

*Cahiers de recherche*

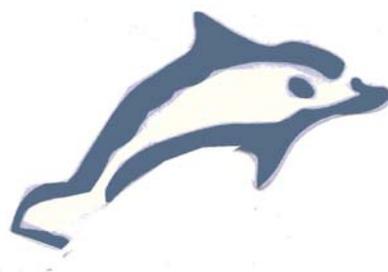
**EURISCO**

*cahier n° 2003-01*

***Moving beyond a drug budget mentality :  
the french case***

*par*

***Claude Le Pen***



EURISCO, Université Paris Dauphine

email: [eurisco@dauphine.fr](mailto:eurisco@dauphine.fr), site web: <http://www.dauphine.fr/eurisco/>

## **Moving beyond a Drug Budget Mentality: The French Case**

Claude LE PEN  
EURISCO-LEGOS  
University of Paris-Dauphine  
75116 – Paris – France  
e-mail : [claude.lepen@dauphine.fr](mailto:claude.lepen@dauphine.fr)

### **Abstract :**

Since 1996 The French health care system is committed to a complex system of budgetary constraints which applies to the health insurance expenditures as a whole, but also to each of its components, especially hospital expenditures and pharmaceutical expenditures. As the targets are set by reference to the GDP growth while health care expenditure is driven by demographic factors, technology and expectations there is inevitably a gap between the top-down budget and the bottom-up cost pressures. The pharmaceutical budget is achieved by a payback system which “taxes” companies when the growth target for aggregated pharmaceutical expenditure is exceeded. This system produces a perverse incentive for companies to heavily promote new products in the knowledge that the budget overruns will be spread across all companies. Besides it lacks incentives to use pharmaceuticals efficiently. The government is now seeking to set more realistic overall global budgets and for pharmaceuticals in particular. It is also encouraging generics, delisting from reimbursement drugs of limited therapeutic value, making a special budget for new drug purchase available to hospitals, and replacing price control for innovative products with a more selective process of intervention in the expectation that companies will seek to price at a European level. Although these measures will increase the efficiency of pharmaceutical expenditure, it is not apparent that they change the poor incentives facing doctors, hospitals and insurers to use pharmaceuticals cost-effectively to achieve the optimal gain in health care. They will not remove “silo budgeting” effect at the national level for pharmaceuticals which inhibits the efficient substitution of drug therapy for hospital treatment.

### **Keywords:**

France, Drug Policy, Health Care Budgets, Health Policy, Health Insurance, Health Care Expenditure

**JEL Classification:** I11 – I18

*This paper was commissioned by the International Society of Pharmacoeconomics and Outcome Research (ISPOR) as part of its project "Moving beyond a Drug Budget Mentality in Europe". It will be published in a special issue of Value in Health in 2003 (edited by Bengt Jonsson and Mike Drummond) along with other papers from Germany, Italy, The Netherlands, Spain and UK.*

## **1. The French Drug Market**

France<sup>1</sup> is known as being one of the western countries which devotes a large part of its GDP to health care. According to OECD Health Data, the ratio of Total Health Expenditure to GDP was 9.5% in 2000, which was beaten only by the USA (13%) and Germany (10.6%). Various economic as well as institutional factors explain this position. France in fact combines a high per capita GDP and a Social Health Insurance system, which are both factors generally associated with high health expenditure rates (1).

The share of pharmaceuticals in total health care is was 20% in 2000, which was also high compared to the OECD average. This is a common feature of the southern European countries. Total drug consumption in France was about 27.3 billion Euros in 2000, and the total turnover of the pharmaceutical industry, 31.5 billion Euros (2). The average per capita expense is one of the biggest among western countries (448 Euros in 2000).

The French drug market is a low price and high quantity market. A recent study computed a series of price and quantity indexes, from IMS 1997 data, comparing the USA to different European countries for a set of identical products: the resulting (Laspeyre) quantity index was more than 2 for France compared to the USA whereas the (Laspeyre) price index was 0.5. The corresponding figures are 1 and 0.9 for UK and 1.1 and 0.9 for Germany (3). The market share of homeopathic and herbal products is high compared to other countries. The market for plant extracts products, mainly produced by small family companies, is also high. Finally, the generic drugs market share is about 3.5% (2001) of the total market, which is low compared to the UK, Germany or the USA. In fact, prescription and reimbursement conditions create little incentives for generic consumption in France.

In France, as in most other western countries, drug costs have continuously risen more rapidly (nominal growth rate was 8% in 2001) than the costs of other health care sectors (total health care expenditure growth rate was about 5.7% in 2001). This growth is ascribable neither to the quantities of consumed drugs which grow slightly (+ 1.6% in 2000) nor to the prices of the existing drugs which rather tends to lower (-0.7% in 2000). It explains primarily by the launching of new innovating products which replace the old ones and which, for various reasons, are often much more expensive.

