Economic Committee for Health Products

Annual Report 2001

April 2002

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In accordance with article D. 162-2-4 of the Social Security Code, each year, the Economic Committee for Health Products hands a report on its activities in to the ministers responsible for social security, health, the economy and industry. The newly introduced article L. 162-17-3 of the Social Security Code also makes provision for the submission of this report to Parliament.

This report outlines the main activities of the Committee in 2001, a year marked by the extension of its remit to health products other than proprietary medicines [1].

. Part one deals with proprietary medicines.

Chapter one is devoted to the proprietary medicines market in 2001.

Chapter two deals with the regulation of the proprietary medicines market in 2001 and actions taken to that end by the Committee in application of the Social Security Code and ministerial guidelines.

Chapter three relates to pricing. Firstly it presents a statistical overview of the Committee's activities on this matter (type of applications, processing periods). It also describes the methods implemented by the Committee in 2001 for price negotiations and gives an indication of pricing levels.

. Part two concerns health products other than proprietary medicines.

Chapter one is devoted to the description and trends in the medical devices market.

Chapter two deals with the reform in the reimbursement of the cost of medical devices and the action taken by the Committee for the implementation of this reform.

Chapter three is devoted to special opinions of the Committee.

[1] The Social Security Financing Act for 2000 extended the remit of the Committee to reimbursable health products other than proprietary medicines; the decrees for implementation dated 26 March 2001 were published in the Journal Officiel of 28 March 2001.

PART 1 - PROPRIETARY MEDICINES

Chapter I – THE REIMBURSABLE PROPRIETARY MEDICINES MARKET

1. THE BACKGROUND TO THE TREND IN DRUG EXPENDITURE IN 2001

The Committee's action in 2001 was taken against a backdrop of a general increase in sales of proprietary medicines which remained strong; by aggregating all sales of reimbursed ambulatory drugs, growth will have been of similar to that recorded in 2000, namely around 7.7% (see 2.1 below).

The increase in the consumption of proprietary medicines is, without doubt, for reasons which effects are observable in all comparable countries. This growth is partly explained by the increase in the prevalence of chronic diseases, the emergence of new disorders, increased medicalisation of the elderly together with an ageing population. The arrival of new molecules for diseases previously poorly covered also plays a role in this process. It is also true that by reference to comparable countries where, over recent years, sales of proprietary medicines have often shown a double-figure growth, the increase recorded in France might well seem a comparatively satisfactory result. Yet, the fact cannot be overlooked that the average level of drug consumption per inhabitant already reached in France is, according to the criteria adopted, the highest or amongst the highest in the world.

With regards to sales of reimbursable ambulatory drugs, the growth in 2001 was significantly lower than the previous year (7.2% against 8.9%). This cannot however, be regarded as a good result since the difference can be explained by various short-term reasons.

As such, 2000 saw the bulk of the effects from the introduction of the *Couverture Maladie Universelle* (CMU, universal sickness cover) and of the launch of major ambulatory drugs previously sold to hospitals. This accounts for at least one growth point. In 2001, in the absence of any such launch (which corresponds in fact to changes in distribution though not to changes in the growth rate of drug consumption), the rise in ambulatory sales has not been affected, whilst hospital sales are escalating at a rapid rate. With a greater or lesser time lag depending on the products, there is a close link between sales of ambulatory or hospitals drugs and their trend.

All things being equal, the price reductions imposed at the close of 2000 were also supposed to reduce sales in 2001 by more than 1%. However, the reductions agreed

in the summer of 2001 were such as to further reduce the growth in sales by a few tenths of a point.

Finally, 2001 experienced no marked epidemic, thereby resulting in a somewhat atypical trend in antibiotic sales.

All of this leads us to think that contrary to what the figures suggest, the trend has not fundamentally changed in reality.

2. RISING SALES AND RISING COSTS

The explanations that follow are largely due to the work carried out on behalf of the Committee by the research and financial forecasts Sub-Directorate of the *Direction de la Sécurité Sociale* (DSS, Social Security Directorate).

2.1 THE INCREASE IN TURNOVER

- The increase in the global reimbursable or reimbursed turnover of manufacturers will have reached 7.7% in 2001, matching 2000.

This growth was achieved by aggregating sales of ambulatory drugs sold in pharmacies and estimated sales of proprietary medicines to health institutions. The overall stability noted stems in fact from a contrasting trend in sales of ambulatory drugs and sales to health institutions. According to the data currently available, sales to health institutions in 2001 should increase by over 10% at a steadier pace than that of ambulatory sales that rose by 7.2%. The situation is opposite to that of 2000 during which sales to health institutions rose only slightly, whereas ambulatory sales increased by 8.9%.

2.1.1 Sales to health institutions

In 2000, the pharmacy sale of ambulatory drugs previously reserved for health institutions and reassigned, had led to a 1-point increase in ambulatory sales. By contrast, the annual growth in sales of proprietary medicines to health institutions, which had previously been of the same order as that of ambulatory sales, had approximately fallen by 5 points.

In 2001, a two-digit increase in sales of proprietary medicines to health institutions was expected. This was most notably due to extending the use of expensive cancer and rheumatoid arthritis drugs. The impact of the move of some drugs from the hospital budget to the national health insurance budget accounted only for a slight change in pharmacies' turnover, the effects of which were limited mainly to the carry-over effect of 2000.

2.1.2 The growth in pharmacy sales

The gross turnover achieved by pharmacies in 2001 stood at €14.32 billion, up by 7.2% (€ 0.95 billion) from the previous year. This increase, albeit sharp, is nonetheless slower than that recorded in 2000 (+ 8.9 %).

The growth in pharmacy sales in 2001 was achieved from an atypical trend during the year. After a rapid rise of 3.3% in the first quarter, which accelerated to 4.3% in the second quarter, turnover in the last quarter fell by 2% compared with the previous quarter. This is the first time since 1998 that such a fall has occurred. The contrasting character of this trend stems primarily from the sales of high volume therapeutic classes. Falling prices, the absence of epidemics and strike action by general practitioners in December also led to a reduction in care and ambulatory prescriptions compared to normal.

2.2 THE INCREASE IN HEALTH INSURANCE REIMBURSEMENTS

- The costs of reimbursing proprietary medicines by all mandatory health insurances will have increased by approximately 8.5% in 2001.

The recorded rate of increase in expenditure from proprietary medicines' reimbursment stands at 8.9% for the general regime managed by the *Caisse Nationale d'Assurance Maladie des Travailleurs Salariés* (CNAMTS, health insurance for salaried employees). The CNAMTS spending is increasing faster than spending of other mandatory regimes. On the basis of the variations previously observed, it is estimated that the increase in reimbursement spending for all systems combined is 8.5%.

Although the rates of growth ought to be similar, there is a discrepancy (for which an explanation should be attempted) of 1.3% between the growth in ambulatory sales at manufacturer's price (7.2%) and that of reimbursements by the mandatory health insurance system (8.5 %).

Determining factors in the discrepancy:

a) Distribution margins

Since distribution margins (wholesaler margin + pharmacist margin) are degressive, reimbursements should increase more slowly since the growth in sales partly corresponds to an increase in higher-priced packs (see 3.3. below) that may exceed the degressivity thresholds; conversely, for generic medicines which margins are proportionally much greater. As the two effects are the reverse of one another and partially cancel each other out there are no grounds to assume, with the legislation as it stands in 2001, that the distribution margins will exert a significant impact on the discrepancy between sales and reimbursements.

b) The reimbursement rate

The rise in the actual mean rate of reimbursements is leading to a more rapid rise in reimbursements than that of manufacturer sales. There are several reasons for this growth; one of the most significant reasons, linked to the ageing population, is the increase in the proportion of chronic and/or serious diseases that are fully reimbursed under the terms of the ALD system (*Affections de Longue Durée*). Likewise, the fact that sales of proprietary medicines reimbursable at 65% or 100% are growing much

faster than those of proprietary medicines reimbursable at 35% plays a part. In 2001, the actual mean rate of reimbursement for the general system was 73.9%, against 73.7% in 2000. This higher rate, applied to a reimbursable turnover also on the increase, explains the discrepancy of 0.3% recorded.

c) The hospital reassignment effect

Drugs that are subject to reassignment are dispensed at the hospital level although they give rise to a specific reimbursement charged to the ambulatory budget. They are thus included in the mandatory health insurance spending though not in manufacturers' turnover which retraces sales to pharmacies. Such an unmeasurable effect might exert a role in a scenario where the rise in costs corresponding to these reassigned drugs was greater than that of ambulatory sales. It would seem that in 2001, with the reassignment of erythropoietins and the arrival of new drugs, this rise has been considerable. Although it is not possible to put a figure on it, it may explain most of the residual discrepancy between the rise in reimbursements and that of sales.

d) The discrepancy between the accounting dates

The discrepancy might stem from the time lag between sales entered into accounts upon delivery to pharmacies and the costs recorded upon reimbursement. Although such a phenomenon may, as in 2000, apply in a given year[2], the resulting discrepancy could not be repeated the following year.

3. ANALYSIS OF THE GROWTH IN REIMBURSABLE AMBULATORY SALES

3.1 THE GENERIC DRUGS MARKET

Despite the expansion of the generics register to new products, generics potential market share (comprising reference drugs and their generics) compared with the overall market fell by 5% in 2001, from 14.7% of the overall market in 2000 to 13.9% in 2001. This decline is due to the fact that, generic brands are older and their growth weaker than that of the overall market. Conversely, the share held by generic drugs within their potential market increased by 20%, from 18.6% of the market in 2000 to 22.3% in 2001.

In 2001, generic drugs accounted for 6.7% of the total reimbursable ambulatory drug market volume and for 3.1% of the net turnover achieved on this market. On the basis on the 9th register of generics, the turnover achieved in 2001 stands at €443 million, up 22% from the previous year.

[2] Driven by a fear of stock shortages on account of the year 2000 computer bug, some pharmacists are thought to have built up emergency stocks thereby boosting 1999 sales, while the reimbursements relating to these stocks helped to swell reimbursement costs in 2000.

Table 1: The generic drugs market

units in millions / value in millions €

Market share		2000*		2001**	
		units	value	units	value
Generic groups market / total market	no.	543	1960	543	1985
	%	20.2 %	14.7 %	19.9 %	13.9%
Generics market	**no.**	**155**	**364**	**182**	**443**
Generics market/ generic groups market	%	28.6 %	18.6 %	33.5 %	22.3 %
Generics market / total market	**%**	**5.8 %**	**2.7 %**	**6.7 %**	**3.1 %**

* on the basis of register no. 7(2) of 8 August 2000 – JO of 2 September 2000.
** on the basis of register no. 9 of 13 June 2001 – JO of 21 June 2001.

3.2 PRICE REDUCTIONS IMPOSED IN 2001

Beyond the price reduction measures imposed in 2000, the impact of the price reductions imposed in 2001 was felt towards the end of the year, following the decisions taken in 2000 or as part of the propriety drug plan of the summer of 2001. This explains in part the decline in sales recorded in the 3rd quarter. Over the year as a whole, the impact of the reductions imposed in 2001 accounts for 0.9% of sales.

3.3 GROWTH COMPONENTS

The 7.2% increase in turnover can be analysed as:

- A reduction in drug pack prices of –1.3% compared with the previous year (price effect);
- A growth in the number of packs sold between 2000 and 2001 of +1.2% (quantity effect). This rate is lower than in 2000 where the effects of the introduction of the CMU might explain in part the 2.9% rise in ambulatory sales volumes;
- A constant rise in the average price per pack of 7.2% (structure effect). This effect corresponds to a distortion in the structure of sales towards more expensive drugs or presentations, whether it be a shift in sales towards costly therapeutic classes (inter-class structure effect: +2.0%), or, within the same therapeutic class[3], a shift in consumption towards higher priced proprietary medicines (intra-class structure effect: +5.1%).

Table 2: Sales growth components

Year	Price effect	Quantity effect	Intra-class effect	Inter-class effect	Total growth
Year 2001	- 1.3 %	+ 1.2 %	+ 5.1 %	+ 2.0 %	**7.2 %**
Year 2000	- 0.9 %	+ 2.9 %	+ 4.3 %	+ 2.4 %	**8.9 %**
Year 1999	- 0,7 %	+ 1.8 %	+ 3.0 %	+ 2.3 %	**6.6 %**

[3] The classes used for this assessment are those of level 4 of the EPHMRA classification

The price effect and the quantity effect are of the same order and act in opposite directions. The rise in ambulatory sales in 2001 originates essentially from the structure effect within which the intra-class effect plays an increasing role (72% of the structure effect in 2001 against 57% in 1999).

3.4 THE TREND BY THERAPEUTIC CLASS

- The trend of certain classes explains its contrasting character during the year.

The contrasting character of the trend in the growth of sales during the year lies to a great extent in the special trend in sales in certain therapeutic classes.

The rise in COX-2 sales was immediate. The level of € 19 million around which total monthly sales throughout the year fluctuated was achieved as early as January. Alone, the relative sales progression compared with the previous quarter represents almost 40% of the growth recorded in the first quarter.

The withdrawal of cerivastatin in August 2001 resulted in a fall in statin sales in the third quarter. The impact of this decline was huge, as it is the largest class in terms of turnover and which, until the summer, contributed to most of the recorded growth.

- The bulk of the growth in turnover (TO) in 2001 is confined to a small number of therapeutic classes.

The breakdown of the €0.96 billion increase in turnover leads to the realisation that over 70% of the increase is attributable to 12 of the 320 existing therapeutic classes.

Table 3: Contribution to sale growth by class

millions €

Therapeutic class	TO (net of tax) 2000	TO (net of tax) 2001	Difference TO (net of tax)	Growth by class	Contribution to overall growth
Non-steroidal antiinflammatorie drugs only	295	469	174	58.9%	18.2%
Proton pump inhibitors	583	701	118	20.3%	12.4%
HMG-CoA reductase inhibitors	676	772	96	14.2%	10.1%
Antidepressants	484	543	59	12.2%	6.2%
β2 stimulants, inhaled corticosteroids and combined*	483	540	57	11.9%	6.0%
Platelet anti-aggregants	175	225	50	28.8%	5.3%
Angiotensin II receptor antagonists, combinations	109	151	42	38.3%	4.4%
Angiotensin II receptor antagonists, alone	204	235	31	15.3%	3.3%
β interferons	95	122	27	28.6%	2.8%
Atypical antipsychotics	99	124	25	25.6%	2.7%
Total 12 classes	**3 202**	**3 882**	**680**	**21.2%**	**71.3%**
Total reimbursable market	**13 366**	**14 322**	**956**	**7.2%**	

*Grouping of 3 classes, β2 stimulants, inhaled corticosteroids and combinations, β2 stimulants with inhaled corticosteroids, the latter, giving rise to the overall growth, constitutes a new class by partly replacing the existing classes.

The average growth of these classes was 20% higher in 2001, with a maximum close to 60% for NSAIDs on account of the sharp rise in COX-2s.

- ***Unlike these classes that experienced very strong growth, only 2 classes make a significant contribution to the reduction in overall growth.***

Table 4: Declining classes

millions €

Therapeutic classes	TO (net of tax) 2000	TO (net of tax) 2001	Difference TO (net of tax)	Growth	Contribution to overall growth
Cerebral vasodilator SF calcium antagonist	340	309	31	- 9.2 %	- 3.3 %
Increased gastrointestinal motility	120	103	17	- 14.2 %	- 1.8 %
Total 2 classes	**460**	**402**	**48**	**- 12.6 %**	**-5.0 %**
Total reimbursable market	**13 366**	**14 322**	**956**	**7.2 %**	**-**

Chapter II – REGULATION ADOPTED BY AGREEMENT

Having noted the high level of growth in sales of proprietary medicines in 2000, and as no sign of a slowdown emerged in the early months of 2001, ministers asked the Committee to implement the financial regulation instruments at its disposal, in the hope that this regulation would be brought to bear through price reductions, wherever such a reduction was justified.

1. PRICE REDUCTIONS

In their guideline letter for 2001, the ministers asked the Committee:

- To step up the implementation of the plan to lower the price of proprietary medicines for which the *Service Médical Rendu* (SMR, medical service to the patient) rating was declared insufficient by the *Commission de la Transparence* (CT, transparency commission). The first stage was conducted in 2000.

- And, for proprietary medicines with a sufficient SMR rating, to systematically examine the expediency of reducing their prices, especially in classes which, by virtue of their volume and development, are known to contribute largely to the overall growth in sales.

Furthermore, the ministers explicitly stated their wish for these measures to be achieved via agreements.

It was in this context that the Committee entered into discussions with pharmaceutical companies in the summer of 2001. Discussions regarded price reductions for products with an insufficient SMR rating and targeted price reductions for products in rapidly expanding classes.

1.1 REDUCTIONS IN THE PRICE OF PRODUCTS WITH AN INSUFFICIENT SMR RATING

Similarly to the previous year, having established reduction scales for all products rendering an insufficient medical service, the Committee submitted a formal proposal to all manufacturers for a reduction consistent with these scales.

During negotiations, the Committee agreed on the one hand to set a ceiling for businesses whose turnover was overly affected by the reductions requested. On the other hand, the Committee acceded to the adjustment of the proposed reductions, so long as the overall impact on the business remained constant and did not lead do any distortion between comparable drugs. With the consent of the registration authorities, the Committee also agreed that the price reductions requested be replaced by the withdrawal of reimbursements, when it appeared that the risks of transferring prescriptions over to existing reimbursable drug were low.

The negotiated reductions range from 2% to 20%, averaging approximately 7%. The impact of the reductions, applied to volumes sold in 2000, would have accounted for €83 million. These reductions related to 232 products and 374 presentations. Most occurred towards the end of the year. The choice of delisting was made for 96 presentations corresponding to 69 products. Turnover for these presentations totalled €55 million in 2000.

Overall, 470 presentations, corresponding to 315 products from 145 different manufacturers, were either withdrawn from reimbursement or received a price reduction due to an insufficient SMR rating.

1.2 TARGETED REDUCTIONS

On the basis of the criteria set forth in the ministerial guidelines, the Committee targeted 9 product classes: statins, proton pump inhibitors (PPIs), some antibiotics, antidepressants, angiotensin II receptor antagonists, H1 antihistamines, growth hormones, triptans, setrons, to which it added four isolated products, virtually constituting classes in themselves.

The common feature of these classes and products is that they all have experienced and, in most cases are still experiencing, strong growth. All have also benefited from high prices at the outset. This class rationale has however led to reducing the price of relatively recent molecules. This is due to the fact that the classes were established before their launch and it was inconceivable, from the point of view of the

Social Security Code, that the prices of these drugs would not be affected by the price reduction of their predecessors, particularly when the *Amélioration du Service Médical Rendu* (ASMR, improvement of the medical service over comparators) rating did not reflect any improvement.

In classes where drug prices are similar, the Committee sought uniform reductions. In other classes, the Committee's requests depended on the relative price level or costs of treatment.

As is normal practice in arrangements adopted under agreements, during the negotiations the Committee acceded certain counter-proposals put by the firms in relation to its initial demands. The counter-proposals accepted consisted either in sparing, among the various presentations, proprietary products for which a reduction was requested, some which had been only recently marketed or whose price was judged by the firms to be particularly sensitive. It also consisted in adjusting the reduction according to different presentations, in reducing the rate of the requested reductions, offset by a reduction in other products, and finally, in adjusting the dates on which the reductions come into force, to a very marginal extent.

The only constraints imposed by the Committee on these adjustments were to avoid abnormal discrepancies in the relative positioning of prices in each of the classes and to maintain the overall efficiency of the reduction operation.

