmaceutical company may apply to the Commission de Transparence for a drug to be granted approval for professional use, which really means hospital use. Once it has been approved the drug can be priced freely. As a price does not have to be granted, CEM is not involved. It is, however, planning to investigate the prices of drugs initially sold as hospital only but later also made available through pharmacies, such as protease inhibitors. It is unlikely though that CEM will as a result intervene in the pricing of pharmaceutical products.

3. Reimbursement

In France there are two lists of reimbursable pharmaceuticals: one list of reimbursable pharmaceuticals for the sales by pharmacies (liste des medicaments remboursables agreees aux assure sociaux) and a list for the hospital sector (liste des medicaments agreees aux collectivites).

Reimbursement recommendations are based on the determination and assessment of three elements:
- The medical benefit obtained by the drug, called “Service Médical Rendu” or SMR
- The improvement of the SMR that is offered by the drug compared to alternatives and gold standards. This is called “Amélioration du Service Médical Rendu”
- The identification and definition of a therapeutic strategy.

The therapeutic relevance of each drug submitted for reimbursement status is assessed by the Transparency Committee. Its findings are passed to the CEM, which sets the reimbursement price and level of all drugs. It holds discussions with the company involved, but its deliberations are private and the reasons for its conclusions are not disclosed. CEM does not have to accept the recommendations of the Transparency Committee.

Medicines granted reimbursement status are assigned to one of three rates based on Commission de Transparence recommendations. The rate depends on the main indication of a product, rather than its degree of efficacy or cost:

- 100% for medicines used in life threatening conditions — approximately 100 products have obtained this rate (white barred price labels). Drugs in this category include agents against diabetes, AIDS, cancer, chronic diseases, and hospital-only pharmaceuticals.
- 65% for reimbursed drugs not included in one of the other two groups (white price labels, for example, antibiotics, pharmaceuticals against certain infectious diseases).
- 35% for drugs mainly used for non-serious conditions and disorders (blue price labels, for example, a number of acute conditions).

More than half of the registered pharmaceuticals for human use are classified as reimbursable and the reimbursement rate for the majority of them is 35%.

3.1. The SMR

The SMR is a criterion for the reimbursement decision. Several characteristics of the drug are taken into account in the definition of a SMR.
Efficacy (or effectiveness) and side effects

Characteristics of the disease (severity, chronic disease or not, preventable disease or not)

Existing alternative therapies and the role the drug within the overall therapeutic strategy.

Public health impact

The level of reimbursement is based on the SMR classification of a drug. A drug with a major or important SMR can have a reimbursement rate of 65% while a drug with a moderate or low SMR can have a reimbursement rate of 35%.

3.2. The ASMR

As it has been already mentioned in the pricing section, all registered pharmaceuticals are subjected to Evaluation of Therapeutic Benefit (*Amelioration du Service Medical Rendu*, or ASMR), that is expressed as a classification between 1 & 6. One is given to innovative products of significant therapeutic benefit, while 6 is given to those products that are not considered eligible to be included in the reimbursement list.

3.3 The therapeutic strategy

The aim of the therapeutic strategy is to identify and recommend the situations in which the drug should be preferentially used considering other similar drugs. It also estimates the size of the population group that this medicine will be relevant to. For the re-inclusion of a pharmaceutical product in the reimbursement list (a process that takes place every 5 years), prescription profiles are analysed in order to assess whether the drug has been correctly prescribed.

In general, information on the budget impact of a drug is required. In this context, pharmacoeconomic studies can be considered. A pharmacoeconomic group has been created by both directors of AFSSAPS and of the “Comite Economique des Produits de Sante” which are responsible for reimbursement and pricing decisions respectively. A group of five experts in economic evaluation gives advice on the quality of the
materials and the methods used in the pharmacoeconomic study but also on the relevance of their results in assisting reimbursement of pricing decisions.