---

<sup>1</sup> I thank Adrian TOWSE, Bengt JONSSON and Mike DRUMMOND for helpful comments on an earlier draft. I am of course the only responsible for all remaining mistakes, errors and omissions

## 2. Health Care Financing

### *Health Funds*

France has a Social Insurance System in which health insurance is mainly provided through sickness funds independent from the state and financed through social contributions, equally shared between employers and employees. Agricultural workers (salaried and farmers) and independent professions (such as self-employed workers, shopkeepers, and lawyers) have their own fund (respectively the MSA, "*Mutualité Sociale Agricole*", and the CANAM, "*Caisse d'Assurance-Maladie des Professions Indépendantes*"), separate from the general wage-earners sickness fund (The CNAMTS, "*Caisse Nationale d'Assurance-Maladie des Travailleurs Saliés*"). This latter reassembles nevertheless about 80% of the total population. Apart from these three main funds, others minor funds cover some specific populations, for instance the miners.

One of the major changes that have recently occurred in the French public healthy insurance system is the shift of a substantial part of the financing from social insurance contribution to taxes. A special tax, named "Generalized Social Contribution" (CSG) was introduced in 1990 to tackle rising social protection expenses. The tax base constitutes all wage and non-wage incomes, including real estate income and financial investment income. In 1998, this tax replaced the employees' social insurance contribution which was almost completely abolished. The initial 2.4% CSG flat rate was consequently raised to 7.5% of gross income. As a consequence, whereas in 1997 fiscal taxes represented less than 10% of the financing of public health insurance, they now account for about 40% (Table 2). This change had political consequences as it reinforced the role of the state in the management of the health care system at the expense of employers' and employees' representatives.

### *Complementary Health Insurance*

In France, most of the population holds an optional private health insurance coverage, which "complements" the mandatory public coverage, i.e. reimburses totally or partly the public insurance co-payment. This two-level system of health insurance (public mandatory plus private optional) is unique to France. Three types of institutions provide complementary health insurance, the "*Mutuelles*", the "*Institutions de Prévoyance*" and most of the commercial insurance companies. "*Mutuelles*" are the heirs of the 19<sup>th</sup> century mutual assistance societies spontaneously organised by workers on a professional basis. These non-profit institutions survived the creation of the public health insurance ("*Sécurité Sociale*") in 1945 and specialised in delivering complementary health insurance to their members. They are especially strong in the public sector. The "*institutions de prévoyance*" are private non profit institutions managed both by employers and employees. Initially created to provide supplementary retirement pensions in the private sector, they have extended their activity to complementary health insurance. They are dominant in the private sector through collective contracts, partly paid by employers, which are considered as an employment fringe benefit. In both cases, insurance premiums are based on gross income and not on

the insured people's health risk. Commercial insurance companies have two markets. They compete with "*institutions de prévoyance*" to provide collective contracts to private sector wage-earners and their employers and they sell individual contract to self-employed or unemployed people. In the latter case, premiums are risk dependant. In the past, the existence of a private level of complementary health insurance has limited the impact of government cost-sharing strategies to contain health care cost rise.

### *Universal Coverage*

Practically all French people (99.5%) are covered by Public Health Insurance, mainly through their professional status (including the scheme for unemployed people). The 1.8% of the population that are without a definite professional affiliation (for instance divorced non working women) have access to public insurance through a direct personal application (called "residential status"). The population holding a complementary health insurance is now estimated at 92%. This number was substantially raised by a law ("Universal Sickness Coverage Law"), passed in 1999, which entitled poor people to free complementary coverage. In July 2002, 3.5 million people benefited from this measure.

The basic benefit package is extensive and includes a full range of goods and services. Hydrotherapy, homeopathy, transportation and of course pharmaceuticals are all included. Inclusion or exclusion of a service is a state decision which does not depend on the views of the Sickness Funds. The package covered by the complementary institutions is generally the same as that of public insurance with some (albeit rare) exceptions. Some complementary institutions, especially commercial companies, have started to cover services that are not reimbursed by public insurance (for instance the Relenza® anti-flu drug). This tendency will certainly grow in importance in years to come.

On average, the three public sickness funds cover 76.6% of total health care expenditure. 12.4% is financed through complementary health insurance institutions and the remaining 11% is out-of-pocket spending (table 1). The division of financing as between public insurance, complementary health insurance institutions and out of pocket spending by patients varies according to the type of care. The share of public insurance is above 90% for hospital care whereas it is only 35% for dental care. For pharmaceuticals, the relative shares of public insurance, complementary insurance and out-of-pocket payment are respectively 64%, 19% and 18%.

## **4. Health Care Budgeting: Public Hospitals**

Since the middle of the 1980's hospital care in France has been strictly regulated by budgets, annually set by the government. Initially the rate of annual budget increase was the same for all public hospitals and computed, roughly, from a combination of expected economic growth and the public sector wage index. Staff expenses account for about 70% of hospital budgets (4). Later, in the 1990s, productivity indexes were computed for each public hospital, as a by-product of the introduction of a DRG system (the French version being called

PMSI, which stands for “*Programme de Médicalisation des Systèmes d’Information*”.) Costs per DRG are available for each public hospital but they are not presently used to finance hospitals. They are used, instead, to make hospital budget comparisons on a case-mix adjusted basis. More “productive” hospitals are thus likely to negotiate higher budgets. Less productive hospitals will be asked to make productivity gains before they can expect to benefit from budget increases.