Overall in 2001, 103 products, corresponding to 253 presentations, for which the CT did not consider the SMR to be insufficient, were warned of a price reduction. Almost all of these reductions fall within the framework of the targeted reductions. The reduction rates range from 1% to 15%, with most around 4 to 5%. The estimated average reduction rate is 6%, corresponding to €202 million on the basis of 2000 sales volumes.

1.3 OTHER PRICE REDUCTIONS

Similarly to previous years, a number of price reductions were directly caused by the application of agreed clauses (dosage, cost of daily treatment by dosage range, volume, etc.). However, in so far as a number of them related to products otherwise implicated in the general reduction plan, their effect has been included in the above figures.

Conversely, in 2001, the Committee did not request any reduction as the result of an advertising ban. By doing so, it abided by the terms of a decision delivered by the *Conseil d'Etat* on the appeal against a decree requesting a price reduction following an advertising ban. Such price reductions must now be justified on the basis of common law as laid down by the Social Security Code for fixing or adjusting prices. What transpires from this is that the risk to public health linked to the misuse brought about by banned advertising cannot justify a price reduction, unless it is demonstrated that the advertising caused or could have caused measurable economic damage to the mandatory health insurance. The Committee was not able to establish any such finding in any of the cases of advertising bans examined in 2001 within the time available.

2. DISCOUNTS

2.1 PRIORITY TO DISCOUNTS BY CLASSES

These are year-end quantitative discounts which, according to the *Accord Sectoriel,* manufacturers undertake to pay to the mandatory health insurance, after entering into a multiannual accord with the Committee excluding them from fiscal contributions. The Committee, as in previous years, placed great emphasis on discounts linked to the overall trend in sales in pharmacotherapeutic classes in relation to those based directly on the turnover of each business.

A revised version of the table of thresholds triggering discounts by class was submitted in spring 2001, for consultation to all businesses, via the *Syndicat National de l'Industrie Pharmaceutique* (SNIP, National Pharmaceutical Manufacturers' Association). After account was taken by the Committee of a number of remarks made by businesses during this consultation process, the 2001 table was circulated to all businesses for its incorporation in the supplementary agreements relating to the year 2001.

The Committee points out again that the rates of growth which appear in this table are neither forecasts nor ceilings limiting the prescription or sale of the proprietary medicines concerned, but thresholds beyond which it estimates that the community should pay proportionally less for these products by obtaining year-end quantitative discounts.

It also points out that the real significance of those rates is revealed only when compared to natural growth trends in sales of the corresponding classes. A rate, even negative, applied to a class which foreseeable trend is of even sharper decline, does not mean that the Committee wishes to scale down the net resources devoted to these proprietary medicines, but on the contrary that it wishes to curb the decline. Conversely, a positive and even high rate, when applied to a class, which expected rise in costs is greater, means that the Committee feels justified in moderating the increase in public resources allocated to this class.

Over and above the principles on which the table is established and operated, for which please refer to annex 2, its review for 2001 calls for comment. The Committee first decided to roll the table until 2004, namely beyond the validity period of the agreements, taking the view that the agreements were intended to be extended and that the 4-year visibility period offered by the table ought to be retained. The 2001-2003 rates themselves were adjusted, either to make room for the arrival of new proprietary medicines or to take into account real sales in 2000, particularly where these sales have far exceeded the set thresholds. This " readjustment " therefore warranted a reduction in the thresholds initially forecast for the forthcoming years.

Finally, no alteration was made in relation to the previous year either to the various rates applicable to discounts by classes or to the exemption arrangements.

2.2 THE INCREASING BURDEN OF SPECIFIC DISCOUNTS BY PRODUCT

In the total discounts paid by businesses, the sum ascribable to the clauses of special product agreements rose fairly sharply, primarily on account of the effect of the clauses adopted by agreement for the daily cost of treatment by dosage range. It did in fact emerge in a number of cases that the share of sales achieved on high dosages far exceeded what had been announced by businesses at the time of registration.

3. THE 2001 EXEMPTION AGREEMENTS

The law provides that "those firms which have entered into (…) an agreement (*convention*) with the CEPS (…) which is valid on 31 December of the calendar year under which the contribution is due, are not liable for the contribution provided in article L. 138-10".

Early September, the Committee therefore put forward a proposal to all firms for a supplementary convention relating to methods for calculating year-end quantitative discounts. Acceptance of the convention was required to exempt from the conventions for 2001, without prejudice to special provisions to be negotiated between each firm and the Committee.

This year-end negotiation was largely simplified by the very fact that many firms had already settled, fully or in very large part, their contribution to the 2001 regulation through the agreed price reductions.

Presented below, by way of a record, is a statement of the principles that guided the Committee in these negotiations as well as a statistical review of the arrangements.

3.1 PRINCIPLES USED IN NEGOTIATIONS

As in 2000, the Committee adhered strictly to the provisions of the sector-based agreement and to the rules, which it itself had published, governing the calculation of discounts. Specifically, the exemptions from discounts by class were agreed on the basis of entirely uniform principles.

As discounts are linked to the overall turnover of each firm, the negotiation of supplementary agreements used the fiscal contribution that would have had to pay in the absence of an agreement as an indicator. However, in the context of the sector-based agreement, these indicators were systematically adjusted for those firms whose growth in the ambulatory market in 2001 had been strongly affected by the rise in their generic sales or by the transition to ambulatory distribution. The thresholds which trigger discounts were agreed with the aim that the year-end total quantitative discounts payable by each firm are such that, for firms benefiting from relative advantages in terms of discounts (recent innovations, products in classes not subject to discounts, etc.) and in application of the sector-based agreement, this advantage would be retained; for the others, total discounts remained lower than what would have had to be paid outside the arrangements. In practice, turnover discounts rarely exceeded 25% of the guideline clause.

Companies requested that discount ceilings be set by conventions, either for all discounts or for turnover discounts only, more frequently than in 2000. Turnover discount ceilings were set, particularly in the case of a disagreement between the firm and the Committee over sales estimates for 2001, where the Committee's forecast was lower than that of the firm. Similarly, a threshold was set at a level that allowed the expected yield to be achieved if the Committee's forecast proved right. A ceiling was decided upon in order that the firm is not penalised were its own forecast to prove accurate. A ceiling on total discounts was most wanted by the larger companies, in order to secure their provisions when drafting annual accounts. In most cases, the Committee made its acceptance conditional upon the setting of a ceiling higher than the expected yield from discounts. In fact the agreed ceilings were generally not reached, largely because of a slump in sales in December.

The Committee maintained the simplified conventions system, introduced in 1999 for the benefit of small laboratories. The main advantage of these conventions, apart from the formal simplification, is the 1% discount ceiling on their turnover. In 2001, these simplified conventions affected 84 laboratories whose overall sum of fiscal contributions (which would have been payable in the absence of an agreement) represented, as in 2000, just over 1% of what the total industry contribution would have been.

As regards, finally, the question of offsets between discounts and price reductions, the Committee applied the following principles: reductions for insufficient SMRs gave rise, as previously, to a discount credit to the sum of their effect throughout the year on the basis of volumes sold in 2000. Reductions brought about by the application of price review clauses adopted by agreement were of course not offset. Reductions relating to products with an undisputed SMR, the initiative for which was taken by the Committee in accordance with ministerial guidelines, were generally offset in the discounts at 50% of their value on the basis of 2000 sales. In a few cases, the setoff was lower for reductions whose cause, even without explicit clause, was independent of the general plan implemented by the Committee. Finally, the rare reductions proposed spontaneously by firms were deducted fully from the discounts.

3.2 STATISTICAL REVIEW OF THE 2001 CONVENTIONS

174 pharmaceutical companies and groups concluded conventions or codicil of conventions providing exemption from the fiscal contribution for 2001. In all, these companies accounted for 99.9% of the industry's reimbursable ambulatory drug turnover. Approximately fifteen very small firms declined the agreements proposed to them.

It should be noted that, in all, the number of firms marketing reimbursable drugs and therefore likely to enter into agreements, rose in 2001, even in the face of the continued drive towards concentration involving large and medium-sized enterprises. This is due to the arrival on the French market of three types of business for which sales in France are currently very poor without exception: small-sized biotechnology firms with generally only one product; large or medium-sized foreign businesses who have

until now licensed laboratories established in France for the sale of their proprietary medicines and who have decided to create sales subsidiaries; finally, small businesses set up by pharmaceutical industry executives, often to exploit old proprietary medicines from large companies wishing to streamline their product portfolio.

3.3 OVERALL RESULTS OF THE REGULATION

Overall, all the agreed measures adopted in 2001, whether agreements on discounts, price reductions or withdrawal from reimbursement, could cut €543 million off the pharmaceutical industry's turnover of reimbursable drugs. This amount comprises €183 million in discounts payable in 2002 under the agreements still in force at end of 2001 and €360 million in impact of price reductions and withdrawals from reimbursement decided in 2001.

The impact of price reductions and reimbursement withdrawals corresponds to a forecast. The real effect of these measures is directly dependent on the volume of proprietary medicines affected by the reductions effectively sold. For withdrawals from reimbursement, the real effect depends on an estimation of transfers of prescription to drugs remaining reimbursable. For the price reductions, this forecast was made by estimating the 2002 sales volume from growths or declines observed at the time of the reductions. For the withdrawals from reimbursement, it was assumed that the impact on sales in 2002 would amount to two thirds of 2000 sales.

Expressed as an impact of the increase of net sales of reimbursable proprietary medicines, these measures will reduce this increase by 1.9 points, all things being equal. This represents the difference between the effect of price reductions (2.5 points) and the counter-effect of discounts (-0.6 points) due to the fact that the discounts paid in 2002 will have been lower than those paid in 2001 (€ 275 million). Bearing in mind that, in 2001, the application date for the price reductions was quite often late, this impact will be focused primarily on 2002.

For the record, the sum of the fiscal contributions that firms would have paid in the absence of agreements would have been €370 million

Chapter III - NEGOTIATION OF THE DRUG PRICE

The pricing of proprietary medicines is the primary task of the Economic Committee for Health Products (CEPS) and is its core activity.

This activity will be examined,

- From a quantitative viewpoint, by examining and analysing the cases sent and processed by the Committee in 2001;
- By presenting the pricing methods to which the Committee refers in negotiations with firms;
- Through the price level of the proprietary medicines.

1. ACTIVITY OF THE PROPRIETARY MEDICINE SECTION IN 2001

2001 saw a steep rise in the number of cases filed with the Committee, matched by the intensification of its own activity measured in numbers of cases processed. For all that, the backlog of cases not yet closed at the end of the year is large. The overall periods for processing cases have grown in length. Difficulties emerge which give rise to additional delays in the processing of cases, not all of which attributable to the Committee alone (delays by the Transparency Commission and periods for discussion and signature by the firms).

Below is a review of activities for 2001 (applications[4] filed and processed), an analysis of processing periods, and finally an analysis of the backlog of pending cases at the close of 2001.

1.1 REVIEW OF THE ACTIVITY OF THE PROPRIETARY MEDICINES SECTION IN 2001

1.1.1 Applications submitted to the Committee in 2001

1785 applications filed with the Committee between 1 January and 31 December 2001[5]. Compared with the previous year, the number of demands has risen by 8%. In total, the number of applications filed has risen by 2/3rds in three years.

Table 5: Trend in the number of applications filed

Year	1998	1999	2000	2001
No. of applications	1076	1364	1649	1785
No. of additional applications		288	285	136
Rate of increase		+ 27 %	+ 21 %	+ 8 %

Of the applications filed in 2001, 31% correspond to presentations of generic drugs.

The bulk of the rise in applications sent to the Committee is due to re-registrations, whilst the number of initial registrations has fallen compared with the previous year.

These statistics do not include cases opened by the Committee, in particular price reductions made as part of the proprietary medicine plan enacted by the Government for 2001 and those stemming from the application of specific clauses. Likewise, overall work relating to the introduction of the euro is not included in this breakdown.

Figure 1: Rate at which applications were filed with the CEPS in 2001

[4] Price application is understood to mean applications which were made at the time of a registration, registration renewal, price alteration or extension of therapeutic indications. An application corresponds to a presentation (i.e. a CIP number) ; there are as many applications as presentations : for instance, a proprietary medicine in 5ml and 10ml packs corresponds to two presentations and hence two applications.

[5] This breakdown does not include radiation applications.

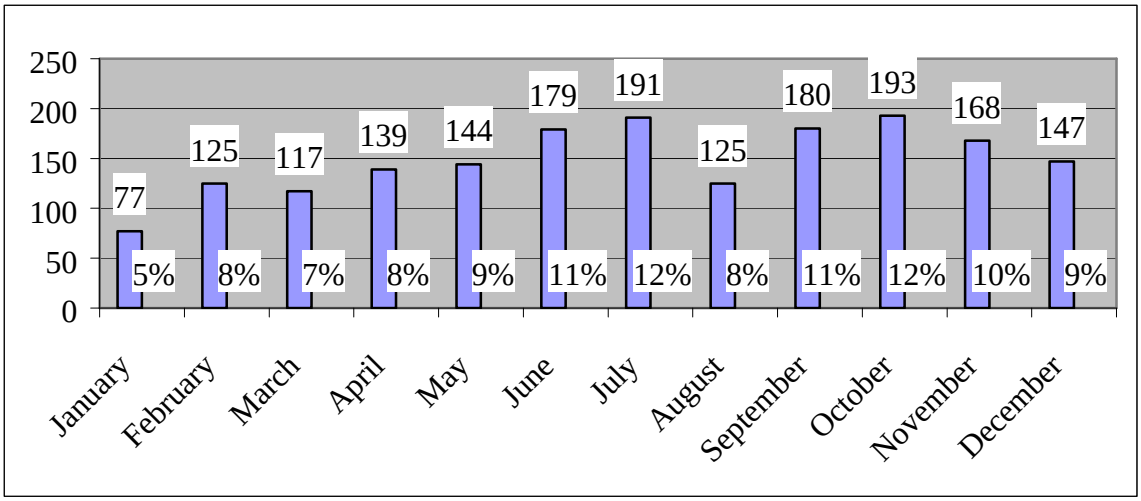
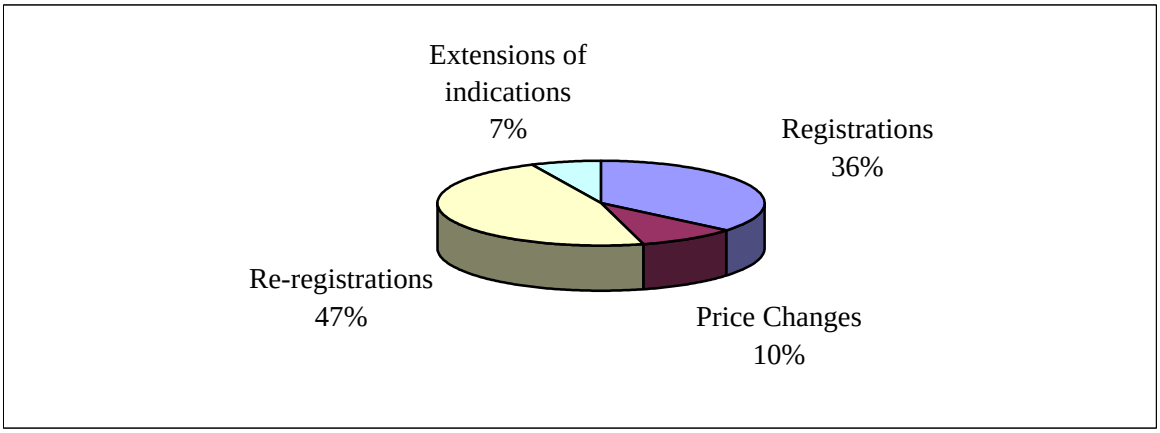


Table 6: Features of applications filed in 2001

	1st registration	Re-registration	Price alteration	Extension of indication	Total
Generics	283	250	24	-	**557**
Others	360	589	153	126	**1228**
Overall	**643**	**839**	**177**	**126**	**1785**

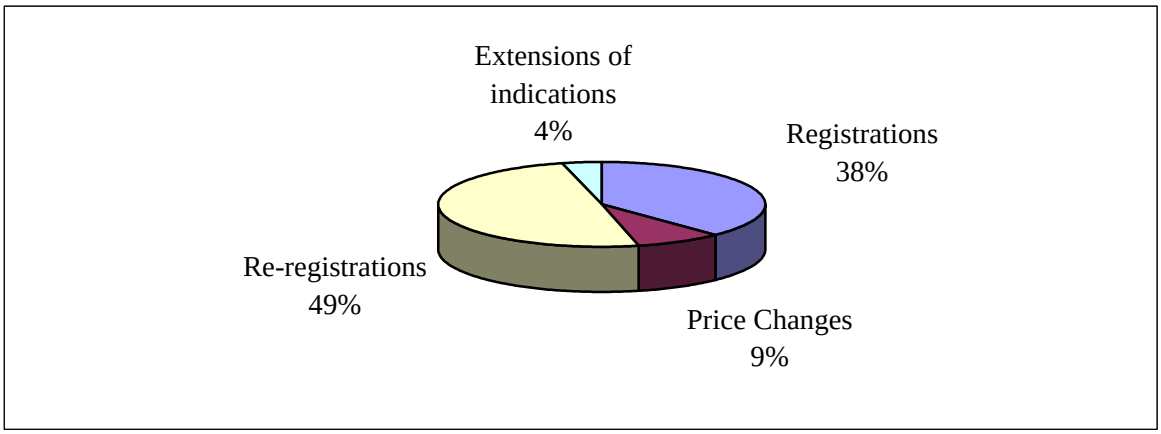
Figure 2: Type of applications filed with the CEPS (all applications)



1.1.2 Cases concluded in 2001

In 2001, 1508 cases were successfully concluded, whether it is an agreement between the firm and the Committee leading to a decree published in the *Journal Officiel* (official journal), a rejection or abandonment. The number of cases rose by 8% compared with 2000, in which 1398 cases had been closed.

Figure 3: Distribution of applications processed in 2001 according to type of application



The 1508 applications processed by the Committee in 2001 relate to 146 different companies, i.e. averaging over 10 presentations per company and a maximum of 60 presentations for one of them

Table 7: Number of applications processed in 2001 according to type of application and decision

Type of decision	Registrations	Re-registrations	Price alterations	Extension of indication	**Total**
Agreement	469	741	70		**1280**
Abandonment*	94***	10	3		**107**
Notice**				57	**57**
Rejection	5	2	57		**64**
Total	**568**	**753**	**130**	**57**	**1508**

* Abandonments are decided by the Committee either in the case of explicit withdrawal by a firm of its application, or when it does not accept the Committee's proposal and persistently fails to come forward. Abandonments may also be decided in relation to products that were found by the Committee at the time of their re-registration not to have been marketed.
** Extensions of indications established after the 180-day deadline gave rise to formal notice.
*** Decisions to abandon registration applications relate in most cases to erythropoietins currently employed in hospitals.

It is observable, as in 2000, that the number of applications conclusively dealt with is lower than that of applications made to the Committee in the course of the year. The outcome of this discrepancy of 277 applications is a backlog of cases pending at the close of the year (see 3 below).

There is no doubt that this unsatisfactory result is due primarily to the inflow of re-registrations, which is of little consequence to patients and firms alike but which also deflects from initial registrations and hence calls for rapid redress.