The Commission also evaluates new and expensive products in terms of their clinical and economic benefit. For this type of drugs, the Commission must define in a specific document called “Fiche d’Information Therapeutic” or FIT the restrictive conditions with respect to the reimbursement of the pharmaceutical. Prescribers are required to give a written undertaking to comply with those indications. In case of non-compliance with the FIT, the drugs can not be reimbursed.

3.4. Body responsible for reimbursement decisions

The Commission of Transparence is responsible to reassess pharmaceutical every five years in order to decide their inclusion or not in the reimbursement list. Its 18 members are appointed by the Minister of Health.

The composition of this committee is as follows:

The chairman
The vice chairman
A representative of the Department of Health
A representative of the Department of Social Security
A representative of the AFSSAPS
A representative of the National Association of Physicians
A representative of the National Association of Pharmacists
4 representatives of the Third Party Payers (2 for CNAMTS, 1 for the MSA and 1 for the CANAM)
A representative of the National Syndicate of Pharmaceutical Firms
6 experts chosen according to their medical, scientific, or economic expertise.

3.5. Patient co-payments

There are three levels of co-payments for reimbursed pharmaceutical products. These are:
• 0% for medicines used in life threatening conditions, and particularly expensive: approximately 100 products have obtained this rate (white barred price labels)
• 35% for all reimbursed medicines that do not qualify for either of the other two rates (white price labels)
• 65% for medicines mainly intended for non-serious conditions and disorders (blue price labels)

Patients afflicted with one of 30 specified long-term diseases, or the ‘31st disease’, ie another serious disease for which a special request has been made to Sécurité Sociale and accepted after examination of the patient’s medical file, are exempt from co-payment of all medicines relevant to their condition. Patients afflicted by multiple diseases, such as those suffering from HIV and AIDS, are exempt from all co-payments. Regionally funded medical assistance is available to those who cannot afford their co-payments.

4. Health economic evaluations

Guidelines are being prepared by Commission de Transparence regarding the conduct of health economic studies. Once these are published, the benefits and cost of the medicine under consideration may be taken into account by CEM. In April 1999, CNAM announced the formation of a committee to develop pharmacoeconomic guidelines that would be used in pricing and/or reimbursement decisions (see section on pricing).

5. Paying Providers

Practitioners’ fees for each medical act are determined by the medical convention to which they belong and their speciality. The very few practitioners (less than 1%) who are members of a convention can charge as much as they like. While there has been a little monitoring of what is prescribed, the number of checks has been increased since the introduction of practice guidelines. These are described in the next section.
5.1. Targets for French "Gate-keeping" GPs

A significant step forward in the French health care reforms was made when the general practitioner union, MG-France, signed its contract with the national health insurance agency (CNAM). The contract brings about significant changes in the delivery of health services in the ambulatory sector. At present, there is freedom of choice and patients can see any number of doctors as often as they want, whether GPs or specialists. Fees charged by specialists are usually higher than those of GPs, as are their prescribing levels. This is generally agreed to be a major contributor to France's high per capita drug consumption compared with other EC countries. In addition, GPs may not know which drugs a specialist has prescribed, and vice-versa, leaving the way open to drug interactions.

The new agreement is intended to address this problem and to help rationalise both prescribing and spending. To ensure continuity of care, doctors entering the system will keep a patient dossier recording all treatment, consultations, referrals, etc. Protocols for monitoring treatment will be drafted by the national health evaluation agency (ANAES) and the Medicines Agency. Participating GPs will also be expected to prescribe generics wherever possible. Doctors will also be encouraged to install computer systems as prescribing aids and sources of medico-economic information, with financial assistance from the government.

The contract, which was signed on November 26th 1998 after lengthy negotiations, will reorganise the relationship between GPs, their patients and health insurers, and better co-ordinate the activities of health professionals. It is aimed at promoting better quality of care while making the best use of available resources. It is based around the concept of the "gatekeeper GP", under which patients can volunteer to register and stay with one GP, receiving in return benefits such as dispensation from prior payment of the doctor's fee (and possibly higher reimbursement rates).