Since 1996, budgets are determined by regional state agencies called ARHs (“*Agences Régionale d’Hospitalisation*”), but they are still paid by Health Insurance. So the state determines the budgets but does not pay the hospitals, leaving the Health Insurers paying but not determining the budgets. This situation creates tensions between the state and the Health Insurers, especially in 1999 when health insurance claimed a greater control on hospitals expenditures. This was refused by the government which wanted to keep a direct control on public hospitals. The ARHs also have a mission to restructure the hospital beds available at the regional level. Hospitals are requested to produce 5-year development plans and ARHs may encourage financially some development projects that seem consistent with their regional hospitalisation policy. Globally, nevertheless, this budget system resulted in a significant slow down in annual cost increase during the eighties and the nineties. Despite the introduction of a productivity measure, budgets acted more and more as severe and effective rationing devices. Hospitals have some difficulties buying some innovative expensive drugs such as the new TNF-alpha inhibitors in RA, which are in France restricted to hospital use only. Although there are officially no waiting lists, some surgical interventions have to be delayed at the end of the year. Shortages for some categories of medical and non medical personnel appear. Most hospitals are simply not in a position to comply with the recent reducing work time law which limits to 35-hours the duration of the weekly working time. The resulting crisis burst out in summer 2002 and the future of public hospitals has become a sensitive political issue. This induced the new ministry of health to prepare a 1 billion Euros emergency plan for public hospitalisation (2003-2007).

## **5. Total Health Care Budgeting: Process and Issues**

### *Budgeting total reimbursed health care expenditures*

In 1996 the government made a comprehensive attempt to dramatically reduce the Social Security deficit, which was at that time about 9 billions Euros, as a result of slow economic growth in 1994 and 1995. Public deficits had to be quickly reduced in order to qualify the country to join the Euro. The “Juppé Plan” (named after the French Prime Minister) established a sophisticated system of budgets covering all health care sectors.

At the top of this system the parliament votes a National Objective for Health Insurance Expenditures (“*Objectif National d’Assurance-Maladie*”, ONDAM). This objective was thus set at 112.8 billions Euros in December 2001, for the year 2002 and at 136.3 billions Euros in December 2002 for year 2003. No formal justification has ever been produced for this kind of figure. It mainly de-

depends on macro-economic variables such as the predicted rate of GDP growth or the public deficit. In a second step, this budget is broken down by the government (not the Parliament) into four sub-budgets, respectively for short term public hospital (43.2 billions Euros in 2001), long term hospitals (called "medico-social institutions", 7.9 billions Euros), private hospitals (7 billions Euros) and ambulatory care (51.5 billions Euros). Hospital budgets (short term, long term and private) are directly managed by the state through the regional agencies as described previously. Within the ambulatory budget, the part relating to pharmaceuticals is also directly managed by the state according to the procedure that will be described in the next section. Public Health Insurance (mainly the CNAMTS) is entrusted with managing the rest of the ambulatory care budget, which essentially relates to doctors' and other health care professionals (HCP) fees.

To reconcile between the tight financial budgetary envelope and the strong growth in consumption volume, the government mainly: i) exerts a downwards pressure on prices in the ambulatory sector; ii) rations financial resources to the hospital sector. As this is not enough, there is a third adjustment variable: the budget overrun! Since the implementation of this mechanism (1996), the government has never been able to contain health insurance expenditures within the limit it fixed itself (table 3). At the time it is voted, it is already known that the objective will not be achieved. The solemn vote of a fictive objective is more and more perceived as a denial of the parliamentary mission.

### *Budget or Target?*

The status of the total budget for health care is highly ambiguous: is it a financial budget which has to be respected by the various stakeholders (mainly hospitals managers, insurance funds managers and health care professionals) or a simple target, acting as a political signal from the government, setting the level of reimbursed health care expenditure the nation can afford at a constant tax and social contributions rate? This has never been clarified. On the one hand, as already mentioned, the total budget is set mainly by reference to macro-economic variables. No demand variables such as demographic growth, population ageing, technical progress and changes in sociological attitudes towards health and well-being are taken into account or even considered. So the stakeholders do not feel committed in fulfilling the target. But on the other hand, each year, Health Insurance and HCPs' representatives are urged by the government to find ways to limit the gap between the objective and the reality. Every three months, a round of negotiations is started between HCP unions and the Public Sickness Funds. The most common decision is a negative measure: not to raise official tariffs! Thus GPs' fee for an ordinary consultation has long been frozen at its 1996 level, namely 16.8 Euros (110 F). In September 2001, the claim for a raise to 20 € was rejected both by the government and the sickness funds and GPs came out on strike for all emergency consultations and visits from November 2001 to June 2002 (all night and week-end calls were redirected towards overloaded hospitals). Public opinion supported the doctors' action and one of the first decisions of the new government, elected in June 2002, was to give satisfaction to the GPs, imputing responsibility for the crisis to the previous gov-

ernment! This kind of situation and crisis is frequent and happened for the same reasons with each of the HCP, including dentists, nurses, and midwives.