1.2 CASE PROCESSING PERIODS

Article R.163-7-I specifies that for the registration of a proprietary medicine " decision (…) must be taken and notification given to the firm exploiting the medicine

within a period of one hundred and eighty days from receipt of the application (…). The registration of the proprietary medicine on the list and the fixing of its price shall be published in the *Journal Officiel* within this period." As regards price change applications filed by firms, the Committee is required to reach a decision within a period of less than 3 months.

The following section analyses, according to the type of application and decision taken by the Committee, the processing periods for cases, from their filing with the Committee until publication, as appropriate, of orders or opinions in the *Journal Officiel* (abandonments or rejections do not give rise to publication in the JO). It therefore incorporates the periods for the processing of cases by the Committee but also the periods relating to the checking of these cases by the Transparency Commission.

1.2.1 Overall period

1.2.1.1 Overall period according to application type

The average period for the processing of applications conclusively dealt with in 2001 was 202 days, namely 6 days longer than in 2000. The following table presents these periods according to type of application submitted by firms.

As regards the length of the period for re-registration applications, it is worth pointing out that it stems in part from the fact that the publication of the corresponding decisions is adjusted on the re-registration expiry date, whereas the re-registration applications may have been filed by firms more than 180 days prior to the expiry date.

Table 8: Overall period for processing applications according to type (number of days)

Type of application	Average Period	Median period	Standard deviation	Max. period	Min. period
Registration	186	154	118	621	21
Re-registration	229	215	79	562	35
Price changes	87	90	35	195	9
Extension of indication	237	244	92	538	22
Overall	202	184	102	621	9

The shortest average and median processing periods are recorded for price change applications. Under the regulations, the Committee is required to rule on price change applications within 90 days. As regards the rejection of these applications, the average period recorded in 2001 is 81 days (median period 78 days). Longer periods, at times over 90 days, are observed in the event of an agreement due primarily to the time involved in the collection of signatures and publication of notices.

1.2.1.2 Overall periods according to drug type

The average period for the processing of cases corresponding to generic drugs was 138 days. It is much the same as in 2000 (140 days). This average period

corresponds to 111 days for initial registration applications, 181 days for re-registration and 94 days for price change applications.

The processing period for applications relating to generic drugs accounts only for 60% of the processing period for applications concerning non-generic drugs. The discrepancy stems from the fact that generic drug cases no longer have to be examined by the Transparency Commission, even though some of them were in 2001.

Table 9: Overall average period according to drug type (number of days)

Type of application		Average period	Median period	Standard deviation
Registration	Generics	111	94	55
	Others	239	208	122
Re-registration	Generics	181	162	61
	Others	243	236	79
Price change	Generics	94	80	59
	Others	86	90	36
Extension of indication	Others	237	244	92
Overall	Generics	138	129	67
	Others	227	216	103

The average period for processing applications relating to other proprietary medicines was 227 days, which corresponds to 239 days for initial registrations, 243 days for re-registrations and 100 days for price change applications.

Registration periods seldom hinder patients' access to the most innovative drugs since they are available very early on thanks to the *Autorisation Temporaire d'Utilisation* (ATU, temporary use procedure) procedures.

1.2.2 Intermediate periods

The analysis of intermediate periods relates exclusively to applications for initial registration culminating in publication in the Journal Officiel; excluded therefore are abandonments and rejections not giving rise to publication[6].

This period for processing an initial registration case has been broken down into 5 stages, from the filing of the case with CEPS to the forwarding to the Committee of the Transparency Commission's report (TC), from the forwarding of the report to the first session of the Committee (Investigation), from the first to the last session of the Committee devoted to the one case (Negotiation), from the last session to the signing of the supplementary agreement (Agreement) and the period prior to publication of notice of the corresponding price in the Journal Officiel (JO).

[6] The analysis of intermediate periods relates to the 469 registration applications culminating in publication in the Journal Officiel, the average processing period for which - 171 days - is less than that of all registration applications - 186 days - primarily on account of the exclusion of abandonments which are only recorded at the end of a longer average period (260 days).

Table 10 : Periods for processing initial registration applications

Number of days

Proprietary medicines	TC	Investigation	Negotiation	Agreement	JO	**TOTAL**
Non generics	98	49	29	18	42	**236**
Generics	1*	42	1**	21	39	**103**
Overall	51	45	15	20	40	**171**

* 3 generics cases concluding in 2001 were subjected to scrutiny by the TC.

** 4 generics cases were subjected to more than one examination by the Committee in session.

Overall, the initial registration cases were processed in a period of 171 days between the date of their filing and the date of their publication in the Journal Officiel, i.e. averaging 6 days less than in 2000.

The discrepancy in the average period between the generic drugs and the other drugs is very wide (103 days and 236 days respectively). Apart from the Committee's desire to speed up the generic application processing, this discrepancy stems mainly from the time required by the Transparency Commission to rule on and issue its opinion on applications relating to non-generic drugs, and from the time involved in negotiating the price of these drugs which, in 40% of cases will be subjected to further scrutiny by the Committee in session.

1.2.2.1 Stage one: Transparency Commission

Cases must be filed simultaneously with the Committee and with the Transparency Commission. This first stage entails scrutiny of the application by the Transparency Commission and issuance of the Commission's opinion to the Committee. As regards applications for initial registration of non-generic drugs, the opinion of the TC is delivered on average within 70 days from when the case is filed.

Added to this period of scrutiny by the TC is that involved in the forwarding of its report to the Committee. On average, in the course of 2001, for applications necessitating the opinion of the Transparency Commission, its reports were forwarded to the Committee 29 days after their adoption.

In total, the average period of this first stage is 98 days for initial registrations of non-generic drugs.

1.2.2.2 Stage two: Rapporteurs' instructions

This stage spans from the date on which the Transparency Commission's opinion is forwarded to the Committee to the time when the Committee first examines the submission in session. It includes the instruction of the dossier by the rapporteur in liaison with the firm and the period relating to its inclusion on the Committee's Agenda (one week after the report has been forwarded to the Committee Members).

An average of 45 days will have elapsed between the filing of the application for generic drugs (or the forwarding of the Transparency Commission's opinion where non-generic drugs are concerned) and the scrutiny of the case by the Committee in session.

This period is one week less on average for generic drugs, 42 days as opposed to 49 days for non-generic drugs.

1.2.2.3 Stage three: Negotiation

The period between the dates of the Committee's first and last examination in session partly provides the time necessary for the Committee to formulate its proposal if one has not been adopted in a single session. It also serves as a phase of negotiations between the Committee and the company. If the Committee's proposal is turned down by the firm, its counter-proposals are then examined, following discussions with the rapporteur. This period lasts an average of 29 days for non-generic drugs, and 1 day for generics. Approximately 40% of registrations of non-generic drugs give rise to more than one examination in session whereas it is the case for only 2% of generics' registrations. As this third stage comprises negotiations with the firm, it is only formally separated from the next stage. Overall, all proprietary medicines combined, this period lasts 15 days.

1.2.2.4 Stage four: Convention

This is the period between the last session of the Committee devoted to a case and the signing of the relevant codicil to the Convention. It is a time for finalising the codicils and providing the logistical time frame necessary for exchanges of proposals and signatures between the firm and the Committee. Moreover, the length of this stage may vary depending on the urgency felt by the firm to market its product and hence the time it will take to sign the codicil. The fourth stage does in fact include a negotiation deadline that is hard to dissociate from the logistical periods. On average the delay is 20 days, much the same for generics and non-generics alike.

1.2.2.5 Stage five: Signature and publication in the Journal Officiel

This last stage includes the preparation and signing of price notices by the Committee Chairman and of registration orders for reimbursement by the relevant departments of the Ministry of Health, along with their transmission to the *Journal Officiel* and their publication.

This period lasts an average of 40 days, 42 days for non-generic drugs and 39 days for generic drugs.

Overall, the 133-day discrepancy in the periods for the processing of generic drugs and non-generic drugs lies in the time it takes for the Transparency Commission to make its ruling and forward its opinion to the Committee (70% of the discrepancy) and in the negotiation time (20% of the discrepancy).

1.3 APPLICATIONS PENDING

The " outgoing " flow made up of the number of applications conclusively dealt with in 2001 (which stands at 1508 cases) should be brought more closely into line with the " incoming " flow in the same year, namely 1785 applications. The difference between these two figures, i.e. 277, leads to a proportionate increase in numbers of

applications pending which stood at 1319 at the close of 2001 (the number of applications pending at 31 December 2000 was 1042 cases).

For 152 of the applications pending at 31 December 2001, a decision was reached and the Committee's proposals signed by firms, or the corresponding orders were signed or distributed for publication in the *Journal Officiel*. Another 394 applications had, prior to the close of 2001, been the subject of at least one initial examination by the Committee.

As at 31 December 2001, the backlog of applications for initial registrations not yet conclusively dealt with stood at 442 applications, 262 of which (approximately 60%) had already been scrutinised in session by the Committee, including 83 on which a decision had been reached. For 114 of the 180 applications not subjected to scrutiny in session, the Committee was still awaiting as at 31 December the opinion of the Transparency Commission.

2. PRICE NEGOTIATION METHODS APPLIED BY THE COMMITTEE IN 2001

For information purposes, the chapter relating to methods applied by the Committee for the negotiation of drug prices, which already appeared in the 2000 Management Report, is reproduced in annex 5. The price negotiation methods applied by the Committee have in fact undergone only marginal changes, affecting, on the one hand, the pricing of new generic drugs and, on the other hand, the inclusion of stepwise reductions in the pricing clauses according to volumes sold or dosages used.

2.1 THE PRICING OF GENERIC DRUGS

Since 1996 it has been the practice of the Committee to accept all price proposals for the registration of a generic brand, so long as the proposed price was at least 30% lower than the manufacturer's price net of tax of the benchmark branded pharmaceutical.

This practice related to the generics of benchmark branded pharmaceuticals formerly marketed and whose price was at times set at a relatively low level in relation to those charged in other European Union countries. Now that the patents of the latest molecules are about to expire, the prices of which were set at higher levels than in the past and are more or less on a par with average prices elsewhere in Europe, this is no longer the case. In these circumstances, the Committee feels that an increase in the relative price advantage of generic drugs is justified and proposes to set at 40% the price differential between the benchmark branded pharmaceutical and the generic brand, below which price proposals put by firms will be systematically accepted. Different price proposals motivated by special circumstances will nonetheless be examined.

2.2 STEPWISE REDUCTIONS IN THE APPLICATION OF CLAUSES

In 2001, the Committee was repeatedly forced to limit, by stages whose level and duration are determined by agreement, the price reductions likely to result from

volume or dosage clauses (see annex 6). The aim in this instance, for the companies concerned, is to prevent the rapid creation of too great a discrepancy between the French prices lowered in application of these clauses and the prices charged abroad, the possible consequence of which being parallel exports. In the event that the reductions are temporarily limited by the stages, the firm pays a refund offsetting the reduction limitation.

3. THE PRICE LEVEL OF DRUGS

3.1 THE INSEE PRICE INDICES

The *Institut National des Statistiques et Etudes Economiques* (INSEE, national institute for statistics and economic studies) calculates annually the price indices of drugs reimbursable & non-reimbursable by the Social Security. The following table traces the trend in these indices over the past 4 years, 100 base on 1998 annual average[7].

Table 11: Prices indices of pharmaceutical specialities

Year	Reimbursable brands		Non-reimbursable brands	
	December	Annual Average	December	Annual Average
1998	99.8	100.0	100.8	100.0
1999	99.1	99.5	103.4	102.4
2000	98.2	98.8	105.1	104.7
2001	96,0	97.5	107.7	106.3

Source INSEE

The prices adopted for calculating these indices (tracking of a sample of 7000 presentations periodically re-updated) are the pharmacy prices, inclusive of tax and incorporating the distribution margins. Their trend, where reimbursable proprietary medicines are concerned, therefore incorporates variation factors (margins, taxation, etc.), which, over and above the manufacturer's price net of tax of particular interest to the Committee, may result in particular variations. The fact remains however that there is a continued downward shift in the index of reimbursable proprietary medicines that became more pronounced in 2001. Bearing in mind the stability of the margins and the taxation applicable to reimbursable proprietary medicines over the past two years, this trend should stem mainly from that of manufacturer's prices net of tax. However, even in the absence of a regulatory modification of the margins, either due to their degressivity or to the more important place occupied by generic drugs for which the margins are disproportionate to manufacturer's prices net of tax, all drifts in consumption towards more expensive products or towards generic products are likely to lead to a growth on the part of margins in these public price indices.

The 1.3% fall between 2000 and 2001 in the INSEE price index is found to be of the same order as the price effect calculated from GERS sales in 2000 and 2001 (see A.3.3).

[7] INSEE – Monthly statistical bulletin– February 2002 – no. 2.

However, by its construction, the INSEE index and the price effect thus calculated result in the failure to take into account newly registered products and hence to only measure the price trend of products already marketed. This approach is inherent in the formulation of a price index. Yet in a sector such as that of medicines, the rise in real prices is due almost entirely to the replacement of less expensive products by more expensive products, whose direct comparison entails enormous methodological difficulties (quality effect).

The Committee was therefore interested in the trend in the average price of packs - as the main component of the increase in expenditure - and in the determining factors of this trend.

3.2 THE AVERAGE PRICE OF PROPRIETARY MEDICINE PACKS

The average price of " packs " sold is obtained by dividing the annual turnover net of tax by the number of units (packs) sold that same year. It relates to all products sold in a given year whatever their market share. It therefore incorporates prices and their variation but equally the " structure " effects (see Chapter 1, point 3.3 above).

Table 12: The trend from 1998 to 2001 in the average price of proprietary medicine packs

Year	1998	1999	2000	2001
Average price of " pack "	€ 4.48	€ 4.69	€ 4.98	€ 5.29
Annual rate of growth		+ 4.7 %	+ 6.2 %	+ 6.2 %

This trend also incorporates the effect due to packaging modifications. When for example, for a given pharmaceutical brand, a pack of 28 tablets substitutes a pack of 14, the average price of the packs increases without repercussions (expect for the margin effect) on the general level of prices or expenditure. This effect is however estimated to be very marginal, in the absence of any ordered and sizeable change in the packaging.

3.3 DETERMINING FACTORS IN THE RISE IN AVERAGE PRICES

This growth is clearly due, originally, to the registration of new proprietary medicines. The Committee has therefore calculated, for the four years from 1998 to 2001, the average prices of packs of newly registered proprietary medicines as well as those of re-registered products. Three registration categories have been distinguished: non-generic drugs without ASMR, proprietary medicines with ASMR, all ASMRs combined and generic drugs. The detailed results of these calculations are devoid of significance in absolute terms in that, by their structure for registrations, they are not weighted by sales and, above all, they are, each year, highly dependent on the uncertainties of registration applications or the re-registration timetable. This is why, in order to cancel out the absence of weighting by sales, the median price has been used for the newly registered proprietary medicines.

In order of size, the information that can be drawn from them is nonetheless interesting. It transpires in effect that:

- the median price of packs of proprietary medicines registered without ASMR is stable from year to year, and of the same order as the average price of proprietary medicines already registered.

- the median price of proprietary medicines with ASMR is far greater than the average price of proprietary medicines already registered.

- the median price of re-registrations is considerably higher than that of registrations of proprietary medicines without ASMR, as is normal insofar as the re-registrations relate in part to proprietary medicines whose initial registration was made with ASMR.

- the registration price of generics, clearly lower than that of non-generics without ASMR, is on the contrary growing steadily as the Register increases in higher priced classes, while however re-registrations of generics, corresponding by definition to older classes, are made at lower median prices.

PART TWO – MEDICAL DEVICES

Chapter I – REIMBURSED COSTS AND THEIR TREND

1. THE MEDICAL DEVICES MARKET

The market for reimbursable medical devices is encompassed within the overall medical technologies market, the turnover for which is estimated to be worth €7.6 billion in France (source: association Eucomed), which corresponds to 4.5% of the world market and 18% of the European market.

This sector boasts some 250 industrial companies, employing 35,000 people in France. The top ten companies achieve 45% of total sales and account for 31% of jobs. The firms are either multinational businesses (more than one half of the top 20 firms operating in France are subsidiaries of international groups) or firms based solely in France (around 200) consisting mainly of small to medium-sized enterprises (SMEs), more often than not occupying " technological niches ". It has a balance of trade deficit of approximately €0.7 billion.

For the most part, sales in the sector relate to hospital equipment (imaging, operating theatres, medicosurgical equipment) and are therefore financed directly by the resources of these institutions. The market for products and services registered on the list contained in article L. 165-1 of the Social Security Code amounted in 2000 to approximately €2.7 billion. €2.2 billion of this was for the value of sales reimbursable on the basis of the list, at manufacturer's price net of tax; €0.5 billion (estimate) was purchased by hospitals from their overall allocation for the needs of their patients, mainly from among the products shown in part III of the list.

Expenditures reimbursable in the strict sense and including therefore the amounts reimbursable by patients or their additional insurance schemes, rose that year to around €5.1 billion, adding adjustment, distribution costs and VAT to the manufacturer's prices.

These reimbursable expenditures gave rise to reimbursements worth €2.65 billion. For several product categories, there is in fact a discrepancy, at times wide (most notably glasses and hearing aids), between sale prices and reimbursement tariffs. Furthermore, the reimbursement rate is ordinarily 65% of the tariff even if, for certain products, for patients with an ALD (Affection de Longue Durée, long-term illness), or on account of a KC of over 50, this rate rises to 100%.

All the figures stated above are estimates, with the exception of the sum of reimbursements, which is accurately known from the statistics of the compulsory health insurance[8]. In fact, the extreme diversity of the products or services in question, as well as that of the distribution channels, has made it so far impossible to gather precise and reliable statistics on consumption, apart from one or two notable exceptions for certain market segments.

In short, this sector is in fairly sharp growth, judging by the trend in obligatory health insurance reimbursements, which rose by 15% on average over the three years from 1998 to 2000.

2. REIMBURSED COSTS: DESCRIPTION AND TREND IN 2000

The Committee deemed useful to present in a fairly detailed costs devoted to this area by compulsory health insurance when rendering account of its activity involving medical devices, for the first time in its annual report. The results which follow stem wholly from the data gathered and processed by CNAMTS. The corresponding data by chapter for 2001 were unfortunately not available at the time that this report was drafted. The encoding should soon significantly improve the precision of the information gathered and the speed with which it is made available.

Presented below is an overall description of reimbursed costs by parts and chapters of the nomenclature, and a more detailed analysis of each of the four parts.

The statistical data supplied on the distribution of medical devices originate from a variety of sources: reports, professional organisations, disbursement bodies, etc.

[8] The extrapolation of the CNAMTS data to all systems is achieved from rates taken from health accounts.