GPs get a yearly allowance per registered patient (payment by capitation), and agree to ensure that 15% of the value of their prescriptions is for cheaper products, including 5% of generics. GPs also agree to take part in training programmes, play a bigger role in disease prevention, respect prescribing and other guidelines, and
transmit treatment forms to the insurers electronically. They will have to ensure that their spending is in line with the annual health care insurance spending target (ONDAM). A pay-back scheme for excesses over ONDAM was proposed by was abolished in December 1998. The contract is part of a wider drive by the government to have more control over how doctors operate; its signing came after protracted bargaining between GPs and insurers.

The essence of the scheme is that patients can register with a "reference" GP, whom they will consult initially for their medical care. In return for registering with a GP, a patient will only have to pay FFr33 of the standard fee of FFr110. Registration with a GP will be voluntary, and patients can change GP or opt out at any time. They can also consult another doctor or specialist but then they will not benefit from the pre-payment exemption. Doctors will also receive an annual payment per patient, which had been set at FFr 150 for 1998. GPs who use IT services under the terms of a protocol to be agreed by the signatories to the agreement would receive an additional FFr 30. This is likely to cover "prescription supports" involving the use of databases, particularly of pharmaceutical products; electronic transmission of medical recommendations and the prescribing guidelines; and feedback to GPs of medico-economic information relating to their practice.

The government also wanted specialists on board, but they are refusing to sign a contract with the insurers unless the government radically changes its approach. They reject the idea of subjecting their activities to a financial target and of having sanctions if spending is over target, claiming that the GP contract restricts the freedom of choice of both the doctor and the patient.

5.2. Positive and negative lists

A positive list is in operation in France; only those medicines that are added to it have reimbursement status. The government objective of stabilising national health insurance expenditure will entail a constantly evolving positive list of reimbursable drugs. As innovative medicines with therapeutic advantages are launched and added to the positive list, older, less cost effective drugs to the same value will be removed.
The drugs to be removed from the list will be selected during the periodic registration and pricing reviews.

5.3. Prescribing guidelines

As part of their last five-year agreement with Sécurité Sociale, doctors have agreed to apply références médicales opposables (RMOs), or a range of techniques and treatments, in everyday practice. In exchange, they have been granted a more generous annual growth rate for their fees. Guidelines take the form of negative recommendations.

All primary care physicians are required to mark patients’ records and prescriptions with either an R, if the RMOs have been followed, or an HR (hors référence) if treatment falls outside RMO scope. Random checks are made by Sécurité Sociale and there is provision for financial penalties where the guidelines are breached. Some doctors have been fined, but in general doctors prefer to adhere to a system that is based on good medical practice instead of risking the likely introduction of prescribing budgets.

Prior authorisation from Sécurité Sociale will soon be required before doctors are allowed to prescribe particularly expensive drugs or drugs that are subject to specific restrictions. Exceptional products, innovative and very costly medicines — mainly those that were originally restricted to hospital use — must be prescribed on a special form and are subject to particular checks. Guidelines concerning their use are to be issued by Commission de Transparence.

To improve monitoring and provide reliable data with which to assess physicians’ prescribing, there are plans to extend the computerisation of medical practices and prescription data processing system. All records will be anonymous to protect patients’ and doctors’ constitutional right of privacy.
6. Generics and parallel trade

Up to 75% of pharmaceutical expenditure in France is of active ingredients the patent of which has expired. Generics account for about 2% of the value of the total market because:

- Up until recently pharmacists did not have the right to substitute medicines
- Older medicines on the market typically have a low price
- Prescriptions are generally written using brand names
- No incentives are offered for prescribing or dispensing generics

When negotiating their framework contracts, pharmaceutical companies are encouraged to offer to market generics, not necessarily of their own molecules. As a result several companies have launched generic drugs. These have to be priced at least 20–30% lower than the price of the original drug if they are to benefit from reimbursement.