The budgeting system is felt by health care professionals as a mechanism aimed at making them guilty. Each time the budget is overrun (each year in practice), health care professionals are held responsible for the expenditures escalation and the deficit, and there is a call for corrective action. The climate has deteriorated between health care professionals and the government, and public opinion becomes more and more anxious about the future of what has long been considered a national pride, ranked by the WHO as the best performing health care system in the world! (5) Health care management, which has so long been considered as a purely technical cost-containment problem, has become a political sensitive issue, at stake being the survival of a comfortable and balanced public-private system.

## 6. Pharmaceutical Budgeting

As seen previously, the Parliament only votes the global budget for reimbursed health care expenditures. Sub-budgets for each type of care (short term and long term hospitals, HCPs' fees, pharmaceuticals, etc.) are set directly by the government. In particular, drugs are submitted to a rather complicated budgeting system which works as follows.

1. First the government issues unilaterally a rate of "normal" growth for reimbursed pharmaceuticals (called the "k rate"). Again, no justification is given for this rate which was set at 3% in 2001, a lower rate than the general rate for all health care expenditures (3.8%)!
2. If the actual growth is above the planned growth, the whole industry has to pay back to health insurance funds a part of the difference, ranging from 50% to 70% according the magnitude of the difference <sup>2</sup> ("the *safeguard clause*").
3. The global discount has then to be divided among companies. Here, there is a choice for each individual company: whether or not to sign a "convention" with the state (in fact the Drug Price Committee). The method of computation of the individual discounts depends on this choice.
4. If a company chooses not to sign a convention, an individual discount is computed according to a mechanistic formula (the "*safeguard procedure*"), proportionally to its turnover, to the growth of the turnover and to the amount of promotional expense. Only sales of reimbursed prescription products in

---

<sup>2</sup> If the real growth rate is between 3 and 3.5%, industry has to pay back 50% of the difference between the real and the targeted growth rate. If the real rate is between 3.5 and 4%, the payment back is 50% of the difference between 3% and 3.5%, plus 60% of the difference between the real rate and 4%. If the real rate is above 4%, the payment back is 50% of the difference between 3% and 3.5%, plus 60% of the difference between 3.5 and 4%, plus 70% of the difference above 4%. These discount rates can be adjusted from one year to the other.

France on the pharmacy market (excluding OTC, exports and hospital sales) are considered.

5. If, on the contrary, a company chooses to sign an agreement, the “*conventional procedure*” applies. It is far more complicated. First, the Drug Price Committee attributes to each of the 122 therapeutic classes under consideration a “permitted” rate of increase. Again no justification will be provided and the rates are just discretionary. Then, the Drug Price Committee computes the expenses overrun for each of the class and for the aggregated market. The companies are charged collectively 35% of the expenses excess (2001 rate). The amount is broken down according to companies’ turnover and growth of turnover (promotional expenditures are no longer taken into account). Generally speaking, the amount of money which is recovered this way is not enough. So a last negotiation takes place, company by company, to obtain a supplementary discount. This last negotiation is not formulaic and plays the role of “grey area” allowing some form of discrimination among companies.

Companies have developed a certain skill to “play” with these procedures. Simulations have shown that, most of the time, the best solution was to sign the agreement and to engage the complicated conventional procedure. In fact, the discount under the conventional procedure is about 75%-80% of what it would have been under the formulaic application of the “*safeguard procedure*” and 100% of companies signed a convention in 2001.

In 2001, the total discount paid by the industry was 526 millions Euros. The industry also paid substantial special taxes: 183 millions Euros in promotional taxes, 106 millions Euros in direct sales taxes<sup>3</sup> and 89 millions Euros in contributions to the Drug Agency. In 2001, there was also a price cut, targeted on the best-selling drugs. The total amount paid by the industry, directly or indirectly through price-cut, (amounted to about 1.10 billion Euros (apart of normal business taxes). This is approximately the value of the net after tax profit of the whole industry (including export, hospital sales, OTC, etc.)

## **7. Pharmaceutical Budgeting and Expenses Regulation**

We have now to examine how this complex budgeting procedure affects both the regulation of pharmaceuticals expenditures and the use of drugs by prescribers and consumers.

### *Reimbursement*

In France, a system of positive list prevails for drug reimbursement. The listing of a new compound is proposed by the Transparency Commission within the

---

<sup>3</sup> This tax applies to direct sales to retail pharmacists, which do not pass through wholesalers. It creates an incentive to use the conventional “long” distribution track as a compensation for the legal obligations of wholesalers to have in stock at least 90% of existing drugs, to maintain a stock equivalent to two weeks of drug consumption and to deliver any retail pharmacy within 24 hours.

Drug Agency. A drug can be listed if its “*Medical Service Rendered*” (MSR) is deemed “*sufficient*” with regard to a list of criteria formally set by a recent decree (October 1999):

- Drug efficacy and safety
- Severity of the disease
- Place in the therapeutic strategy
- Existence of alternative treatments
- Public health value.