2.1 OVERVIEW

TABLE 13: REIMBURSED COSTS BY PARTS AND CHAPTERS

Part	Chapter	Subject	Cost M€	% / part	% / list
I	1	Respiratory support equipment*	277	20.2 %	10.5 %
	1, 2	Other healthcare equipment	340	24.9 %	12.9 %
	1	Miscellaneous healthcare materials and equipment**	439	32.1 %	16.6 %
	3	Dressings	274	20.0 %	10.4%
		Compression materials and equipment	38	2.8 %	1.4 %
Total part I: Homecare equipment			**1368**	**100%**	**51.7%**
II	1	Ortheses	172	32.3 %	6.5 %
	2	Medical optics	158	29.6 %	6.0 %
	3	Electronic deafness apparatus	44	8.3 %	1.7 %
	4	Non-orthopaedic external prostheses	4	0.8 %	0.2 %
	5	Ocular and facial prostheses	14	2.6 %	0.5 %
	6	Foot ortheses	52	9.8 %	2.0 %
	7	Orthoprostheses	89	16.7 %	3.4 %
Total part II: External Ortheses and Prostheses			**533**	**100 %**	**20.2 %**
III	1, 2, 3	Inert internal prostheses	595	86.4 %	22.5 %
	4	Active internal prostheses	94	13.6 %	3.6 %
Total part III: Implantable MD and human grafts			**689**	**100 %**	**26.0 %**
Total part IV (chap 1,2,3)**: vehicles for the physical handicapped for purchase**			**55**	**100 %**	**2.1 %**
TOTAL ALL PARTS			**2 645**		**100 %**
***including spacers** not including spacers					

2.2 PART I: HOMECARE TREATMENT, LIFE ENHANCEMENT APPLIANCES, DIETARY FOODS AND DRESSINGS

This part is the most important cost item of reimbursable products and services (more than 51 %), up by 19.3% compared with 1999. In this section, the medical devices reimbursed by the State foster the return of patients to their homes. The recorded increase is therefore explainable in the main by the ageing population and by the promotion of the policy of home care for patients.

The products concerned are mainly distributed by pharmacies (45% of total costs in this part), service providers and, for respiratory support and homecare, by the support services. Service providers have experienced in recent years a major shift towards mergers.

Precise statistical data are unavailable, being as they are updated, for all product classes. Moreover, the breakdown of the chapters and sections of this part was altered in

2000, which creates uncertainty over the costs of certain sections. The costs of this section can nonetheless be broken down as follows:

Table 14: Reimbursed costs of Part I

PART I (51.7% of total costs of LPP (products & services list) in 2000)					
Chap	**Sect**	**Products**	**Costs**	**% / of total part**	**Trend**
I	1	Long-term oxygen therapy, not combined with other fixed prices	156.2	11.4 %	
		Continuous positive pressure for sleep apnoea syndrome	77.7	5.7 %	
		Inhaler therapy	39.5	2.9 %	
		Miscellaneous: other treatments: assisted breathing and tracheotomy	1.0	0.1 %	
		Spacer	3.1	0.2 %	
		Respiratory support apparatus: Total	**277.5**	**20.3 %**	**+ 29.8%**
	2	Active infusion system purchase/hire and fixed availability sum	9.2	0.7 %	
		Portable Diffusers and fixed availability sum	30.5	2.2 %	
		MD for home infusion: Total	**39.6**	**2.9 %**	**NA**
	3	Diabetics equipment	251.5	18.4 %	
		Self-testing MD: Total	**251.5**	**18.4 %**	**NA**
	4	Equipment for stoma patients	71.7	5.2 %	
		Equipment for incontinent patients	30.5	2.23 %	
		Vesical catheters	32.0	2.3 %	
		Re-education catheters	6.1	0.5 %	
		Intrauterine contraceptive devices	3.1	0.2 %	
		Others	1.5	0.1 %	
		MD for treatment of incontinence and urogenital system: Total	**144.8**	**10.6 %**	**NA**
	5	Nutriments	18.2	1.3 %	
		Others	7.0	0.5 %	
		Nutrition products and administration equipment	**25.2**	**1.8 %**	**NA**
	6 and 7	Central nervous system stimulator	2.8	0.2 %	
		Others	26.2	1.9 %	
		Treatment and maintenance MD for locomotor system and MD for other treatments and miscellaneous items : Total	**29.0**	**2.1 %**	**NA**
2	1	**Beds and bedding: Total**	**198.0**	**14.5 %**	**NA**
	2	Canes and crutches	10.7	0.8 %	
		Walking frames	7.6	0.6 %	
		Vehicles for the physically handicapped for hire	32.0	2.3 %	
		Shell chairs	4.6	0.3 %	
		Others: commodes, hair-pieces, patient hoists	35.0	2.6 %	
		MD and life enhancement apparatus : Total	**89.9**	**6.6 %**	**NA**
3	1	Traditional dressings and compresses	122.0	8.9 %	
		Biocompatible dressings	76.2	5.6 %	
		Bindings (adhesive tapes, etc.)	53.4	3.9 %	
		Other dressings	22.9	1.7 %	
		Dressings: Total	**274.4**	**20.1 %**	**+13.0 %**
	2	**Compression materials and equipment: Total**	**38.1**	**2.8 %**	**NA**
TOTAL PART I			**1368.1**	**100 %**	**+19.33%**

2.3 PART II : EXTERNAL ORTHESES AND PROSTHESES

This part is the 3rd cost item (more than 20%) of reimbursable products and services, up by 10.4% compared with 1999. It is made up of widely differing products: life enhancement aids (optics, hearing aids, etc.) and prevention or treatment devices (compression ortheses, compressive clothing, etc.).

The manufacturers to whom this part relates are, according to the chapters, either very large firms (optical glass, nutrition, dressings), or " adapter " craftsmen (foot ortheses, orthoprostheses).

The distribution likewise varies according to chapters. As a brief guide:

- The distribution of chapter 1 (mass-produced ortheses) is carried out by some 1200 shops, basically orthotists and, more and more often, pharmacists and service providers following specialist training.

- The distribution of chapter 2 (optics) is covered by 7600 shops, one third of which are independent, more than one half are part of a chain and approximately 350 belong to the mutuality network.

- The distribution of chapter 3 (hearing aids) is carried out by 1715 centres, 98 of which are mutualists, for 270,000 devices sold in 2000.

- The distribution of chapter 4 (non-orthopaedic external prostheses) is carried out either directly by the manufacturers/distributors (breathing prostheses for tracheotomies) or by orthotists (external breast prostheses).

- The distribution of chapter 5 (ocular prostheses) is carried out by craftsmen (80 ocularists).

- The distribution of chapter 6 (foot ortheses) is carried out by craftsmen (160 foot orthotists, shoemakers).

- The distribution of chapter 7 (foot prostheses) is carried out by SMEs and by craftsmen (200 ortho-prosthetists) who also sell mass-produced ortheses listed in chapter 1 of part II and life enhancement aids of part I or IV.

Table 15: Reimbursed costs Part II

PART II (20.2 % of total LPP (products & services list) in 2000)					
Chap	**Products**	**Costs M€**	**% / part**	**% / chap**	**Trend 1999/2000**
1	Sundry: major burns dressings + mass-produced shoes + heelpieces + trusses	23.6	4.4 %	14 %	
	Splints	19.8	3.7 %	11 %	
	Compression ortheses: hosiery	76.2	14.3 %	44 %	
	Compression ortheses other than hosiery	9.2	1.7 %	5 %	
	Medicosurgical girdles	30.5	5.7 %	18 %	
	Plantar ortheses (orthopaedic soles)	6.10	1.1 %	4 %	
	Neck collars	6.10	1.1 %	4 %	
	Ortheses: total	**2232,02**	**32.2 %**	**100 %**	**+17.7 %**
2	**Medical optics: total**	**158.6**	**29.8 %**	**100 %**	**+17.1 %**
3	**Deafness correction apparatus: total**	**44.2**	**8.3 %**	**100 %**	**+12.1 %**
4	External breast prostheses	3.4	0.6 %	76 %	
	Others: transtympanic drain + tracheal canulas + respiratory prostheses + voice prostheses	1.1	0.2 %	24 %	
	Non-orthopaedic external prostheses: total	**4.4**	**0.8 %**	**100 %**	**+14.1%**
5	**Ocular and facial prostheses: total**	**13.7**	**2.6 %**	**100 %**	**Stable**
6	**Foot ortheses (including repairs): total**	**51.8**	**9.7 %**	**100 %**	**Stable**
7	**Ortho-prostheses (including repairs): total**	**88.7**	**16.7 %**	**100 %**	**Stable**
TOTAL PART II		**533.0**	**100%**		**+10.4 %**

2.4 PART III: IMPLANTABLE MEDICAL DEVICES, HUMAN-DERIVED OR CONSTITUENT IMPLANTS AND HUMAN-DERIVED TISSUE GRAFTS.

This part represents the 2nd cost item (more than 25 %) of reimbursable products and services, up by 8.1% compared with 1999, following a period of stabilisation in 1997 and a slight increase in 1998 and 1999 (around 5%) owing to tariff reductions made when the nomenclatures and their tariff system were being put in place.

The manufacturers to whom this part relates are either foreign multinational companies (primarily American), or French SMEs at times occupying niches.

The past five years have been marked:

- For manufacturers, by a strong trend towards mergers with major companies owing to the buyout of several small or medium-sized companies by foreign multinationals.

- For distributors, by the disappearance of a large number of distribution companies owing to the set tariff levels which often no longer permitted " multi-stage sales " by several intermediaries.

The medical devices relating to this part are used in health institutions and bought either by direct purchase from manufacturers/distributors or from exclusive or non-exclusive distribution companies.

The breakdown of this part is summarised in the following table:

Table 16: Reimbursed costs Part III

PART III (26.0 % of total costs of LPP (products & services list) in 2000)					
Chap	**Products**	**Costs M€**	**% / part**	**% / chapter**	**Trend 2000/1999**
1, 2 and 3	Hip prostheses	111.3		19%	
	Knee prostheses	82.3		14%	
	Osteosynthesis	15.2		3%	
	Other orthopaedic implants	16.8		3%	
	Spinal column implants	3.1		1%	
	Shoulder implants	5.0		1%	
	Orthopaedic implants: Total	***233.7***	***33.9 %***	***40%***	
	Mechanical sutures	***76.2***	***11.1 %***	***13%***	
	Cardiovascular stents	38.1		6%	+20%
	By-pass implants	13.7		2%	
	Catheter chambers	12.8		2%	
	Other Cardiovascular implants	25.5		4%	
	Cardiovascular implants*: Total*	***90.1***	***13.1%***	***14%***	
	Lens implants	42.7		7%	
	Other ophthalmological implants	3.4		1%	
	Ophthalmological implants*: Total*	***46.0***	***6.7 %***	***8%***	
	Tissue integration implants	***30.5***	***4.4 %***	***5%***	
	Stents other than cardiovascular	***7.5***	***1.1 %***	***1%***	
	Other implantable medical devices	***110.5***	***16.0 %***	***19%***	
	Inert internal prostheses including human tissue grafts: Total	**30576**	**86.3 %**	**100%**	
4	Pacemakers	70.1	10.2 %	74%	
	Catheters	22.9	3.3 %	24%	
	Other active medical devices	1.5	0.2 %	2%	
	Active internal prostheses: Total	**94.5**	**13.7 %**	**100%**	
TOTAL PART III		**689.1**	**100%**		**+ 8.1%**

2.5 PART IV: VEHICLES FOR THE PHYSICALLY HANDICCAPED, FOR PURCHASE.

This part represents a cost of €54.9 million which rose steadily for several years and by 12.6% in 2000. This rise is due increasingly to wheelchairs purchased in respect of hired ones and to the registration on the list of more efficient, yet more expensive, electrical and/or reclining wheelchairs.

These products are manufactured either by large foreign firms (German and American), or by French SMEs who have cornered certain niches by supplying bespoke vehicles for the disabled or ones which have been adapted to the specific needs of certain types of disability.

The distribution of vehicles for the physically handicapped is carried out by the same service providers as for part I and to a lesser extent by pharmacists.

Table 17: Reimbursed costs Part IV

PART IV (2.1 % of total costs of LPP (products & services list) in 2000)				
Chap	**Products**	**Costs M€**	**% /part**	**Trend 2000/1999**
1	Mechanical wheelchairs	25.9	47 %	
	Electrical wheelchairs	18.3	33 %	
	Wheelchairs: Total	**2057,01**	**80.6 %**	
2 et 3	Miscellaneous (pushchairs, recliners…) and repairs	10.7	19.4 %	
	Miscellaneous vehicles, attachments and repairs:	**10.7**	**19.4 %**	
Total part 4		**2091,01.**	**100 %**	**+12.6%**

3. 2001TREND IN REIMBURSED COSTS

The growth in reimbursed costs in 2001 compared with 2000 (see following table created from data supplied by CNAMTS) is 13 %, slightly down on the two previous years.

Table 18: 2001 reimbursements from the general regime

Part	Chap/Service	2001	2001/2000
I	1. Respiratory support apparatus	328	18.4 %
	1,2. Other healthcare equipment	410	20.7 %
	1. Miscellaneous healthcare materials and equipment	552	25.8 %
	3. Dressings	264	-3.7 %
	3. Compression materials and equipment	37	-2.6 %
Total Part I Homecare equipment		**1 592**	**16.4 %**
II	1. Ortheses	194	12.9 %
	2. Medical optics	177	12.2 %
	3. Electronic deafness apparatus	51	15.6 %
	4. Non-orthopaedic external prostheses	5	13.5 %
	5. Ocular and facial prostheses	14	-2.6 %
	6. Foot ortheses	56	8.5 %
	7. Orthoprostheses	97	8.8 %
Total Part II External ortheses and prostheses		**593**	**11.3 %**
III	1,2 Inert internal prostheses	639	7.4 %
	4. Active internal prostheses	99	5.1 %
Total Part III Implantable medical devices and human grafts		**739**	**7.3 %**
Total Part IV Vehicles for the physically handicapped for purchase		**65**	**18.8 %**
TOTAL		**2 989**	**13.0 %**

In 2001, the measures adopted at the close of 2000 to improve public reimbursement of costs have proved more or less ineffectual owing to a slower than expected rise in costs for insulin pumps.

They have however contributed to the rise in costs of parts I and II.

These measures relate in effect:

- To part I: the registration of insulin pumps (cost of €21 million in 2001, whereas the estimated annual cost ranged between €60 and 90 million) and of products (materials, nutriments and fixed service rate) for domiciliary enteral nutrition (cost of €45 million whereas the estimated annual cost was around €15 million).

- To part II: the improvement in the public reimbursement, at a cost of €12 million, of glasses (extension from 16 to 18 years of the " improved " public reimbursement of glasses) and of electronic hearing aids (extension from 16 to 20 years with an extension to deaf-blind persons of the " improved " public reimbursement of hearing aids and a tariff revaluation of tips for these patients with an increase in the rate of renewal of tips for children aged under 2 years).

Chapter II – INTRODUCTION OF THE REFORM

1. AN EXPLANATION OF THE REFORM

The reform of the registration for reimbursement of medical devices was enacted by the Social Security Finance Act for 2000 and brought into force with the publication of the two implementing decrees of 26 March 2001 relating to the definition of procedures and to the composition and operation of the Assessment Commission respectively. It was eagerly awaited by manufacturers and the various professions who contribute to the supply, adaptation and distribution of the products and services concerned. It has however prompted them to raise a number of questions.

This is why the Committee has first and foremost endeavoured, through a vast consultation and information campaign, to raise awareness of the reform and to answer queries. Even before the publication of the decrees, its endeavours were pursued in close cooperation with the Health Services Advisory Commission (CCPS), overseen by the administrations chiefly responsible for the wording and implementation of the new texts (Directorate General for Health and the Directorate for Social Security)(Direction Générale de la Santé, DGS, and Direction de la Sécurité Sociale, DSS, respectively).

Thus, for example, in the first quarter of 2001, the CCPS and the Committee jointly held nine meetings attended by a total of 175 firms, with a view to examine with them the consequences of abolishing the reimbursement approval numbers. During

these meetings, and in a number of discussions, seminars or articles appearing in professional journals, the Committee strove to answer the questions put on the breadth of the reform and on the conditions for its introduction.

The main questions raised by firms and their professional organisations during this period related to:

- The breadth of the reform and most particularly the scope of the list of reimbursable products and services (LPP formerly TIPS);
- Recognition of innovations;
- Retention of specifications for registrations in the generic nomenclature;
- The criteria for setting tariffs and prices;
- The practical aspects of the new procedures.

1.1 THE BREADTH OF THE REFORM AND THE SCOPE OF THE LIST.

The broad definition by the new law of the scope of the list provided in article L 165-1 of the Social Security Code, covering most notably " medical devices for individual use " raised questions by and, undoubtedly, the hopes of manufacturers, particularly in terms of the prospect it seemed to offer of the reimbursement of materials for individual use employed in operating theatres.

The Committee was therefore prompted to point out:

- that the object of the reform was primarily procedural, entailing the separation, when formulating opinions, of an assessment stage entrusted to the new *Commission d'Evaluation des Produits et Prestations* (CEPP, Products and Services Assessment Commission) and a possible tariff and price fixing phase entrusted to the CEPS, and entailing the establishment of regulatory periods for examining registration applications.

- that its purpose was not therefore, even if such developments still remain possible, to extend the scope of the former " TIPS " (*Tarif Interministériel des Prestations Sanitaires*, devices formulary listing); that, moreover, the real scope of the list was narrowed by law compared to the potential domain opened up by two decrees which still remain in force: the decree of 26 January 1996, contained in the decree of 26 April 2001, relating to the general conditions of part III of the list and the decree of 26 April 2001 relating to the list of reimbursed products over and above the fixed clinical charges.

- that all manufacturers were nevertheless at liberty to arrange for an assessment of the service rendered by a device by CEPP, and that this new opportunity, apart from its direct consequences on the dissemination of the device, might have the advantage of clarifying the decisions of the State on the principle of public reimbursement of costs if not on the arrangements to be chosen for this reimbursement : LPP, fixed sum for operating theatres or Nomencalture Générale des Actes Professionels (general nomenclature of professional acts, NGAP).

1.2 THE RECOGNITION AND TREATMENT OF INNOVATIONS.

The prospects offered by the new assessment and registration procedure have raised expectations and concerns in firms where the recognition and treatment of innovations is concerned. Expectations centre on the advantage afforded by an independent assessment, on the mechanism for " improvements of the service rendered " and on the explicit possibility of registrations by brand name.

Two sorts of concerns were aired. Firstly that of inappropriate assimilation to proprietary medicine, manufacturers pointing to the rapid renewal of products in the sector and hence the generally short lifetime of innovations. This created a concern over the nature and level of clinical trials required for the assessment, a matter for which the CEPP is responsible. There were also strong expectations of compliance with the regulatory timetables for processing cases. The Committee, while confirming its determination to keep to the deadlines, indicated the scope of the rule, which is that expiry of the 180-day period can be regarded by the applicant as tacit refusal of registration, the grounds for which can be sought and appealed against before the administrative court.

The second concern related to the risk that the initial registration of a new product, based on the assessment file provided by the applicant, may lead to the opening of a generic line, as rivals can then market it with less effort and without the same constraints. The Committee stated that in its opinion, the texts did not stand in the way of registration by brand on a temporary basis for a new product category, if only to ensure that tracking of the service effectively rendered was carried out uniformly.

1.3 THE RETENTION OF SPECIFICATIONS FOR PRODUCTS REGISTERED IN THE GENERIC NOMENCLATURE

An issue which came under debate was whether the compulsory specifications established for a number of generic lines in the former procedure could exist with the new texts, thus arousing the concern of many firms that their markets might be challenged by products not offering the same quality guarantees. The Committee indicated that the new drafting of the Social Security Code unequivocally subjected the registration of a product to technical specifications, thereby allowing exactly the same thing to be done as with the old specifications.

It was also noted:

- That the former specifications should be gradually reviewed in order to remove prescriptions relating to product safety only, which falls within the scope of CE marking and is the responsibility of the DirectorGeneral of the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS, French Health Products Safety Agency).

- That the technical specifications should be limited to those which ensure the level of service rendered for which registration had been justified.

- That provision could be made for monitoring the technical specifications according to the same diversity of procedures as before, including testing by a reputable and independent laboratory.