Generics can be sold either under their INN/DCI designation (generic name) or a brand name. Whichever name is chosen, it must be followed by a suffix identifying the supplier, either manufacturer or importer. Under these conditions, the sale of generic medicines will only grow if pharmacists have the right and the incentive to substitute, or physicians have an incentive to prescribe them.

Pharmacists have agreed with the government on generic substitution, a new mark-up system, changes to the geographical limitations on new pharmacies (numerus clausus), continuing education, and a contract with the national health insurers. Their association signed an agreement with the government in autumn 1998. Substitution would occur by the pharmacist for products with the same active ingredient, the same dosage and the same pharmaceutical form.

The mutuelles have for many years conducted a campaign aimed at persuading doctors to prescribe the cheapest version of interchangeable drugs. Companies marketing generics have also launched campaigns aimed at increasing doctors’ awareness of how prescribing generics can help reduce costs. France is a source of
parallel exports. The level of parallel trade from France is likely to diminish if the system whereby companies have a higher nominal price and pay a rebate to the government becomes widespread.

7. OTC products

OTC products and all those which are not reimbursed can be priced freely. Retail price maintenance and even printing the price on the pack are illegal. Traditionally, the French consulted physicians and were prescribed large amounts of subsidised medicines when ill. They were less used to selecting and paying for drugs. This is changing. In 1995, patients selected and paid in full for 18% of all drugs sold outside hospitals. About two-thirds were non-reimbursable and the remainder medicines which would have been reimbursed had they been prescribed.

8. Margins for wholesalers and pharmacists

There are no dispensing incentives for reimbursed drugs. Currently, pharmacy margins are regulated, as is the maximum discount that wholesalers can offer.

Wholesalers are allowed to add a mark-up of 10.74% on the ex-factory price for pharmaceutical specialities, or a margin of 9.7% of the pharmacy purchase price. However, they must pay a levy of 1.2% of pre-tax sales to social security, and so their margin is only 8.5%. Wholesalers are restricted to granting pharmacists a maximum discount of 2.5%.

Pharmacy margins are regressive and are calculated on the basis of three bands:

- for ex-factory prices FFr 0 – FFr 10;
- for FFr 10 – FFr 200; and
- for over FFr 200.

The central band, which covers 90% of reimbursable products, attracts a pharmacy mark-up of 26.42% on the ex-factory price. Scaling coefficients of 2.5 and 0.2 are
applied to prices in the lowest and highest bands, respectively. Therefore the pharmacist’s margin can be between 8.28% to 44.83% of the ex-factory price.

In France, VAT is added to the cost of all pharmaceutical products, whether reimbursed or not, at a rate of 2.1% for prescription medicines and 5.5% for non-prescription drugs, compared to a standard rate of 18.6%. France has officially been reprimanded by the European Commission twice (1995 and 1996), because its reduced VAT rate of 2.1% is regarded as too low and, according to the EU, is used in a discriminatory way.

9. Hospital procurement

The purchase of products for hospitals is carried out by the hospital pharmacist. In some major hospital buying groups, a committee composed of physicians, pharmacists and hospital managers determines drug needs and supervises their purchase. The government is keen to promote efficient buying and has issued guidelines specifying how to issue tenders and specifying the type of tender required according to the value of the purchase. Economic studies may be used to estimate the relative value of alternative drugs, but the drug selection committees are mainly interested in elements that directly impinge on their budgets and on the outcomes of hospital treatments. Hospital agreements are monitored by the Ministry of Health for anti-competitive practices.


Medical products that have received a marketing authorisation approval can be sold only in pharmacies.