In fact, as proved by a statistical analysis performed on the results of the MSR evaluation of 1453 drugs in 5 therapeutic areas only two criteria – efficacy and seriousness of the disease – suffice to very largely explain the MSR classification (6). The other criteria contribute little added value.

The point here is that there is no relationship between the budgeting system and the reimbursement procedure. The pharmaceutical budget is fixed independently of the number and the nature of the new products that are agreed for reimbursement. Under these conditions, it is practically unavoidable that the budget is systematically overcome, especially when breakthrough innovative products are launched. Besides, in that case, there is a strange and paradoxical effect. Whereas the benefit of marketing of new innovative product accrues to a single company, all the industry is jointly liable to pay the discount which results from the new drug! It is thus in the interest of this latter company to promote and advertise heavily its breakthrough product, as the payback payment is partly socialized!

### *Pricing*

Drug price control has long been the main regulation tool for pharmaceutical expenditures. In fact, only reimbursable drugs on the pharmacy market are price regulated. There is no price regulation for OTC drugs and for Hospital Only Drugs<sup>4</sup>. Regulated prices are set by a state committee (the Drug Price Committee within the Ministry of health) after a price negotiation with applicant companies. There are no formal rules and the open negotiation is based on various criteria such as the innovative nature of the product, the benefit to patients, the projected market size, the competitor domestic prices and the foreign prices. Unlike some other countries, there is not in France a formal comparison with prices from a set of defined countries. Nevertheless there is a clear tendency on the part of companies to align innovative product prices with the “European Price” in order to prevent parallel trade. This argument is generally accepted by the Drug Price Committee, especially for innovative products. In fact, because of the budgeting and payback system, price regulation appears to be less necessary as a cost-containment tool. A clear tendency of the Price Committee, at least for innovative products, is to rely less on cost-containment through price regulation, and more on raising additional resources through the

---

<sup>4</sup> In the latter case, prices are discussed freely between the industry and the hospital pharmacist, who is often the chairman of the local P&T committee.

discount system. In that sense, there is a clear impact of the budgeting policy on the pricing policy.

### *Drug Utilization*

The budgeting system operates only at the central level and only drug companies are concerned by the discount payment. There are thus no individual prescribers' budgets and no financial incentives for physicians to reduce or to improve their prescribing practices.

In 1993-94 yet, initiatives were taken at the national level, with the help and support of the main physicians' union, to develop a set of mandatory clinical practice guidelines. These guidelines were formulated in negative terms (for instance: "*there is not cause to use together two anti-cholesterol drugs, unless...*"). Later on, some more traditional positive clinical recommendations were issued either by the Drug Agency or by the Agency for Health Care Technology Assessment (ANAES). Although these recommendations had a great impact on physicians, this strategy aiming at improving the quality of drug utilisation became more or less obsolete.

A similarly timid policy was conducted with respect to generic drugs. In 1999, pharmacists were given a limited substitution rights for true generic products, which are officially listed by the Drug Agency. The commercial profit margin on generics was maintained at the same level as that of the reference product – although the generic price is lower – in order to neutralise the pharmacists' negative incentives. But, patients, doctors and pharmacists still face no positive incentives to consume, prescribe or deliver generic drugs. Recently, in June 2002, the physicians' unions agreed to develop generic prescribing as a counter-part of the agreement on fees revision, but no quantitative objectives and no sanctions were set out in the agreement. There is therefore nothing surprising about the very low market share of generic drugs in France (less than 4%). In fact the budget policy has progressively occupied all the government's attention, since it was launched in 1996, at the expense of more qualitative policy measures aiming at improving the quality and efficiency of drug use.

### *Pharmacoeconomics and pharmacoepidemiologic studies*

Health economic evaluation studies applied to pharmaceuticals ("Pharmacoeconomic" studies) developed in France as in some other countries in the mid-eighties. But it remained an academic discipline or a consultancy product for the industry. Pharmacoeconomic studies have a little role to play in a macroeconomic budgeting process. Public authorities in France were always reluctant to use it in public decision making about reimbursement or pricing. The reasons certainly relate, at least partly, to the alleged "lack of credibility" of pharmacoeconomics. But the fact that it proves to be a poor cost-containment tool is probably a more decisive explaining factor<sup>5</sup>.

---

<sup>5</sup> Nevertheless, submitted studies are examined by a group of independent experts within the Drug Agency. Public authority representatives were also part of the elaboration of the "Guidelines for Economic Evaluation in Health Care, undertaken under the auspices of the French "Collège des Economistes de la Santé".

A recent tendency from public authorities is to encourage pharmacoepidemiologic studies, once products are on the market. The reasons are twofold. First to monitor physicians' prescribing practice and then to check new products' effectiveness in "real life" conditions. This last objective, although it is highly desirable, raises some very difficult methodological issues; especially the traditional question of knowing whether observed real life effects are to be attributed to the drug itself or to the use of the drug, which depends on other actors, especially prescribers. The status of these studies remain somewhat obscure especially the relationship to the regulation process:

## **8. Breaking with the budgeting logic**

In France, health care policy was progressively reduced to be nothing else but a financial budgeting policy. This was especially obvious during the period 1996-2001. Each year the discussions of the "Social Security Financing Bill", which leads to the vote of the National Financial Objective (ONDAM), mainly consists in setting the targets and looking for repressive means to achieve them.