1.4 THE CRITERIA FOR FIXING TARIFFS OR PRICES

The Committee pointed out the rules laid down in the texts relating to:

- Tariff fixing: article R 165-4 of the Social Security Code, which provides that " products cannot be entered on the list … which bring neither improvement to the service rendered nor savings in the cost of treatment or which are likely to give rise to unjustified expenses for the health insurance scheme " and article R. 165-14, pursuant to which " the setting of tariffs takes into account principally the service rendered, its possible improvement, the tariffs and prices of comparable products or services entered on the list, forecast sales volumes and foreseeable and actual conditions of use ".

- Pricing: the very broad provisions of article L. 162-38 of the same code, according to which the possible fixing by decree of prices or margins for products or services reimbursed by the compulsory social security systems " takes into account the trend in charges, income and volume of activity of the practitioners or enterprises concerned ".

The application of these rules seldom poses problems for the products and services that bring no improvement to the service rendered. This is because, by definition, the existence of generic lines permits the placing of products without ASR (Improvement in Service Rendered) on the reimbursable market and at a tariff equivalent to that applicable to products already registered. In practice, the rule of savings in the cost of treatment of article R.165-4 only applies to registrations under brand name of products without ASR or in what should be fairly rare cases of registrations of a new generic line intended to accommodate products constituting an alternative without ASR to a generic line already registered.

For those products with an ASR, the Committee indicated that the criteria explicitly set forth in the texts, although providing a framework and guidance for tariff fixing, did not in themselves determine them.

The rule of article R. 165-4 permits in this case an additional cost, yet makes no mention of the sum of this additional cost. At most it is possible to surmise that in general a low-level ASR does not allow acceptance of a wide tariff differential with the comparator. Moreover, the recognition of an ASR is a necessary but insufficient condition for justifying an additional cost and the regulations do not prohibit therefore the registration of a new product with ASR at a lower tariff than that of the comparators already registered.

Likewise the explicit – but not restrictive – criteria of article R. 165-14 are insufficient to set in absolute terms the tariff of a new device; their scope is essentially relative by comparison with the tariffs of other products, where direct comparisons exist or, with regard to volumes or conditions of use, where a possible increase in the tariff of the device in question is concerned.

Finally, even valid and pertinent medicoeconomic studies, while extremely useful in clarifying decision about defraying public costs, do not allow for the definition of a tariff. Since:

- It is not essential that a product offer " value for money " in order for its reimbursement to be justified.

- The fact that a product can generate, at a certain tariff, higher savings than its costs is not sufficient cause to adopt this tariff, since the savings would be greater still if the tariff were reduced.

The Committee therefore pointed out that the setting of tariffs for innovations could only come from open consultation with firms, in the light of full and useful information such as prices charged in other countries or to public health institutions or all costs incurred by the firms.

The Committee concluded by stating that, in all cases where the importance of the service rendered by a new device justified the prevention of a differential being created between the reimbursement tariff, the price charged and the fixing of an upper-limit sale price at the same level as the tariff, this common tariff and price value ought also to be fixed by reference to the criteria of article L. 162-38 and in particular to the notion of business charges. Even apart from these cases, the administration cannot ignore the differential between the price charged and the tariff and must take it into account.

1.5 PRACTICAL GUIDE FOR USE BY BUSINESSES

The greatest number of questions raised was in relation to the practical aspects of the procedures: establishment of files, channels, timetables, etc. The administrations responsible for registration therefore entrusted the Committee with the task of coordinating, in liaison with AFSSAPS for the part relating to the assessment, the preparation of a practical guide for use by businesses. A draft guide was sent for feedback to professional organisations and then circulated from June 2001.

The guide is designed to evolve in line with needs and consists of three sections:

- A description of the situations facing manufacturers who are seeking the public reimbursement of a product;

- A description of timetables according to application type and of the place where the case is filed. Particular attention is drawn to the fact that the Committee is tasked with the management of timetables (for suspension or

otherwise) and of the procedure on behalf of the Social Security Minister. All cases or additional information must therefore be forwarded to him initially with a copy of medico-technical section to the CEPP Secretary's Office situated within AFSSAPS.

- A description of the application papers divided into three sections: identification of the application, medico-technical section and economic section. As there is only one description of the papers for all products, certain items may therefore not be relevant to certain types of product. This highly detailed and comprehensive description gives manufacturers an indication of all the facts that the administration deems necessary in order to reach its decision in the most consistent and rapid manner possible.

2. INITIAL GENERAL MEASURES

2.1 THE CONVERSION OF APPROVAL NUMBERS

The new texts made it impossible to retain the special registration procedure that entailed, for twenty or so product categories, the reimbursement approval numbers system. As the award of these numbers therefore became impossible upon publication of the decrees, it became a matter of urgency to rule on the nature of the registration of the devices concerned – registration by brand name or generic registration – with the right to prohibit, in practice, all new registrations into these categories.

In general, given that the joint system of approval numbers was more akin in fact to registrations by brand name, it was not felt possible, even when it appeared reasonably expedient, to convert these registrations to generic registrations pure and simple without first receiving the opinion of the Assessment Commission, to whom the matter was therefore referred. While awaiting its opinions, the products were registered under brand name, thereby making it legally possible to file and process registration applications for new products in these categories.

The tariffs for new products were set at the same level as those for products already registered, and the Committee linked this registration to the tariff system for a generic nomenclature.

By way of an exception, four product categories were directly registered in the generic nomenclature, since in their case, there was no doubt as to the relevance of such a registration given the various criteria: maturity and stability of markets, existence of suitable quality controls, absence of health risk which a registration by brand would have prevented. These categories are as follows: non-woven compresses, compressive clothing, elastic compression bandages and ortheses and gluten-free foods.

2.2 THE FIXING OF AN UPPER-LIMIT SALE PRICE AND THE END OF THE " INVOCABILITY " OF TARIFFS

Before the new texts, equality between the reimbursement tariffs and the prices charged, wherever it was deemed necessary, was ensured by legal provisions which varied according to the relevant parts and chapters of the nomenclature: compulsory agreements between the health insurance scheme and professionals (for orthoprostheses for example), general conditions of reimbursement laid down by decree (for implants for example), decisions taken pursuant to article L. 162-38 (for intrauterine devices for example), and finally simple practices (for ocular prostheses for example).

In the main, these provisions were founded on the notion of invocable tariff, which amounts to regarding a product subjected to this rule as only really reimbursable, notwithstanding its registration on the list, if its sale price was equal at most to the tariff. This was of course a very powerful incentive to ensuring that the tariffs were observed.

Having noted that the new rules provided no basis for the charging of invocable tariffs and no longer allowed a way of setting upper-limit sale prices other than by application of article L. 162-38, the Committee first proposed to apply this article to all cases where such limitations had previously been ensured on other bases (See chapter III The Opinions of the Committee).

To better ensure compliance with upper-limit sale prices where set, the Committee also suggested that powers of control be reinstated for the health insurance funds, but on such conditions (unlike the invocability of tariffs) that the risk of a price overrun can on no account be incurred by the patient; this is so that the patient can be certain whatever happens of being at least reimbursed on the basis of the tariff. Such was the purpose of the new article L. 165-3-1 of the Social Security Code (art. 24 of the Social Security Finance Act for 2002) prohibiting suppliers from price overruns, where an upper-limit sale price is set for the public by decree. This requires them to reimburse the patient the difference between the tariff and the price charged, insofar as the difference is not due to any particular demand of the insured.

2.3 THE CONVERSION OF TARIFFS TO EUROS

The transition to the euro was admittedly unrelated to the introduction of the reform. However, the arrangements made to ease the transition to the euro, which involved primarily the re-publication of the entire nomenclature with the new tariffs, provided an opportunity for a few adjustments.

As regards the transition to the euro *stricto sensu*, over and above the tariff conversion, the Committee was prompted to rule on the principles governing product labelling and stock turnover.

The adjustments made on this occasion centred chiefly on four points:

- Legal implementation of the conversion of approval numbers;

- Harmonised extensions of end-dates for public defrayal of costs in order to give firms time to prepare re-registration papers conforming to the new procedure and to stagger the consignment of these papers to the Assessment Commission;

- Harmonisation of the submission of the technical specifications;

- Finally, in two cases (insulin and growth hormone syringes and pouch filters for stoma patients, reimbursement per unit), a tariff increase because the conversion rounding rules ordinarily applied would have led to an unjustified tariff reduction.

Chapter III - THE OPINIONS OF THE COMMITTEE

1. CASES RECEIVED

The breakdown of the 90 cases filed by firms is as follows:
- Registration applications: 67
- Registration renewal applications: 18
- Tariff revaluation applications: 5.

Furthermore:
- 22 cases relating to part I
- 22 cases relating to part II (17 of which hearing aids)
- 36 cases relating to part III (10 of which implantable cardiac defibrillators and their catheters)
- 4 cases relating to part IV,
- 6 of which pose the problem of their public reimbursement methods (LPP, fixed operating theatre charge (FSO), act or other).

The 4 other cases recorded are distinguishable as follows:
- 2 applications for the revaluation of tariffs for generic lines filed by professional organisations commissioned by firms
- 1 registration application by the Health and Social Security Ministers, by direct referral to CEPP and subsequent submission before CEPS
- 1 tariff review proposed by CEPS.

Table 19: Committee cases

2001	TOTAL CASES FILED (registration, registration renewal, tariff review)										
	A: Filing by firms						B: Others (ministers – assoc.)				Total A+B
Part	I	II	III	IV	Uncertain field	Total	I	II	III	IV	
June	3	10	1	0	1	15	0	1	1	0	17
July	2	4	1	0	1	8	0	1	0	0	9
August	1	3	5	1	2	12	0	0	0	0	12
September	3	2	3	2	0	10	0	0	0	0	10
October	3	2	4	0	0	9	1	0	0	0	10
November	5	1	1	1	0	8	0	0	0	0	8
December	5	0	21	0	2	28	0	0	0	0	28
TOTAL	22	22	36	4	6	**90**	1	2	1	0	**94**

2001	REGISTRATIONS										
	A: Filing by firms						B: Others (ministers – assoc.)				Total A+B
Part	I	II	III	IV	Uncertain field	Total	I	II	III	IV	
June	3	10	0	0	1	14	0	0	0	0	14
July	2	4	1	0	1	8	0	0	0	0	8
August	1	3	3	1	2	10	0	0	0	0	10
September	2	1	2	0	0	5	0	0	0	0	5
October	3	1	1	0	0	5	1	0	0	0	6
November	3	0	1	0	0	4	0	0	0	0	4
December	4	0	15	0	2	21	0	0	0	0	21
TOTAL	18	19	23	1	6	**67**	1	0	0	0	**68**

2001	REGISTRATION RENEWALS									
	A: Filing by firms					B: Others (ministers – assoc.)				Total A+B
Part	Part I	Part II	Part III	Part IV	Total	Part I	Part II	Part III	Part IV	
June	0	0	1	0	1	0	0	0	0	1
July	0	0	0	0	0	0	0	0	0	0
August	0	0	1	0	1	0	0	0	0	1
September	1	1	0	2	4	0	0	0	0	4
October	0	0	2	0	2	0	0	0	0	2
November	2	1	0	1	4	0	0	0	0	4
December	1	0	5	0	6	0	0	0	0	6
TOTAL	4	2	9	3	**18**	0	0	0	0	**18**

2001	TARIFF REVIEWS									
	A: Filing by firms					B: Others (ministers – assoc.)				Total A+B
Part	Part I	Part II	Part III	Part IV	Total	Part I	Part II	Part III	Part IV	
June	0	0	0	0	0	0	1	1	0	2
July	0	0	0	0	0	0	1	0	0	1
August	0	0	1	0	1	0	0	0	0	1
September	0	0	1	0	1	0	0	0	0	1
October	0	1	1	0	2	0	0	0	0	2
November	0	0	0	0	0	0	0	0	0	0
December	0	0	1	0	0	0	0	0	0	0
TOTAL	0	1	4	0	**5**	0	2	1	0	**7**

2. CASES PROCESSED

9 decrees and 1 notice were published in the *Journal Officiel* in 2001 (table below). The 9 decrees are broken down into:

- Registration: 1
- Tariff revaluations: 3
- Fixing of upper-limit sale price to public: 4
- General measure (conversion of tariffs to euros): 1
- Notice of 2 decisions to reject tariff revaluation applications was given to applicants (table below).

As at 31 December 2001, 5 decrees were pending publication; these are broken down as follows:

- Registration: 1,
- Modification of conditions of defrayal: 1
- Tariff revaluation: 1
- Fixing of upper-limit sale price to public: 1
- General measure (extension of date): 1.

They were published in January 2002.

Table 20: Decrees (or notices) published

Part	Chap	Subject of decree	Date	JO
II	7	Decree on the revaluation of major orthopaedic apparatus	18/07/01	28/07/01
I	1	Decree on registration of One Touch Ultra	28/08/01	08/09/01
All	All	Decree on conversion of tariffs to euros	06/08/01	02/10/01
I	1	Decree revaluing IUCDs	09/10/01	18/10/01
I	1	Decree fixing the price of IUCDs	09/10/01	18/10/01
III	All	Decree fixing the prices of all part III	28/09/01	07/11/01
II	7	Decree fixing the prices of the entire GAO	28/09/01	07/11/01
III	1	Report on price and tariff reduction of mechanical sutures		27/11/01
III		Decree revaluing human saphenous vein grafts	20/12/01	30/12/01
III	3	Decree fixing the upper-limit sale prices of human saphenous vein grafts	20/12/01	30/12/01
II	6	Decree revaluing the tariffs for orthopaedic shoes	26/12/01	09/01/02
II	6	Decree fixing the upper-limit sale prices of orthopaedic shoes	26/12/01	09/0102
III	2	Decree amending the name of the Collamer intraocular lens implant	28/12/01	12/01/02
IV		Decree registering Breezy 205 by Sunrise Medical	28/12/01	13/01/02
All	All	Decree extending the end-dates for public defrayal of costs	31/12/01	11/01/02

3. PROCESSING PERIODS

Tariff revaluation applications filed by firms and processed solely by CEPS without referring the cases to CEPP, took an average of 56 days to process. Cases filed by firms, all applications combined, giving rise to a decision (publication of a decree, or rejection of the application) in 2001, were processed in 117 days on average.

The other 85 cases outstanding at 31 December are either awaiting the opinion of CEPP or the firm's agreement to the Committee's proposals. They have been filed for an average of 90 days.

ANNEXES

1 Ministers' Guideline Letter

2 The Members of the Economic Committee for Health Products

3 The Rapporteurs on the Committee

4 Table of thresholds triggering discounts by pharmacotherapeutic class

5 The Committee's price negotiation methods

6 Standard clauses

7 The Committee's Organisation Chart

8 Details of Committee Members

9 Declarations of interests

ANNEX 1. MINISTERS' GUIDELINE LETTER

The Minister for the Economy, Finance and industry

The Minister for Employment and Solidarity

The Secretary of State for Industry

The Health Minister

Dear Chairman,

The policy of the Government and, in particular, the work of the Committee over which you preside have together led to a reduction in the costs of medicines incurred by the general public, amounting in 2000 to over 1.4 billion francs. It is vital however that these efforts are extended and redoubled in order to achieve lasting control over the growth in this major item in our health budget.

While reimbursed drug costs rose by 10.5% in 2000, the *Comité Economique des Produits de Santé* (Health Products Economic Committee) must make a significant contribution to compliance with the ONDAM (*Objectif National des Dépenses d'Assurance Maladie,* ambulatory budget target) set for this year, namely 3%. Indeed overruns in drug expenditure occur to the detriment of other public health priorities. This effort must be collective, and the Government intends to take the necessary measures, especially where the mobilisation of prescribers and the role of distribution are concerned.

As regards the pharmaceutical industry and the Committee's remit as assigned by law, pursuant also to article L. 162-17-3 of the Social Security Code, we would like to see your Committee take further action with regard to drug pricing. It is the responsibility of your Committee, pursuant to article L. 162-17-4 of the Social Security Code, to engage in discussions at the earliest opportunity with the pharmaceutical laboratories on the basis of the following guidelines for the year 2001:

1) We ask the Committee, firstly, in the light of the inordinate rise in the sales of drugs in 2000 by comparison with the objectives set by the public authorities, and without witnessing signs of a significant slowdown in this growth in the first months of this year, to vigorously implement the financial regulation instruments available to it pursuant to the Social Security Code.

We would like this regulation to be brought to bear through a price reduction, wherever such a reduction is justified. Specifically, we are asking the Committee to speed up the implementation of the plan to lower the price of proprietary medicines whose medical service rendered (SMR) was declared insufficient by the Transparency Commission, the first stage of which was conducted last year.

For proprietary medicines whose medical service rendered was not challenged, we are also asking it to systematically examine the expediency of reducing their prices, especially in classes which, by virtue of their volume and the speed of their development, are known to contribute to the inordinate overall growth in sales. Against this background, I am asking you to make sure that there is an adequacy between the volumes of sales recorded and the target population identified in the Transparency Commission's reports, especially on the basis of information forwarded by the laboratories, and to take all appropriate measures upon registration for reimbursement and thereafter.

We would prefer these measures to be adopted following consultation and agreement, in accordance with the sector-based agreement signed with the National Pharmaceutical Manufacturers' Association, as a supplement to the multiannual accords to which the firms and the Committee are party. We urge you however, in compliance with the Social Security Code, in those cases where negotiations by treaty fail to achieve the desired outcome, to propose without delay that we issue unilateral pricing orders. The same would apply in the event of a breach by industry of its obligations with regard to direct sales to pharmacies and advertising.

2) For initial pricing upon registration, which is a daily task of the Committee, we ask that it acts with greater selectivity.

Needless to say that those of the new drugs which actually do improve the treatment or prevention of diseases must continue to be made available for reimbursement to patients as soon as possible and we therefore ask the Committee to continue to improve the efficiency of its operation and procedures. We would also like positive incentives to favour the marketing of orphan drugs or paediatric forms that are still missing from our therapeutic arsenal.

In return, we feel it necessary that these innovations be really reserved for those patients who gain advantage from them by comparison with the drugs already available and we therefore urge the Committee, wherever justified by the Transparency Commission's report or by the public health policy guidelines defined by the State, to propose that registration for reimbursement be confined to indications which ensure that needs are adequately met.

We deem it equally desirable, where sales prospects so justify, to repeat and adopt as a matter of course the method, introduced in 2000, to schedule from the time of registration the price reduction of new medicines, following a launch period during which the high price is legitimate compensation for the research and development investment.

For medicines which do not improve the medical service rendered, we ask the Committee to be especially vigilant in the application of the rule which demands that their registration entail a real saving for the social security, notably in cases where the arrival of a new participant is expected to result, on account of the increase in promotional costs devoted to this class of medicines, to an unjustified rise in overall consumption volumes.

3) We ask that the Committee pay particular attention to the tracking over time of medicines already registered, by relying primarily on studies monitoring and evaluating the effects of the actual use of medicines exerting an impact in terms of public health. Provision will have to be made for these studies in agreements entered into with the pharmaceutical laboratories concerned. Such monitoring will also rely on the work of the observatory of prescriptions and data produced by CNAMTS.

4) Finally, as regards generic drugs, we ask the Committee:

- To be careful not to let minor innovations in drugs which have become generic or are poised to do so block in practice the path to the development of generics;
- To consider the expediency, for molecules whose original drug forms are registered at high prices, to increase the price differential, currently set at 30%, demanded for the registration of generics;
- To proceed, with regard to the operation of this market, with appropriate price reductions in original drugs and their generics in keeping with the policy to boost the implementation of the right of substitution;
- To encourage the alignment of the galenic form with the colour of generic drugs.