In France there are two companies that cover the whole of the country and deliver pharmaceutical products to the patient’s house. A courier goes to the patient’s house, gets the medical prescription, then takes it to the pharmacy to be dispensed and finally delivers the drugs to the customer’s house. This mechanism has caused the uproar of the pharmacists. In February 1993, the Central Council of the Pharmacist’s
Association suggested that home delivery violated the Pharmaceutical Act and de-
personalised the pharmaceutical dispense process. Subsequently, the public health
code was forwarded to those companies, and some pharmacies boycotted them by
refusing to sell drugs to the couriers of those companies. The Competition Council
and the Supreme Court have ruled that neither the pharmaceutical association nor the
regional councils have the right to call upon the regulation of the public health code in
order to benefit from an exoneration of the competition right.

11. The carte vitale

The Vitale smartcard, is a plastic card which is gradually replacing the paper card of
social insurance. The card contains confidential data, namely name of the insuree,
social security number, their sickness fund, list of their dependents/beneficiaries and
their date of birth, details on rights and benefits (dates, rates, duration, etc), and rights
to mutual providers. The card, was introduced in the Ile-de-France region (of which
Paris is the capital) in March 1999, having already been implemented elsewhere in
France. It will then be introduced in the French overseas territories of Martinique,
Guadeloupe, Guyana and Reunion. Patients use the Vitale card when claiming
reimbursement for medical expenses; 28 million have already been distributed, out of
a forecast 36 million. A second generation of cards is scheduled for introduction in
2001, which will probably carry additional information such as the patient's medical
treatment history.

The Sesam-Vitale system, which allows electronic transmission of prescribing data
from pharmacies to the insurers, is an intrinsic part of the government's drive to have
reliable information on which drugs are being prescribed for whom, so that it can take
steps to control pharmaceutical spending more effectively. It would involve all
pharmacies being equipped with at least four computer terminals.

Currently, the carte vitale is not used in all regions of France. Two of them (Brittany
and the Paris Region) have been experimenting with the card since January 1999.
Health care professionals must purchase equipment and relevant materials in order to
link themselves up with the insurance funds during the forthcoming months.
The *carte vitale* serves as a means of identification for patients that present themselves to a medical facility (consultation with a doctor, at the hospital, at the pharmacy, for physiotherapy, for medical transportation, etc). The card is placed into a reader and whoever provides services to the patient knows immediately the patient's identity, health status and rights. All services provided are entered into a computer and are then transferred onto the card (previously written on the paper version of the card) and are communicated with the insurance fund.

Payments are conducted as before, by the fund directly to the provider and the flow of monies is immediate. For patients that benefit from paying only a third of their fees/co-payments, with the difference being paid directly by the fund to the medical practitioner or the pharmacist, the fees will be paid to the providers by the fund. If the patient belongs to a civil service *mutuelle*, all the necessary information is transmitted to the mutuality, and the latter reimburses the patient.

### 12. Information systems

Computerisation of doctors' surgeries was made compulsory in April 1996. In order to provide quicker and more accurate claims processing, as well as giving the health ministry, insurers and doctors more information on prescribing and treatment trends, the government decreed that all doctors would have to transmit and receive electronic health insurance claims by the end of 1998. If, by 2000, they are still submitting paper claims, they will incur financial penalties. The backbone for insurance claims will be the Sesam Vitale system, which relies on a combination of smartcards and networks for claims transmission and reimbursement. Claims will be generated using the patient's insurance smartcard, Vitale, and the doctor's or pharmacist's smartcard, known as the CPS. Claims data will have to be transmitted across a network (the Sesam component.

The use of medical data remains a problem area, not only in terms of patient confidentiality, but also in terms of doctors' prescribing freedom. The sale of prescription data was explicitly prohibited in 1996 reforms unless it is anonymous,
with regard to the prescribing doctor as well as the patient. This ruling was pre-empted by the CNIL's decision that Walsh International and the pharmacists' association, FSPF, could only package prescription data for their Pharmastat system if doctors' ID codes were removed.