All other health policy strategies have been more or less given up. Cost-sharing has been reduced with the extension of complementary health insurance and exemption of co-payments for a large part of the population (8.5%). Payment for more than two-thirds of pharmaceuticals acquired by patients is made directly to pharmacists by the Health Insurance via electronic bank transfers, so that patients have the feeling that pharmaceuticals are nothing but a free good. The idea of implementing a dose of competition between sickness funds was not even discussed. More important, looking for financial savings through a quality improvement policy was a strategy which was pursued during a short period (1993-1994) but quickly abandoned because it provides benefits only in the long term, even if the effect on the system efficiency can be immediate.

The emphasis put on the macro-economic budgeting policy was in fact consistent with the raising of the role of state regulation at the expenses of sickness funds, as witnessed by the "Juppé Plan" of 1996. Greater state control and the rise of budgeting strategies were in fact closely connected.

The main drawback with this budgetary system, apart of its complexity, is the lack of incentives for doctors and managers to use pharmaceuticals efficiently. Only the expense side of pharmaceutical innovations is considered, irrespective to the benefits to patients and society. The silo effect of having a separate budget for pharmaceuticals and hospitals forbids a global computation of the financial effect of drug innovation on total health care expenditures when an ambulatory treatment results in financial savings in the hospital sector. This was especially the case when antiretroviral therapies for HIV infection were made available to patients in pharmacies in 1997. Before this date, these treatments were restricted to hospitals only. Now, their costs weigh on the pharmaceutical budget, whereas substantial benefits in term of reduction of hospital stays still accrue to the hospital sector (7,8). No global view of the financial impact of the therapies is thus available to decision maker.

*Towards a new drug policy?*

It has been progressively acknowledged that the budgeting policy, as applied during the period 1996-2001, was not effective. The new government installed in June 2002, after Jacques Chirac was re-elected as president, has started to change health care policy. The new "Health Care Financing Bill for 2003" gave the opportunity to draw new perspectives, especially in the pharmaceutical sector. The following measures were announced:

- A more realistic financial target for total health care (5.4 %) as well as for pharmaceuticals ("k rate" set at 4% compared to 3% the previous year);
- The introduction of a reference pricing system for all molecules with generic competition. For the first time, market price and reimbursement price will be disconnected although competition will certainly tend to align prices, at least in a majority of cases<sup>6</sup>.
- The de-reimbursement of low therapeutic value drugs within the next 3 years. This was the most spectacular and the most courageous measure, as most of these products are marketed by French family companies. This measure concerns 600 compounds with a total turnover estimated to 1 billion Euros. Taking into account the distribution cost and the reimbursement rate (35%), this measure should provide 450 millions Euros savings.
- The adoption of a "Price Notification Procedure" for innovative drugs. In this system, companies will be allowed to market innovative drugs at their own price. Government will have then a time period to oppose if price is exceedingly high. After that period without a reaction from the state, the price becomes definite. This measure is intended to discourage parallel trade as it is expected that drug companies will spontaneously price their new products at the "European level". Another objective is to reduce marketing delays which are excessively long in France, due to a tedious reimbursement and price negotiation process. The scope of that measure (all the new products or only the innovative ones?), the time limit for state intervention, and the definition of an "excessive" price are still to be negotiated.
- Finally, a 350 million Euros special budget for innovative drug acquisition has been allocated to public hospitals.

These measures have been well received by public opinion and by the innovative part of the pharmaceutical industry. In fact, their adoption marks a decline in the political influence of French family drug companies that have long been dominant.

### *New perspectives*

In a longer term, it can be easily foreseen that the political debate around the health care system will bear on a limited number of important topics.

First, the meaning of fixing a global budget for health care is to be clarified. A state commission has been appointed in order to make propositions for a re-definition of financial targets. Physicians unions push the idea of a "scientific"

---

<sup>6</sup> Curiously, this measure was presented as a generic promotion policy, whereas, normally, it would rather advantage the branded version of the molecules: prescribing or delivering a generic drug is strictly of no interest as soon as the reference drug is sold and reimbursed at the same rate.

definition of the total budget based on the identification and quantification of health “needs”. There is a form of illusion to believe that the solution lies in that direction, given the well-known ambiguity about the notion of “need”. As Allan Williams pointed out some years ago, a certain medical rhetoric uses in fact the concept of “need” as a supply concept (9), leading to a form of circular reasoning: most of the time it is possible to invoke “need” to justify any actual level of expenses, leaving thus a limited place for rationalization and improvement of the system management. On the other side, a bureaucratic process for budget determination inevitably leads to tensions, conflicts and rationing. In the French context, a more realistic way may be to consider the budgeting process as a collective negotiation, including all the stakeholders (HCPs, the pharmaceutical industry and the health funds managers) about what is desirable and what is achievable in term of health care growth. In fact, if stakeholders are granted responsibility for the good execution of the budget, they should be associated to its determination.