Finally, it will be your responsibility to ensure that the new enacting terms for the pricing of medical devices are brought into operation at the earliest opportunity, with one and the same intention of contributing to the marketing of new products under satisfactory conditions and of applying the same vigilance in relation to rising costs.

You can count in the Government's examination of drug policy on the wholehearted support of the services under our authority that constitute the membership of the Committee over which you preside.

Yours sincerely.

The Minister for the Economy, Finance and industry

Laurent FABIUS

The Minister for Employment and Solidarity

Elizabeth GUIGOU

The Secretary of State for Industry

Christian PIERRET

The Health Minister

Bernard KOUCHNER

ANNEX 2. THE MEMBERS OF THE ECONOMIC COMMITTEE FOR HEALTH PRODUCTS

Noël RENAUDIN, Chairman

A. Proprietary Medicines section

. Jean-Paul CANO, Committee Vice-Chairman for Proprietary Medicines and Chairman of the Board of Directors of AFSSAPS.
Representatives of the Social Security Director – Ministry for Employment and Solidarity:
. Stéphane SEILLER, Deputy-Director, Sub-Directorate of Finance of the Healthcare System ;
Michèle LARREUR, pharmaceutical adviser, Sub-Directorate of Finance of the Healthcare System.
Representatives of the Director-General of Health – Ministry for Employment and Solidarity :
. Hélène SAINTE MARIE, Deputy-Director, Sub-Directorate of the Policy on Healthcare Products ;
Caroline GARDETTE, Head Clerk, Drugs Office ;
Sophie FEGUEUX, Deputy Head Clerk, Drugs Office ;
Emmanuelle AMPHOUX, Drugs Office ; deputy Nathalie MANTEAU.
Representatives of the Director-General for Competition, Consumption and Fraud Prevention – Ministry for the Economy, Finance and Industry :
. Francis AMAND, Deputy-Director, Sub-Directorate of Health, Industry and Trade
Alain GRAS, Head Clerk, E1 Health Office ;
Olivier CAILLOU, Deputy Head Clerk, E1 Health Office ;
Emmanuelle CONESA, E1 Health Office ; .
Representatives of the Director-General for Industry, Information Technologies and the Post – Ministry for the Economy, Finance and Industry:
. Gérard MATHIEU, Head of the Sub-Directorate for Chemistry, Pharmacy and Biotechnologies ;
François LHOSTE, Economic Representative, Sub-Directorate for Chemistry, Pharmacy and Biotechnologies ;
Sophie RÉMONT, Assistant Deputy Director, Sub-Directorate for Chemistry, Pharmacy and Biotechnologies, deputy Catherine TRENQUE
Representatives of the National Health Insurance Bodies : .
Pierre-Jean LANCRY, Deputy Director, Department for Drugs and Medical Devices – National Health Insurance Fund for Salaried Workers, deputy,
. Christian MARTY, drugs expert, Deputy Director to the director delegated to risks National Health Insurance Fund for Salaried Workers,
Martine PIGEON, Head of the Drugs Division.
Carine BUSIN, Official Representative – Drugs Division,
Representative of the Director for Hospital Admissions and the Organisation of Healthcare :
Dominique LAGARDE, Official Representative.

B. Medical Devices Section

. Dominique LECOMTE, Vice-Chairman.

Representatives of the Social Security Director – Ministry for Employment and Solidarity:
. Stéphane SEILLER, Deputy-Director, Sub-Directorate of Finance of the Healthcare System
Danielle GOLINELLI, Head Clerk Health Products ;
Aude de MARTIN de VIVIES, Health Products Office, deputy Serge PAON.
Representatives of the Social Security Director – Ministry for Employment and Solidarity:
. Hélène SAINTE MARIE, Deputy-Director, Sub-Directorate of the Policy on Health Products ;
Patrick GUYOT, Head Clerk for Medical Devices and other Healthcare Products ;
Françoise WEBER, physician, Office of Medical Devices and other Healthcare Products, Public Defrayal of Medical Devices.
Representative of the Director for Hospital Admissions and the Organisation of Healthcare :
. Françoise CABANE, Official Representative
Representatives of the Director-General for Competition, Consumption and Fraud Prevention – Ministry for the Economy, Finance and Industry :
. Francis AMAND, Deputy-Director, Sub-Directorate of Health, Industry and Trade ;
Alain GRAS, Head Clerk, E1 Health Office ;
Olivier CAILLOU, Deputy Head Clerk, E1 Health Office ,
Daniel MILES, E1 Health Office ;
Arlette THURIER, E1 Health Office.
Representatives of the Director-General for Industry, Information Technologies and the Post – Ministry for the Economy, Finance and Industry:
. Gérard MATHIEU, Head of the Sub-Directorate for Chemistry, Pharmacy and Biotechnologies ;
Marie-Claire SEBAG, Head of the Medical Devices Division
Representatives of the National Health Insurance Bodies : .
Pierre-Jean LANCRY, Director delegated to Risks - National Health Insurance Fund for Salaried Workers ;
Christine VAULONT, Head of Economic Studies – Drugs and Medical Devices Department ;
Frédéric GIRAUDET, Head of Legal Studies – Pharmacy and Medical Devices.

ANNEX 3. RAPPORTEURS TO THE COMMITTEE

Madame Françoise BENOIT-CATTIN, Madame Hélène BOURDEL,
Madame Isabelle CHEINEY, Madame Elisabeth CREPON,
Monsieur Bertrand DIQUET, Monsieur Nicolas GASPARD,
Madame Claire GENDRE-OGET, Monsieur Jean-Marc GROGNET,
Monsieur Philippe LALANDE, Madame Régine LEMEE,
Monsieur Jean-François MATTEI, Madame Michèle MSIKA,
Madame Marie-Françoise PENY, Monsieur Bruno STALLA,
Monsieur André TANTI, Monsieur Bernard TEISSEIRE,
Monsieur Jean-Pierre YVERT.

ANNEX 4. TABLE OF THRESHOLDS TRIGGERING DISCOUNTS BY PHARMACOTHERAPEUTIC CLASS

I – Establishing the table by class

The table is established according to a three-stage process:

- Segmentation of classes;
- Determining those classes in which the likely sales trend is expected to lead to the payment of discounts;
- The general balancing of the table.

A) THE SEGMENTATION OF CLASSES

The purpose of segmenting the classes is to divide all reimbursable medicines into groups of medicines each constituting a market on which firms are in direct competition. The segmentation criterion is therefore that of sufficient substitutability, in the economic sense of the term, between medicines belonging to the one group.

This involves making sure, especially for classes by virtue of which quantitative discounts will be due, that the *de facto* solidarity thus formed between firms is fully justified by the competitive circumstances in which they find themselves for the sale of their products belonging to these classes. Therefore, conversely, no firm is subject to discounts on account of the growth in sales of medicines not competing with its own products.

By way of exception, and for the sake of simplification, certain non-homogenous classes have nonetheless been retained in the table; these are however composed of medicines whose rates of growth are of equal magnitude. These groupings are therefore not likely to lead to anomalies in terms of discounts.

B) DETERMINING CLASSES HAVING TO GIVE RISE TO QUANTITATIVE DISCOUNTS

This is determined by an analysis involving two successive stages. At first, the Committee assesses the prospects of a normal sales trend in each of the classes. It then identifies those of these classes in which it deems discounts to be justified as well as the relative extents to which these discounts are justified.

1) Assessment of the prospects of a normal sales trend

This assessment of the prospects of a normal sales trend in the classes involves forecasting factors but does not constitute a forecast strictly speaking since this supposes that the trend in sales of drugs in the classes corresponds to the trend in medically justified needs. This assessment, moreover, relates to the trend in sales and does not prejudge the normal character – or otherwise – of consumption levels currently observed.

This assessment is based on four criteria:

- ***The trend in the prevalence of the diseases requiring treatment***, whatever the causes of this trend: progress in screening (e.g. diabetes), ageing population (e.g. osteoporosis), environmental changes (e.g. asthma) or eating habits. The transfer to ambulatory healthcare of diseases previously treated only in hospitals is treated as a positive trend in its prevalence (e.g. hepatitis C);
- ***The current or possible introduction of innovations*** onto the reimbursable drugs market;
- ***The penetration of generics*** which is likely, conversely, to reduce the amount of sales in the classes where these drugs are introduced;
- ***Recognised public health priorities***, whether their objective be to increase the use of certain drugs (e.g. vaccines, pain relief drugs) or reduce it (e.g. antibiotics).

2) Identification of classes having to give rise to a more or less large proportion of discounts

As the main purpose of quantitative discounts, at given registration prices, is to reduce the real costs of proprietary medicines incurred by the health insurance scheme, the determination of classes having to give rise to discounts amounts to the identification by the Committee of classes in which it deems that, at current recorded sale levels, the prices are too high (relatively at least, bearing in mind the across-the-board cost constraint voted in by Parliament). The discounts therefore constitute a temporary alternative to price reductions called for by this market situation, the duration of this temporary arrangement being itself dependent on factors of a widely varying nature.

This appraisal too is based on four criteria:

- ***Medical service rendered, as assessed by the Transparency Commission***. It seemed quite natural to the Committee that the discount mechanism should lead, for the health insurance system, to a reduction in costs due to proprietary medicines whose medical service rendered was judged insufficient to justify their inclusion in the list of reimbursable medicines;
- ***Medicines with marketing seniority***. The Committee also considers it normal that, for older classes of drugs, even if these drugs are still protected by patents, and even if the medical service delivered by them is still important, the health insurance cost should be reduced to allow, in observance of the across-the-board constraint, the financing of innovations;
- ***The excessive nature of sales of certain classes of medicine from the viewpoint of medically justified needs***. This is most notably the case of medicines whose medical service rendered is indisputable but whose use has largely grown *per primam intentionem* to the detriment of equally effective and cheaper products, while the price of the medicines concerned is justified only by the specific advantage which they bring to small patient populations or *per secundam intentionem* (e.g. angiotensin II converting enzyme inhibitors in hypertension, inhaled corticosteroids specially indicated in severe asthma but used in all forms of asthma, new generations of antibiotics, etc.);

- ***The intrinsic importance of volumes sold.*** These are classes whose SMR is undisputed, and for which there is nothing to suggest that the volumes are not justified, but whose burden on health insurance expenditure and its growth is considerable (e.g. statins, proton pump inhibitors). The discounts anticipated are likewise purely quantity discounts, justified solely by virtue of the major client status of the French health insurance system. The appraisal of this criterion, as with the previous criterion, may take into account the variances recorded in previous years between the rates used by the Committee and actual attainments, which may account for certain rates being reduced by comparison with what had been initially anticipated for the current and subsequent years.

These criteria, like those of point 1) above, may at times offset one another. They may likewise mutually reinforce one another. It is of course the Committee's responsibility to define, case by case, their weighting in order to infer an outcome.

C) GENERAL BALANCING OF THE TABLE

This balancing must enable three constraints to reconciled as fully as possible.

. The variances between the rates used and the normal trend prospects in the classes, as established according to the criteria of point 1), must be consistent with the analysis of point 2). In other words, and for example, a class in which the criteria of point 2) converge, thereby leading the Committee to consider that the discounts must be proportionally large, will be allocated a much lower rate, positive or negative, than that of the normal trend in its sales. Conversely, a class for which none of the criteria of point 2) justify discounts will be allocated a rate, likewise positive or negative, equal at least to the normal trend in its sales.

. The system adopted must produce results acceptable to firms. This is a practical constraint, which prohibits the use of rates, even where fully justified pursuant to the foregoing principles and criteria, which would however result in requiring discounts from a firm or group of firms with special arrangements with the health insurance scheme representing a disproportionate amount of their turnover.

. The weighted sum of rates used must be equal to the threshold rate triggering the fiscal contribution. This is the core principle behind the establishment of the table, and its very raison d'être. The result in particular is that the rates used have no indisputable value as absolute figures, but that the Committee has endeavoured, on the contrary, to be able to establish, by applying the stated criteria, and with a relative approach between classes, the sense and scale of the variance between the rates used and the normal prospects of the trend in sales in these classes.

The enacting terms put in place culminate for each drug class in a rate of growth expressed as a difference in relation to the ONDAM rate so that the trend on the basis of each of these rates in each of the drug groups leads to an overall result equivalent to the ONDAM forecast. The justification of the rate differences is the adjustment, without change to the nominal price of the medicines, of the actual prices (less discounts) paid by the community for the various drugs groups and their marginal usefulness. This mechanism, coupled with the exemptions provided most notably for generics or highly innovative drugs, ensures a consistency between the financial regulation procedures and the fundamental guidelines of the Government's policy on medicines: proper use of the

medicine and elimination of waste, development of the generics market, support for innovation. Secondarily, this type of regulation may act as a marginal but real incentive for firms to direct their promotional efforts towards the drugs groups for which the threshold triggering discounts is greater than the spontaneous trend in sales and which should not give rise therefore to discounts.

II – Discount calculation methods

A) MECHANISM

1) Total discount

The total discount due under a class in which the sales trend was greater than the rate appearing in the Committee's table is spread between firms marketing products in this class as follows:

- 65 % of the total discount is spread in proportion to the sales achieved during the year;
- 35 % of the total discount is between only firms whose sales trend exceeded the Committee's table, in
- Proportion to the fraction of sales achieved above that rate.

The aim is to not penalise the marketing of new products, including when they are not ASMRs and when they involve social security savings.

2) Exemption of innovations

- Medicines having benefited from an ASMR I are exempted from discounts for the 3 years following their marketing, those having benefited from an ASMR II are exempted for 2 years.
- For medicines having been granted an ASMR by virtue of a particular indication or of an extended indication, the exemptions apply in proportion, determined by agreement, to the turnover achieved in these indications.
- The exemption periods are calculated from the marketing date or, for ASMRs granted by virtue of an extended indication, with effect from the Transparency Commission's report. Where this period ends during a calendar year, the exemption is calculated in proportion to the sales achieved during the exemption period.

3) Exemptions of low-cost products

This exemption relates to generics, largely similar drugs at generic prices and original drugs at generic prices. Most notably, it does not apply to medicines whose cost is simply said to be less than the average treatment cost of the class to which they belong.

B) THE DISCOUNT RATE

The discount rate is set at 35% of the overruns recorded in relation to the rates appearing in the Committee's table. It remains an established fact, in accordance with the sector-based agreement, that the net total (all firms combined having contractual arrangements under the public health insurance scheme) of discounts actually paid pursuant to the discount by class and pursuant to the discount on turnover will not be

greater than the total contributions which the same firms would have had to pay in pursuance of article L. 138-10 of the Social Security Code. To ensure compliance with this limit, the 35% rate will, if necessary, be uniformly reduced for all classes giving rise to payment of discounts.

Table of thresholds triggering discounts by class expressed in relation to the ONDAM rate of growth

Table of thresholds triggering discounts by class expressed in relation to the ONDAM rate of growth					
CLASSES	Trigger rate ONDAM incl. 2001 (%)	Trigger rate excl. ONDAM 2001 (%)	Trigger rate excl. ONDAM 2002 (%)	Trigger rate excl. ONDAM 2003 (%)	Trigger rate excl. ONDAM 2004 (%)
A1 A2+A3+A4+A5+B stomatology	See R2a				
A2 A1+A2+A3+A4+A6+A7(+C) antacids/antiflatulents/others	-3.00	-6.00	-6.00	-7.00	-8.00
A2 B1 H2 receptor antagonists	0.00	-3.00	-3.00	-2.00	-1.00
A2 B2 Proton pump inhibitors	4.50	1.50	0.00	0.00	0.00
A2 B3+B9 prostaglandins and other anti-ulcer drugs	-3.00	-6.00	-5.00	-4.00	-3.00
A3 A+C+D(+E)+F Antispasmodics /anticholinergics /prokinetic drugs (anti-emetics, excluding metoclopramide type)	0.00	-3.00	-3.00	-3.00	-3.00
A4 A1 anti-emetics, serotonin antagonist	3.00	0.00	0.00	0.00	0.00
A4A9 other anti-emetics, including metoclopramide type (A3F)	0.00	-3.00	-3.00	-3.00	-3.00
A5 A1+A2+B+C Choleretics-liver-protectors	*Identification of A5A2*				
A5 A1+B+C Choleretics-liver-protectors	-22.00	-25.00	-15.00	-15.00	-20.00
A5 A2 Gall stone treatment	3.00	0.00	0.00	0.00	0.00
A6 A1+A2+A3+A4+A5+A6 Laxatives	-4.60	-7.60	-7.60	-3.00	-3.00
A7A+B+F+H+X Antidiarrhoeals + **cromoglycate for digestive purposes**	0.00	-3.00	-5.00	-3.00	-3.00
A7 E Antiinflammat. intest **(Nalcron, Intercron excl.)**	3.00	0.00	0.00	0.00	0.00
A9 A Digest. products enzymes incl.	-6.60	-9.60	-11.00	-11.00	0.00
A10 B1+B2+B5 Oral anti-diabetic drugs	8.00	5.00	4.00	4.50	3.40
A10 C+D Insulins and analogues	8.00	5.00	3.40	3.40	3.40
A11 C1+C2+C3+D1+F0+H2 Vitamins + **A11A2**	-3.60	-6.60	-6.00	-6.00	-6.00
A11 H3 Other vitamins alone (vitamin E)					
A12 A Calcium	1.00	-2.00	0.00	0.00	0.00
A12 B Potassium	1.00	-2.00	0.00	0.00	0.00
A12 C1+C2+A13A2 Magnesium, other mineral supp. and tonics	-1.00	-4.00	-4.00	-4.00	-4.00
A14 A1(+B) Anabolics, hormones and others	3.00	0.00	0.00	0.00	0.00
A15 A Orexigenic agents	-2.10	-5.10	-5.50	-5.50	-5.50
A16 A Miscellaneous digestive system	-4.60	-7.60	-8.00	-8.00	-8.00
B1 A Non-inject. anticoagulants	3.00	0.00	0.00	0.00	0.00
B1 B1+B2(+B9) Inject. anticoagulants	0.00	-3.00	-2.00	2.00	4.00
B1 C Platelet aggregation inhibitors	8.00	5.00	3.00	2.00	0.00
B1D Fibrinolytics	1.00	-2.00	0.00	0.00	0.00
B2 A1+B1+B2(+C3)+G Anti-haemorrhagics, haemostatics	0.00	-3.00	-2.00	-2.00	-2.00
B3 A1+A2(+B) Anti-anaemics	3.00	0.00	0.00	0.00	0.00
B3X Aut. anti-anaemics (folic, folinic acid..)	3.00	0.00	0.00	0.00	0.00
C1 A1+C1C+C6A Glyco. cardiac pacemakers (see dopa) and others	3.00	0.00	0.00	0.00	0.00

C1 B Antiarrhythmics	0.00	-3.00	-3.00	-3.00	-3.00
C1 D Coronary therapy see C1E+C8 (excluding molsidomine, nicorandil)	-2.00	-5.00	-5.00	-5.00	-5.00
C1 E Nitrates (including molsidomine, nicorandil)	-1.00	-4.00	-1.00	-1.00	-1.00
C2 A1+A2(+B2)+D Antihypertensives	0.00	-3.00	-3.00	-3.00	-3.00
C3 A1+A2+A3+A4+A5 Diuretics	2.00	-1.00	1.00	1.00	1.00
C4 A1+A2+ N6 D Vasodilatators and nootropes	-5.00	-8.00	-3.50	-3.00	-3.00
C5 A1+A2 Topical antihaemarrhoidals	0.00	-3.00	-3.00	-3.00	-3.00
C5 B Topical anti-varicose preparations	-3.00	-6.00	-4.00	-3.00	-3.00
C5 C General vasoprotectors	-8.00	-11.00	-8.00	-6.00	-3.00
C7 A+B1 Beta blockers (alone or combined)	4.00	1.00	2.00	2.00	2.00
C8 A+B2 Ca Antagonists (alone or combined)	-2.60	-5.60	-5.60	-3.00	0.00
C9 A+C +B1B3 + D Converting enzyme inhibitors alone + angiotensin II antagonists alone or combined	3.00	0.00	0.00	0.00	0.00
C10 A1 HMG-CoA reductase inhibitors	5.40	2.40	1.50	0.00	0.00
C10 A2 Fibrates	-2.00	-5.00	-2.00	0.00	0.00
C10 A3 Ion exchange resins	0.00	-3.00	-2.00	-2.00	0.00
C10 A9 Aut. cholesterol & triglyceride reduct.	-4.00	-7.00	-7.00	-7.00	-7.00
C10B+A11H3 Anti-atherosclerotics,orig.nature, Vit. E	0.00	-3.00	-4.00	-4.00	-4.00
D1 A1+A2 +A3 Derm. antimycotics + Lamisil per os	2.00	-1.00	-3.00	-3.00	0.00
D2A D3A D4A D8A+D11A emollients, citrac (incl. Regranex),antipruritics, antiseptics, others (rosacea products, excluding meladinine and Aldara)	-1.00	-4.00	-2.60	-2.60	-2.60
D5A et B Antipsoriasis + meladinine (D11A)	3.00	0.00	0.00	0.00	0.00
D6A Antibiotics+sulfam. alone	-5.00	-8.00	-3.00	-3.00	-3.00
D6D1 Topical antivirals podoxyphyllotoxin – (Condyline, Wartec and Aldara)	-5.00	-8.00	0.00	0.00	0.00
D7A Corticosteroids alone	3.00	0.00	0.00	0.00	0.00
D7 B1+B2+B3+B4 Corticosteroids combined	0.00	-3.00	-3.00	-3.00	-3.00
D10A et B Oral and topical anti-acne products + rosacea products (D11A)	3.00	0.00	0.00	0.00	0.00
G1A1+A2+B+D gynaecological anti-infectives	1.00	-2.00	-2.00	-2.00	-2.00
G2A+D+E+F+X9 Ocytocin. prolactin inhibitors, labour inh., topical sex horm, others	3.00	0.00	0.00	0.00	0.00
G3 A1+A2+A3+A4+A5+A9 Ovulation inhibitors	32.00	29.00	5.00	5.00	5.00
G3B Androgens excl.G3E,G3F	-1.00	-4.00	-4.50	-4.50	-4.50
G3C+D+F Oestrog.,Progest.,Androgens (G3E no longer exists)	8.00	5.00	5.00	5.00	5.00
G3G Gonadotrophins/ ovul. induction	3.00	0.00	0.00	0.00	0.00
G3H Various sex hormones	2.00	-1.00	0.00	0.00	0.00
G4 A1+A2+A3 Antibiotics + sulf, quinolones, other urinary antiseptics	0.00	-3.00	-3.00	-3.00	-3.00
G4B2B4B9 Urology (prostate, enuresis, others)	0.00	-3.00	-4.00	-4.00	-4.00
G4B3 Erectal dysfunction	503.00	500.00	60.00	25.00	10.00
H1A ACTH	-2.00	-5.00	-2.00	-2.00	-2.00
H01C GnRH analogues	303.00	300.00	50.00	15.00	0.00
H2 A1+A2+A3+B Corticosteroids	5.00	2.00	0.00	0.00	0.00
H3A H3B Thyroid and antithyroid hormones	3.00	0.00	0.00	0.00	0.00
H4A Calcitonins	-10.00	-13.00	-8.00	-3.00	-2.00

H4B Glucagon	1.00	-2.00	0.00	0.00	0.00
H4C Growth hormones	9.00	6.00	4.00	-3.00	-3.00
H4D Antidiuretic hormones	3.00	0.00	0.00	0.00	0.00
H4V Aut. hormones and similar	3.00	0.00	0.00	0.00	0.00
J1A+B+C1C2+E+H+K+X2+J3A Group II antiobiot.	-2.00	-5.00	-3.00	-2.00	0.00
J1D1D2+F+G1+X9 Group II antibiotics	-3.50	-6.50	-3.00	-2.00	0.00
J2A Antimycotics v gener. (lamisil excl.)	4.00	1.00	0.00	0.00	0.00
J4A J1M J4B (Antituberculous drugs, Rifampicin,Rifamycine, anti-leprotic drugs)	10.00	7.00	2.00	2.00	2.00
J5B Antivirals except anti HIV					
group 1: products intended for treatment of hepatitis (type Rebetol, Zeffix)	15.00	12.00	10.00	5.00	0.00
group 2: other non-HIV antivirals (type Zovirax, Zelitrex)	6.00	3.00	3.00	0.00	0.00
J5B0 Antivirals except anti HIV	*nil base see two groups above*				
J5C HIV antiretrovirals (Zeffix excl.)	13.00	10.00	7.70	7.40	7.40
J6(A3)A4A6(E)(F)G1(H4)J+J7A1A2A3(A4)A5A6 A7A9B1B2B3 Serums, vaccines	8.00	5.00	3.00	0.00	0.00
J7C Other vaccines	-5.00	-8.00	-6.00	-4.00	-4.00
K1a3a5a7b1b3b4c1d2e1f1K2cK4b1c solutes	3.00	0.00	0.00	0.00	0.00
L1ABCDX+L2A1A2*A3*A9B1B2B9 anti-cancer **and antineoplastic hormones** (Novatrex excl. see M01C products specific to rheumatoid arthritis)	10.00	7.00	3.00	3.00	2.00
L3A Immunostimulants see interferons (cell growth factors)					
L3B1 alpha interferons	13.00	10.00	7.40	5.00	3.00
L3B2 beta interferons	7.00	4.00	2.00	0.00	0.00
L4A Immunosuppressive agents (Arava excl. see M01C products specific to rheumatoid arthritis)	3.00	0.00	0.00	0.00	0.00
M1A (Art 50 and Zondar, Jonctum excl.)					
Group 1 : Products with anti-inflammatory action (coxibs excl.)	-9.00	-12.00	-6.00	0.00	0.00
Group 2 : Coxibs	525.00	522.00	3.00	0.00	0.00
M1C + Acadione + *Arava +Novatrex*	23.00	20.00	15.00	10.00	10.00
M1A(Art 50 and Zondar, Jonctum excl.) + M1C +Acadione	*nil base see above*				
M5X other locomotor apparatus products **+ Art50, Zondar, Jonctum**	3.00	0.00	0.00	0.00	0.00
M2A + M6A, topical products (NSAIDs, balms, revulsants)+ antiinfl. enzymes (excl. alpha amylase-based specialities see R)	0.00	-3.00	-2.00	-2.00	0.00
M3A+M3B Muscle relaxants peripheral and/or central action	-3.00	-6.00	-3.00	-3.00	-3.00
M4A Gout treatment drugs	-1.00	-4.00	-3.00	-3.00	-2.00
M5B antiosteoclastics					
Group 1 : osteoclastics not indicated in osteoporosis	6.40	3.40	3.40	3.40	3.40
Group 2 : diphosphonate indicated in treatment of osteoporosis (Didronel 400, Fosamax 10, Actonel 5) + Evista	35.00	32.00	20.00	15.00	10.00
N1(a2)b1b3b9 Anaesthetics	8.00	5.00	4.00	3.00	2.00

N2A Narcotic analgesics					
group 1 : narcotics apart from replacement therapy	6.00	3.00	4.00	4.00	2.00
group 2 : replacement therapy	6.00	3.00	4.00	4.00	2.00
N2A Narcotic analgesics	*nil base see 2 groups above*				
N2B Non-narcotic antipyretic analgesics	2.00	-1.00	-1.00	-1.00	-1.00
N2C Anti-migraine analgesics					
group 1 : TRIPTANS	6.00	3.00	2.00	1.00	0.00
group 2 : Other migraine treatments (crisis therapy and core therapy)	-2.00	-5.00	0.00	0.00	0.00
N2C Anti-migraine analgesics	*nil base see 2 groups above*				
N3A Anticonvulsants	6.00	3.00	2.00	2.00	2.00
N4A Drugs treating Parkinsonism (Apokinon incl.)	5.00	2.00	2.00	2.00	2.00
N5A1 Atypical antipsychotics	3.00	0.00	0.00	0.00	0.00
N5A9 Conventional antipsychotics					
N5A9 Conventional antipsychotics **+ lithium salts + Depamide**	2.00	-1.00	0.00	0.00	0.00
N5b1 Hypnotics benzodiazepine and suchlike (other branded pharmaceuticals excl.)	-1.00	-4.00	-3.60	-3.60	-1.00
N5b3 Barbituric hypnotics alone	-1.00	-4.00	-3.60	-3.60	-1.00
N5b2+N5B4+C1X Non-barb. hypnotics comb.+ non-barb. hypnotics alone other than benzodiazepines and suchlike (of N5b1) + barb. hypnotics comb. + other cardiac therapy **+ cimipax**	-1.00	-4.00	-3.60	-3.60	-1.00
N5C Tranquillisers	-2.00	-5.00	-4.00	-3.00	-3.00
N6A Antidepressants (excluding lithium salts, Depamide and levotonine)					
group 1 : imipramines +MAOIs	3.00	0.00	0.00	0.00	0.00
group 2 : other antidepressants (including SRIs)	-4.00	-7.00	-5.00	-5.00	-4.00
N6A Antidepressants	*nil base see above*				
N6B psychotonics	*see N7X group 1*				
N7C Vertigo treatments	-2.00	-5.00	-4.00	-3.00	-3.00
N7D1 Alzheimer treatment products	19.80	16.80	16.80	15.00	15.00
N7X Aut. active CNS products (excluding cimipax)					
group 1 : rilutek, revia,aotal, nalorex, modiodal **+N6B Ritalin +Levotonine**	10.00	7.00	5.00	5.00	3.00
Group 2 : olmifon, yohimbine, procaine	0.00	-3.00	-3.00	-3.00	0.00
P1A+B+C+D+G Antiparasitics	3.00	0.00	0.00	0.00	0.00
R1a1a3**a6** Cortic (alone or combined) and other specialities for allergic rhinitis	0.00	-3.00	-3.00	-3.00	-3.00
R1a4a7a9b Corticosteroids for rhinological infections	-1.00	-4.00	-5.00	-5.00	-5.00
R2a+ A1a2+a3+a4+a5+b Oropharygeal anti-infectives, decongestants	-1.00	-4.00	-4.00	-4.00	-4.00
R3a1a2d1f1 B2 stimulants, inhaled corticosteroids **alone or combined**	7.00	4.00	4.00	2.00	2.00
R3b2c1c2g1j2 Xanthines, non-steroidal anti-inflammatory drugs, b2+anticholinergics,antileukotrienes	33.00	30.00	15.00	0.00	0.00
R4aR5abd1d2f +**R3x**,Revulsants, Antitussives, bronchopulmonary products, other bronchodilators **+ alphaamylase**	-2.00	-5.00	-5.00	-4.00	-4.00

R5C Expectorants	-3.00	-6.00	-6.00	-4.00	-3.00
R6A Antihistamines	3.00	0.00	0.00	0.00	0.00
R7A Respiratory stimulants	-1.00	-4.00	-2.00	-1.00	-1.00
S1abcdfghr(s9) ophthalmological (excluding sophtal, ophtalmine, vita3, boroclarine, benzododecinium, posine,laiter bleu, martigene, sodium propionate, soothing antiseptic, vitasedine, vitableu, vitargenol)	2.00	-1.00	0.00	0.00	0.00
S1mn1n2x1x2 (excluding visudyne) + sophtal, ophtalmine, vita3, boroclarine, benzododecinium, posine,laiter bleu,martigene, sodium propionate, soothing antiseptic, vitasedine,vitableu, vitargenol	-7.00	-10.00	-10.00	-10.00	-7.00
Visudyne	1 503.00	1 500.0	27.00	17.00	0.00
S1abcdfghmn1n2rs9x1x2 ophthalmological prods.	*nil base see above*				
S1e1e2 Miotics, glaucoma treatments	8.00	5.00	3.00	2.00	2.00
S1k Artificial tears. Ocular lubricants	0.00	-3.00	-2.00	-2.00	-2.00
S2a Ear infection preparations	1.00	-2.00	-2.00	-2.00	-2.00
S2cd Corticosteroid + antibiotic and sundry aural preparations	-2.00	-5.00	-5.00	-4.00	-4.00
T1abcdefx Diagnostic Products	8.20	5.20	5.20	4.50	4.00
T2X Other diagnostic tests	2.00	-1.00	0.00	0.00	0.00
V1A Allergens	1.00	-2.00	0.00	0.00	0.00
V3A Miscellaneous medicines+V6C,D. V7A2. V9 other medicines	3.00	0.00	0.00	0.00	0.00

ANNEX 5. DRUG PRICE NEGOTIATION METHODS [9]

Article L.162-16-1 of the Social Security Code lays down the rules for the pricing of reimbursable proprietary medicines by the Social Security:

> " The sale price to the public of each of the proprietary medicines mentioned in subparagraph 1 of article L. 162-17 is fixed by agreement between the firm exploiting the proprietary medicine and the drug's Economic Committee in pursuance of article L. 162-17-4 or, failing that, by decree of the Social Security Ministers, following the Committee's report. Account is primarily taken, when setting the price, of the improvement to the Medical Service Rendered by the proprietary medicine, the prices of proprietary medicines serving the same therapeutic purpose, forecast or recorded sales volumes and the foreseeable and real conditions for use of the proprietary medicine ".

The law is clarified by the rules governing reimbursement registration (Art. R.163-5-I-2°) which specify that "proprietary medicines which deliver no improvement to the Medical Service Rendered, as assessed by the Commission, mentioned in article R.163-15, or savings in the cost of drug treatment" may be entered on the list provided in article L.162-17 of the Social Security Code.

These public policy rules form the basis of the Committee's action. It is useful however to look at the methods used by the Committee in its relations with firms by drawing a distinction between the general principles and those applied during initial price negotiations, and at the time of the price review, be it upwards or downwards.

1. The general negotiating framework

The Committee's task is to secure the most advantageous prices and conditions for the Health Insurance System mindful both of the global market for proprietary medicines and ONDAM constraints, public health needs and the necessity to treat firms equally.

The principle underlying the public reimbursement of the global proprietary medicines market calls for clarification of all detailed discussions concerning the price of a medicine, over and above the bilateral framework of the negotiation, through an analysis of the economic consequences of this price on the market trend and on the costs of health insurance: direct and immediate consequences on the price structures in the classes, indirect consequences on class-related trends, medium-term consequences when it comes to estimating the financial burden of the reimbursement on ONDAM, and more remote consequences also, where it is possible to anticipate the subsequent arrival of medicines sharing the same indications.

[9] The exposition that follows is taken unaltered from the 2000 report, as the Committee deemed it useful for the readers of its report to be given once again a comprehensive account of the pricing principles.

The principle of the priority to meet health needs means that by its action the Committee must allow for the supply of the reimbursable medicines market, of which pricing is just one of the various means.

The principle of equal treatment among firms is rather a principle of equal treatment among medicines, whichever firms market them. One of the consequences of this principle is that the Committee does not consider it justified, whatever interest it shows in research and innovation, to pre-finance research through the price of medicines which do not in themselves incorporate the successful outcome of such research, nor, *a fortiori*, where innovative medicines are concerned, to treat them differently according to the territory on which the innovation is made.

2. Registration prices

In order to determine the initial price of a drug when first registered, the rule laid down by the reimbursement decree distinguishes between two situations only:

- Either the candidate medicine for reimbursement is devoid of ASMR status, and its registration must give rise to savings for the Social Security;
- Or it possesses ASMR status and its registration may give rise to an additional cost.

The Committee cannot discuss the ASMR level awarded by the Transparency Commission. The scope of the negotiation is therefore clearly set out once the Commission has delivered its opinion, it being noted that the text by no means prevents the Committee from claiming a saving for the Social Security – or at the very least a neutrality of costs – even when the medicine has ASMR status, especially minor ASMR status.

Pricing must be accompanied by review clauses whenever the initial price is set to allow for scenarios that only time and usage will invalidate or confirm.

2.1 Pricing

2.1.1 Medicines devoid of ASMR status

The Committee must secure a negotiated price that leads to savings for the Social Security. Four main points arise from the application of this rule:

The first is that the saving is not necessarily measured as the difference in unit prices between the new medicine and those already registered with which it was compared by the Transparency Commission, but as a cost saving, which is the outcome of price differentials by volume. A consequence is that the Committee was able to accept prices which were not set below that of the last registered comparison drug, when it seemed to it that a lower price would be a competitive handicap for the exploiter of the candidate medicine, in terms of its promotion among prescribers, and that very few would be sold. The Committee considered in such an instance that it might be advantageous to the health insurance system for the new competitor to have the resources to play a significant role on the market, so long as the price was lower

than that of biggest selling medicines in the class. For the same reasons, the Committee accepted, in one case as an experiment, a significantly higher price than that of cheaper comparison medicines, but far cheaper than that of the biggest selling medicines in the class. The relevant agreement deals with the repercussions were the expected savings not achieved.

The second point concerns the distinction between the classes in which prescription volume are rigid (reliable diagnostics, precise and limited indications) and those in which there is a risk of an unjustified growth in volumes. In the first classes, the arrival of a new contender may lead only to a shift in market share; hence the rival is welcome, even though the price benefit is relatively insignificant. Quite the reverse applies in the second classes where the relative price benefit linked to the arrival of a new player risks being offset, and undermined even, by the overall rise in volumes which results from the increased promotional pressure on prescribers. The Committee is more exacting in such cases.

The third and more specific point concerns the matter of additional ranges. Very broadly, these new presentations benefit from no ASMR status and the matter facing the Committee is whether the right comparator, when ascertaining the effect of the medicine's registration on social security expenditure, is the range in which the new product fits and which will in part be replaced by it or indeed equivalent products marketed at a potentially lower price by other laboratories. In 2000, the Committee more often than not based its decision on a comparison with cheaper rival medicines.

Final point: the Committee took especial care, in cases of pharmaceutical innovations without ASMR status, to verify whether the effect of registering these new medicines might be, purposely perhaps where products whose patents are due to expire are concerned, to close the path either commercially or legally to the development of generics. In such an event the Committee was able, as a requirement of registration, to demand savings in relation to those made by the corresponding generic.

2.1.2 Medicines with ASMR status

The registration of these medicines was able to generate additional savings for the Social Security. Determining the acceptable additional expenditure was a difficult matter for the Committee, and there is no model on which to base a solution. We shall confine ourselves therefore to stating the few principles that defined, from the Committee's standpoint, the context of the negotiation.

It should be noted first of all that not all ASMRs necessarily justify a price differential in respect of comparison medicines already registered. In numerous cases, especially for minor or modest ASMRs, the Committee deemed that a sufficient " benefit " of the innovation for the firm consisted in the growth of its market share, without there being any reason to add a price advantage to it.