Second, while it is legitimate that the government decides what amount of public resources is to be dedicated to health care, the breakdown into separate budget provides numerous perverse effects. Efficient use of health care resources is prevented simply because cost and benefits are not necessarily located in the same budget. This is especially true for pharmaceuticals. Many drug innovations result in diminished hospital costs. Recently, for instance, we showed that the number of trabeculum surgeries (trabeculectomies and trabeculotomies) performed in France was reduced by 16% (from 19,233 to 16,133 interventions/year) between 1997 and 1999. During the same period, the number of patients treated with a new glaucoma drug increased from 476,000 to 760,000 equivalent patients/year. This increase is due to the launch of 3 new glaucoma drugs. Development of fistulizing or sclerotic surgery may explain part of the reduction observed in private clinics, but not in public hospitals. In fact there is no other explanation for the dramatic reduction of trabecular surgery in hospitals than new medical treatments (mostly latanoprost and brimonidine) providing better IOP control and delaying or avoiding surgery (10) . This kind of benefit of drug treatment cannot be captured in a separate budget structure.

Third, while under above conditions a total budget may be useful to explicit health care policy choices, it cannot substitute all other policy measures, especially those which aim at improving the quality and efficiency of health care, especially prescribed medicines. This strategy has been neglected until now, except for a short period in the mid-90s, although it has a great potential. Government should also look for ways to make patients more responsible about their health care consumption, without necessarily increasing co-payment. Patients’ education programs may provide a solution.

Finally, if the budget resulting from a global negotiation with stakeholders results in expenses that exceed financial resources, new sources of funding should be found or the benefit package should be reduced. Public authorities and public opinion have to accept the idea that growth in health care expenditures at a rate faster than that of GDP is a fact of life, at least for the present

times. It has long been presented as an institutional dysfunction attributable to any one or more of an excess of insurance coverage, ineffective state controls, or manipulating corporatist strategies from HCPs. But such a universal phenomenon throughout the developed world cannot be reduced to French circumstantial and institutional causes. It is a basic characteristic of modern western democracies that should be accepted as such rather than denied. Of course, health care expenditure cannot grow faster than GDP for ever. The history of household consumption shows that some goods may be superior goods during a period of time and then become inferior goods in the continuous course of the economic and social development. But the time horizon for the health care budgeting process is much shorter. In the short-medium term, although the French government has announced it would not raise taxes and social contributions, it is hard to imagine it can successfully face the current difficult situation without finding new sources of funding. A reform of the employers' contributions and an extension of the new CSG tax can be envisaged, although this would further reinforce the leading role of the state.

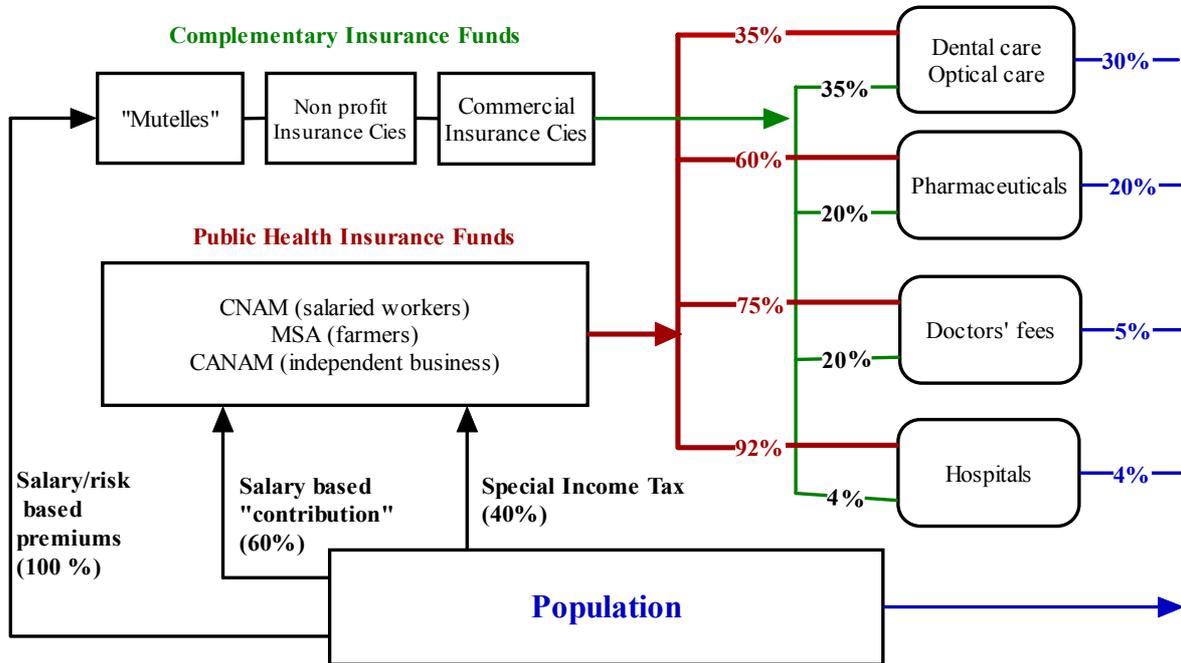
In the French context, it is also clearly possible to think about reconsideration of the public health insurance benefit package and more precisely to the search for a new balance between Public Health Insurance and Complementary Health Insurance institutions. The debate is already launched around the idea of having universal public coverage limited to a (rather large) package of prioritized goods and services, with the rest being financed through complementary health insurance. The fact that more than 90% of the population is now covered by such a complementary insurance limits the potential equity risk that underlies such a construct.

In that perspective, a global budget can be a useful tool for rationalizing health care expenditures and improving transparency in collective choices. It cannot and should not be limited to what it is now: a raw bureaucratic management tool imposed unilaterally to HCPs and patients.

## References

1. Gerdtham UG, Sogaard J, Andersson F, Jonsson B. An econometric analysis of health care expenditure: a cross-section study of the OECD countries. *J Health Econ* 1992;11:63-84.
2. Eco Santé 2002. Paris: CREDES, 2002.
3. Danzon PM, Chao LW. Cross-national price differences for pharmaceuticals: how large, and why? *J Health Econ* 2000;19:159-95.
4. Les comptes des établissements publics de santé, 1999. Paris: La Documentation Française, 2000.
5. The WHO health report 2000: health systems, improving performance. Geneva: WHO, 2000.
6. Le Pen C. Which criteria for pharmaceuticals reimbursement? An empirical analysis of the evaluation of "medical service rendered" by reimbursable drugs in France. *Eur J Health Econ* 2003;In press.
7. Le Pen C, Rozenbaum W, Downs A, Maurel F, Lilliu H, Brun C. Effect of HAART on health status and hospital costs of severe HIV- infected patients: a modeling approach. *HIV Clin Trials* 2001;2:136-45.
8. Le Pen C, Rozenbaum W, Downs A, Lilliu H, Maurel F, Foucher F. [A cost-effectiveness analysis of changes in therapeutic strategies in the treatment of HIV since 1996]. *Therapie* 2002;57:27-33.
9. Williams A. "Need" as a demand concept. In: Culyer AJ, Wright KG, eds., *Economic Aspects of Health Services*. Oxford: Martin Robertson, 1978.
10. Baudoin C, Rouland J, Le Pen C. Changes in medical and surgical treatments of glaucoma between 1997 and 2000 in France. 108th Congress of the French Society of Ophthalmology 2002.

**Figure 1 : The French Health Care System Organization**



**Note:** The figure depicts the main financial flows in the French health care system. Pharmaceuticals for instance are financed 60% from public health insurance funds, 20% from complementary insurance and 20% out-of-pocket. Public funds are financed 60% from social contribution and 40% from a special income tax.

**Table 1: The Financing of Medical Consumption in France (2000)**

	Expenditures		Financing by source of funds (%)		
	Amount (millions €)	%	Social Security	Comp. Insurance	Households
<b>In-patient care</b>	55 264	45.8	91.1	3.7	5.2
<i>Public hospitals</i>	42 729	35.4	92.3	2.3	5.4
<i>Private hospitals</i>	10 679	8.9	84.8	10.1	5.3
<b>Out-patient care</b>	31 861	26.4	67.0	21.4	11.7
<i>Physician services</i>	15 324	12.7	75.6	20.4	4.0
<i>Dental services</i>	6 430	5.3	35.3	35.9	28.7
<b>Pharmaceutical goods</b>	<b>25 069</b>	<b>20.8</b>	<b>63.6</b>	<b>18.6</b>	<b>17.9</b>
<b>Total expenditures on medical services and goods</b>	120 640	100.0	76.6	12.4	11.1

**Table 2 : The Financing of Public Health Insurance in France (2000)**

<i>Billions Euros</i>	1997	%	2001	%
<b>Taxes</b>	<b>7.5</b>	<b>9.2%</b>	<b>39.8</b>	<b>40.0%</b>
General Social Tax (CSG)	5.3	6.5%	36.9	37.1%
Other taxes	2.2	2.7%	2.9	2.9%
<i>Pharmaceutical industry</i>	-	-	0.5	0.5%
<b>Social contribution</b>	<b>73.1</b>	<b>89.9%</b>	<b>59.5</b>	<b>59.8%</b>
Employers (private sector)	42.8	52.6%	47.7	47.9%
Employees (private sector)	19.7	24.2%	2.9	2.9%
Other employees	10.6	13.0%	8.9	8.9%
<b>Other</b>	0.7	0.9%	0.2	0.2%
<b>Total</b>	<b>81.3</b>	100.0%	<b>99.5</b>	<b>100.0%</b>

**Table 3 : Rate of Increase of Reimbursed Health Care Expenditures**

	Budgeted	Realised
1997-98	2.3%	4.0%
1998-99	2.6%	2.8%
1999-00	2.5%	4.7%
2000-01	3.5%	5.8%
2001-02	3.9%	7.2%