Secondly, there is no scale of acceptable price differentials related to the ASMR scale, even if it is true that minor ASMR status cannot justify a large price differential. The discussion of the price of a highly innovative medicine therefore constitutes an

open negotiation where the demands of the firm are confronted by the greater or lesser necessity or urgency, in terms of meeting health needs, to register the medicine for reimbursement. During the negotiation, the so-called “ European ” price of the medicine was regarded realistically by the Committee as a legitimate constraint for the firm, yet was binding on the administration only insofar as it thought that the registration was justified at that price. In other words, the Committee generally understands full well that a firm cannot accept a price which is out of kilter with those it charges on other leading markets within the European Union, yet the risk is that the medicine may not be registered at all, if its innovative contribution is not judged sufficient from the viewpoint of benefits and health needs. Moreover, the Committee has frequently pointed out that France is part of the European Union, that the French proprietary medicines market accounts for a large share of the European market and that as a consequence no firm could cite a truly European price while the French reimbursement price has not been set.

We should add that the registration of highly innovative medicines frequently lends itself to the conclusion of volume clauses, especially in the large number of cases where high ASMR status was awarded to the medicine for restricted indications only.

In one case, the Committee entered into an agreement with a firm wherein not only was the initial registration price of the drug set but also the date and the sum of a scheduled reduction in this price. This new enacting clause was intended by the Committee as a compromise between the constraints of the international launch of the medicine for the firm and the need, with regard to a medicine inaugurating in France a class destined without doubt to give rise to mass prescriptions, to predict from the outset the rapid return to daily treatment costs tolerated by the public purse.

2.2 Price review clauses.

There are two types of price review clause: Daily Treatment Cost (CTJ) clauses and volume clauses. The object of the former is to ensure that the actual cost, per patient, involved in the use of a drug remains consistent in the long-term with what had been agreed with the firm at the time of registration. The object of the latter is to ensure that the overall expenditure devoted to a medicine remains in line with the medically justified “ target ” of that medicine. The main standard-type clauses are featured in annex 6.

2.2.1 Daily Treatment Cost (CTJ) Clauses

The Daily Treatment Cost (CTJ) clauses are divided into two categories: dosage range CTJ clauses and posology clauses.

Dosage range CTJ clauses

Many medicines, when a “ dose effect ” has been established in their use, come with several dosages at the time of their marketing or thereafter with the registration of additional dosages. The Committee took the view in such an instance that the best way of ensuring at one and the same time the proper use of the medicine’s different dosages

and equal treatment among rival firms in the category under consideration was that all dosages of the same medicine be sold at the same price per pharmaceutical unit. The uniform prices discourage firms from specifically promoting the sale of the highest and most costly dosages. They also allow the cost of treatment to be maintained over time and achieve a balance in relative prices between rival laboratories, since the real costs of treatment are then independent of the distribution of sales among the different dosages.

Where it is impossible to fix uniform prices, especially for reasons of international price uniformity, a dosage range CTJ clause is introduced instead in order to achieve approximately equivalent effects. In such an instance, what is agreed with the firm upon registration is in reality a daily treatment cost, translated into nominal prices of the different dosages according to a prescription distribution hypothesis. If it is established that the actual distribution differs, on use, from the supposed distribution, the nominal prices are reviewed to restore the agreed cost of treatment.

Posology clauses

The aim and mechanism of these clauses are exactly the same as in the dosage range CTJ clauses. The agreement is reached at the time of registration of a treatment cost based on an average posology hypothesis (Market Authorisation posology or posology attested by studies conducted prior to registration, including in countries where the proprietary medicine has already been marketed). If the posology established on use varies from the one on the basis of which the sale price was set, then this price is reviewed to restore the agreed treatment cost.

2.2.2 Volume clauses

The Committee felt that the volume clauses where unjustified where their main effect was to divide up the markets among rival firms. Furthermore, they make, without exception, hardly any sense for the registration of products without ASMR status, sales of which lead to a saving for Social Security, the greater the saving the bigger the sales achieved in replacement of more expensive products. The year-end quantitative discount mechanism by therapeutic class therefore seemed more suitable in the Committee’s opinion. In fact, a large number of volume classes were suspended from 1999 onwards at the time when agreements with firms were reached.

Conversely, the Committee negotiated price-volume clauses in cases where the ASMR status of an innovative drug related to only one part of its indications or to a quantifiable and limited patient population but where there is nonetheless a risk that the medicine is prescribed for all its indications instead of cheaper drugs, without advantage to patients.

These clauses also have their place, irrespective of financial considerations, when public health reasons require that a proprietary medicine be used only for restricted indications where strictly indispensable, as is often the case in particular for antibiotics.

Finally, volume clauses have sometimes been used when registering highly innovative drugs, where great market uncertainty has surrounded the new product, in order to limit the financial risk for the Social Security. It has happened, when the innovation resulted from the combined efforts of two or more competing firms, that these firms are then committed jointly and severally in a joint volume clause.

2.3 Price reductions or refunds

The Committee has endeavoured not to enter any longer into agreements that included CTJ or volume clauses whose implementation would only be sanctioned by the payment of refunds. It has however frequently accepted, in order to prevent slight and possibly reversible overruns of the thresholds set by the clauses from leading to marginal and subsequent price changes which are management-costly, to subject the actual application of price reductions to the crossing of a variation threshold, the price reductions not made then being offset by equivalent refunds.

2.4 Price reductions

Price reductions may result from the application of a pre-existing price review clause, on the Committee's initiative or on the firm's initiative.

2.4.1 Price reductions linked to the application of clauses

Price reductions are then automatic, in so far as the review clauses themselves are precise. The Committee has endeavoured in this respect not to enter any longer – or as little as possible – into agreements including loose conjectural clauses such as " if such an event occurs, the prices will be re-examined ".

2.4.2 Price reductions on the Committee's initiative

Even in the absence of all price review clauses, the Committee has felt itself justified in proposing price reductions pursuant to the texts governing its activity (see in particular article L. 162-17-4, subparagraphs 2 and 3 and articles R. 163-9 and R. 163-10 of the Social Security Code). This has often been done, sometimes on the occasion of registration renewals, but not exclusively.

The registration renewal is in effect an opportunity to examine a proprietary medicine's actual place on the market, which may differ widely from what was foreseen at the time of its registration. A notable case, even in the absence of misuse of a medicine, is when it has enjoyed, since its registration, considerable growth in prescribed volumes, especially in the wake of extended indications. The price reduction may also be justified by the marketing, after the initial registration of the proprietary medicine, of rival proprietary products that are equally effective and cheaper.

Price reductions on the initiative of the Committee may relate to an isolated medicine, a group of proprietary medicines belonging to the same class or all proprietary medicines within a class.

2.4.3 Price reductions on the initiative of firms

These are by definition competitive prices, observed until now essentially in the domain of generics, but the practice of which the Committee has not given up hope of extending to patented drugs, as prescribers and patients grow more aware of prices and as firms are forced to state in their promotional leaflets the lowest cost of their medicines, their Medical Service Rendered status being equal.

2.5 Price increases

The Committee is wary of proposals from firms to adjust prices to zero-earnings. Even if the immediate result of these prices is neutral or profitable for the Social Security, they may prove costly in the long run. Furthermore, these provisions are likely to cause relative price imbalances in the pharmacotherapeutic classes.

The Committee has, on the contrary, accepted price rises for medicines which are vital to meeting health needs registered at a price which would no longer allow them to cover their manufacturing and marketing costs. These are generally older products whose market has gradually declined, orphan drugs or proprietary medicines that, without strictly fitting the definition of orphan drug, may be treated as such economically.

Finally, in one case, as an experiment, the Committee entered into a price increase agreement with a firm, the purpose of which being to allow that firm to increase, by intensifying its promotional efforts, the market share of the drug in question in a class where sales were being rapidly overtaken by much more expensive drugs. It is expected of this agreement that the immediate additional expense incurred by the increase will be more than swiftly offset by the savings recorded as a result of the replacement. The agreement also makes provision for the repercussions in the event that this expectation is not met.

ANNEX 6. STANDARD CLAUSES

1. Standard posology clause

Article 1:
The prices shown in the following table are applicable from their publication in the Journal Officiel (or …. will come into effect on dd/mm/yy).

Presentations	EPHMRA Code	PFHT	PPTTC
CIP Code – Presentation aaa	……	---.-- €	---.-- €

Article 2:
2.1. The price set in article 1 (manufacturer's price net of reference tax: $PFHT_R$) is done so on condition that the posology stated (P_C) is equal at least to ……. (reference posology : P_R).

2.2. The posology (P_C) is examined every year and, for the first time, on dd/mm/yy on the basis of the latest DOREMA published prior to that date.
If the stated posology (P_C) is greater than the reference posology (P_R), the PFHT set in article 1 is amended ($PFHT_M$) in order that:

$$PFHT_M = \frac{P_R}{P_C} \times PFHT_R$$

From the moment that an initial price change is made in compliance with this clause, a new price change can only be made in compliance with this clause if the stated posology is greater than the posology on which the previous price change was based.
If $(P_C - P_R) / P_R$ is lower than x %, the $PFHT_R$ is not changed and the firm is liable for a refund (R) calculated according to the formula set out in 2.3.

2.3 If the stated posology (P_C) is greater than the reference posology (P_R), the firm is further liable for a refund (R) calculated according to the formula:

$$R = CAHT_C - (PFHT_M \times V_C)$$

where:

- $CAHT_C$: turnover recorded in the GERS over the 12-month period preceding the date mentioned in 2.2 ;
- V_C: sales volume of the presentation reported in the GERS over the same period.

2.4. Notification of the sum of the refund due will be given to the firm by the Economic Committee for Health Products. Payment of the refund will be made by the firm to ACOSS one month following notification from CEPS. The firm will inform CEPS by mail of the date and of the sum of the payment made.

The sum of this refund will be arrived at, where applicable, by deducting the basis of assessment of the quantitative refund by class set forth in the agreement between the Economic Committee for Health Products and the firm.

2. Standard clause for dosage range daily treatment costs (CTJ)

Article 1:

The initial registration costs (or price changes …) indicated in the following table are applicable from their publication in the Journal Officiel (or …. will come into effect on dd/mm/yy).

Presentations	EPHMRA Code	PFHT	PPTTC
Initial registration – CIP Code – Presentation aaa	……	---.-- €	---.-- €
Initial registration – CIP Code – Presentation bbb	……	---.-- €	---.-- €
Price change –CIP Code – Presentation ccc	……	---.--€	---.--€

Article 2 :

2.1. The prices set in article 1 are done so on condition that the stated dosage range daily treatment cost ($CTJG_C$) calculated on the range made up of aaa, bbb, ccc, …., is equal at least to ---.-- € : reference dosage range daily treatment cost ($CTJG_R$).

2.2. The $CTJG_C$ is examined every year and, for the first time, for the 12-month period preceding dd/mm/yy. It is calculated on the basis of the posologies of each of the presentations mentioned in 2.1 appearing in the latest DOREMA published prior to dd/mm/yy and of sales over 12 months shown in the latest GERS published prior to that date.
The $CTJG_C$ is calculated by dividing the turnover achieved over the entire range (CAHTG) as recorded in the GERS by the number of treatment days of the range (NJTG), namely:

$$CTJG_C = CAHTG/NJTG$$

The NJTG is equal to the sum of the number of treatment days of each of the range's presentations, namely:

$$NJTG = \sum NJT_i$$

For a given presentation, the number of treatment days, NJT_i, is equal to the number of tablets (doses, units) sold for each presentation i of the range divided by the corresponding posology (P_i) recorded in the DOREMA, namely,

$$NJT_i = (\text{number of units per pack} \times \text{number of packs}_i) / P_i$$

If the $CTJG_C$ is greater than the $CTJG_R$, then the PFHT (at least one) of the range's presentations mentioned in 2.1. is reduced in order that the CTJG is equal to the $CTJG_R$.

3. Standard clause of volumes in units

Article 1:

The prices indicated in the following table are applicable from their publication in the Journal Officiel (or …. will come into effect on dd/mm/yy).

Presentations	EPHMRA Code	PFHT	PPTTC
CIP Code – Presentation aaa	…….	---,-- €	---,-- €

Article 2:
2.1. The price (PFHT) mentioned in article 1, (manufacturer's price net of reference tax: $PFHT_R$) is such on condition that the annual sales volume (V_C) is less than or equal to the reference sales volume (V_R).

2.2. The sales volume V_C is examined each year, and for the first time on dd/mm/yy on the basis of the latest GERS published prior to this date.
If the recorded annual sales volume (V_C) is greater than a reference volume (V_R), the PFHT is amended ($PFHT_M$) so that:

$$PFHT_M = x\, PFHT_R + (1 - x)\, PFHT_R \times (V_R / V_C), \text{ with } 0 < x < 1.$$

From the moment that an initial price change is made in compliance with this clause, a new price change can only be made in compliance with this clause if the stated volume is greater than the volume on which the previous price change was based.

ANNEX 7. THE COMMITTEE'S ORGANISATION CHART

ANNEX 8. DETAILS OF COMMITTEE MEMBERS

DETAILS			
NAMES	**Telephone**	**Fax**	**E-MAIL**
Ghislaine de Bentzmann	01 40 56 57 55	01 40 56 40 50	ghislaine.de-bentzmann@sante.gouv.fr
Ghislaine Brouard	01 40 56 78 64	01 43 06 30 02	
Isabelle Cheney	01 40 56 75 54	01 40 56 71 79	isabelle.cheiney@sante.gouv.fr
Marie-Thérèse David	01 40 56 69 51	01 40 56 71 79	
Nathalie Ebeyer	01 40 56 69 07	01 40 56 71 79	
Claire Gendre-Oget	01 40 56 71 27	01 40 56 71 79	claire.oget-gendre@sante.gouv.fr
Sylvette Laplanche	01 40 56 46 95	01 40 56 71 79	sylvette.laplanche@sante.gouv.fr
Dominique Lecomte	01 40 56 56 61	01 40 56 40 50	dominique.lecomte@sante.gouv.fr
Marie Lucet	01 40 56 44 27	01 40 56 71 79	
Dominique de Penanster	01 40 56 56 61	01 40 56 40 50	dominique.de-penanster@sante.gouv.fr
Noël Renaudin	01 40 56 73 76	01 43 06 30 02	noel.renaudin@sante.gouv.fr
Françoise Revechon	01 40 56 46 84	01 40 56 71 79	
Antoinette Richard	01 40 56 71 72	01 40 56 71 79	
Maryvonne Richer	01 40 56 53 46	01 40 56 40 50	
Michel Rousseau	01 40 56 49 51	01 40 56 71 79	michel.rousseau@sante.gouv.fr
Geneviève Uchida-Ernouf	01 40 56 72 14	01 40 56 71 79	genevieve.uchida@sante.gouv.fr

ANNEX 9. DECLARATIONS OF INTERESTS

Notice of
Declaration of interests of the Members
of the Economic Committee for Health Products and participants at meetings

NATURE OF INTERESTS:
Employment contract…….. CT
Financial interest in the share capital of a company…..…….. PF
Remunerated work carried out (involvement in clinical trials, studies, consultations, research, etc)……...……TR
Other declared interests……. A

1 - Members of the Health Products Committee

1 – Committee Members	Nature of interests
Chairman of the Economic Committee for Health Products *Monsieur Noël RENAUDIN*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Vice-Chairman of the Economic Committee for Health Products *Monsieur Jean-Paul CANO*	**CT**: nil **TR**: nil **PF** : nil **A** : a child in the employ of a pharmaceutical company
Vice-Chairman of the Economic Committee for Health Products *Madame Dominique LECOMTE*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Social Security Directorate *Monsieur Stéphane SEILLER*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Directorate-General for Health *Madame Hélène SAINTE-MARIE*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Directorate of Hospital Admissions and the Organisation of Healthcare *Madame Dominique LAGARDE (drugs section)*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Directorate of Hospital Admissions and the Organisation of Healthcare *Madame Françoise CABANE (medical devices section)*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Directorate-General for Competition, Consumption and Fraud Prevention *Monsieur Francis AMAND*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
Directorate-General for Industry, Technologies, Information and the Post *Monsieur Gérard MATHIEU*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
National Health Insurance Bodies *Monsieur Pierre-Jean LANCRY*	**CT**: nil **TR**: nil **PF** : nil **A** : nil
National Health Insurance Bodies *Monsieur Christian MARTY*	**CT**: nil **TR**: nil **PF** : nil **A** : nil

2- Persons attending meetings of the Economic Committee for Health Products

2 – Persons attending Committee Meetings	Nature of Interests
Economic Committee for Health Products	
Madame Isabelle CHEINEY	**CT**: nil **TR**: nil **PF**: air liquide. **A**: nil.
Madame Dominique HUON de PENANSTER	**CT**: nil **TR**: nil **PF**: nil **A**: nil.
Madame Sylvette LAPLANCHE	**CT**: nil **TR**: nil **PF**: nil **A**: nil.
Monsieur Michel ROUSSEAU	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Social Security Directorate	
Madame Danielle GOLINELLI	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Madame Michèle LARREUR	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Madame Aude de MARTIN de VIVIES	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Directorate-General for Health	
Madame Emmanuelle AMPHOUX	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Madame Sophie FEGUEUX	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Madame Caroline GARDETTE	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Monsieur Patrick GUYOT	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Madame Nathalie MANTEAU	**CT**: nil **TR**: nil **PF**: nil **A**: nil
Madame Françoise WEBER	**CT** employed between 1997 and 2000 by pharmaceutical laboratories (PARKE DAVIS and PFIZER) **PF** : financial interest in these firms until end 2000. **TR** : nil **A**: brother medical visitor to a laboratory (PFIZER)
Directorate-General for Competition, Consumption and Fraud Prevention	
Monsieur Olivier CAILLOU	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Madame Emmanuelle CONESA	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Monsieur Daniel MILES	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Directorate-General for Industry, Technologies, Information and the Post	
Monsieur François LHOSTE	**CT**: nil. **TR**: nil. **PF**: nil. **A**: Fee for co-creation of a drug at Laboratoires SERVIER
Madame Sophie REMONT	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Madame Catherine TRENQUE	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Madame Marie-Claire SEBAG	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Compulsory Health Insurance	
Madame Carine BUSIN	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Monsieur Frédéric GIRAUDET	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Madame Martine PIGEON	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Madame Christine VAULONT	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.

3- Rapporteurs to the Economic Committee for Health Products

3 – Rapporteurs to the Committee	NATURE OF INTERESTS
Mme Françoise Benoît-Cattin	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Mme Hélène Bourdel	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Mme Isabelle Cheiney	**CT**: nil. **TR**: nil. **PF**: Air Liquide. **A**: nil.
Mme Elisabeth Crepon	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. Bertrand Diquet	**CT**: nil. **PF**: nil. **TR** : Research work, participation of working party on HIV infection at Glaxo Wellcome, HMR internet question. **A** : wife employed by Aventis.
M. Nicolas Gaspard	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Mme Claire Gendre-Oget	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. Jean-Marc Grognet	**CT**: nil **PF**: nil. **TR** : nil. **A**: wife employed by Glaxo Wellcome.
M. Philippe Lalande	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Mme Régine Lemee-Pecqueur	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. Jean-François Mattei	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
Mme Michèle Msika-Boutigny	**CT** : employed by Jouveinal/Parke Davis 1991/1999. **TR**: nil. **PF**: nil. **A**: nil.
Mme Marie-Françoise Peny	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. Bruno Stalla	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. André Tanti	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. Bernard Teisseire	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.
M. Jean-Pierre Yvert	**CT**: nil. **TR**: nil. **PF**: nil. **A**: nil.