Economic Committee for Health Products

Activity Report 2002

July 2003

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In accordance with Article D.162-2-4 of the Social Security Code, the Economic Committee for Health Products submits a report on its activities to the Ministers for Social Security, Health, Industry and the Economy each year. In addition, Article L.162-17-3 of the Social Security Code provides for this report to be submitted to Parliament.

The present report details the main activities of the Committee during 2002.

The first part relates to medicines and deals successively with medicine costs in 2002 (Section I), regulatory activities carried out by the Committee in application of the Social Security Code and the directives of the ministers (Section II) and the activity of price determination (Section III).

The second part relates to health products other than medicines. Section I is given over to a description of the cost of medical devices and changes in those costs. Section II deals with the Committee's activity in relation to tariffs and prices for the products and services defined in Article L.165-1 of the Social Security Code.

PART ONE – MEDICINES

SECTION I – EXPENDITURE ON MEDICINES

1. CONTEXT OF EVOLUTION IN EXPENDITURE ON MEDICINES IN 2002

The Committee's activity in 2002 was conducted against a background of general increases in medicine sales, which however slowed significantly in comparison with previous years: 5.7% compared with 7.7 % in 2001 and 2000.

The slowing has been much more significant for ambulatory reimbursable medicines, as sales of these medicines increased by a mere 4.2% in 2002[1] compared with 7.2 % in 2001 and 8.9% in 2000. At the same time, however, sales to health institutions continued to grow at a sustained rate (12.9% in 2002, 16% in 2001).

The relatively modest growth in ambulatory sales, which is also modest in relation to what has been observed in other comparable countries, can be explained by a variety of factors, some of which are particular to the economic circumstances that prevailed in 2002. Others, however, are more permanent and may indicate a downward trend in the medium term.

Of the economic factors, the most significant will have been the effect of the major price reductions introduced in Autumn 2001 and as such felt during the first three quarters of 2002. In addition, there was an almost complete absence of transfers of medicines from the hospital budget to the pharmacy budget. Finally, the year 2002 saw a particularly favourable situation as regards epidemics.

Other causes, probably of a more long-term nature, have however played a role in bringing about the drop in ambulatory medicine sales. First of all, the rate of sales of generic medicines has greatly increased as a direct result of the agreement concluded with general practitioners in June 2002. Although the practice of INN prescribing, which appears to have experienced difficulty in making its mark, is far from being the only explanation for the growth, there can be no doubt that the lifting of the barrier to substitution that the behaviour of certain doctors could constitute either directly or through the intermediary of patients, has made a significant contribution to the increased mobilisation of pharmacists.

2002 also saw a major shift in prescriptions of antibiotics, far beyond what can be explained by the situation regarding epidemics. This is a clear indication of the success of the State and Assurance Maladie campaigns about the proper use of these medicines, and is the

[1] This figure is not definitive; indeed, on the basis of the revised GERS 2001 data it may be slightly lower (4%). It is however consistent with the figures published previously, especially in relation to 2001 sales and their developments in relation to the previous year.

consequence, in part, of the circulation of tests that have allowed such medicines to be better targeted in some cases.

Most of all, however, it appears that there have been less significant and costly innovations in medicines targeted at very large sections of the population, of the type that have helped maintain the growth over the last two decades: statins, proton pump blockers, new classes of anti-hypertensives, anti-depressants, inhaled corticosteroids etc. Now that the great rush of Cox-2 selective inhibitors that characterised 2000 and 2001 has levelled out, the only classes of medicines with considerable potential for growth in terms of volume are those used in the treatment of osteoporosis and Alzheimer's disease. Not that the pharmaceutical industry has stopped innovating; rather, its greatest discoveries relate to medicines that may have a very high unit cost but are aimed at narrow and clearly identifiable patient populations. The direct effect of these new costs on medium-term growth is therefore likely to be moderate, although patent expiries in the major growth categories of recent times should increase the potential for generic medicines. It appears that 2002 showed the first signs of this phenomenon.

2. ANALYSIS OF GROWTH IN AMBULATORY REIMBURSABLE SALES

The following analyses have benefited from work conducted on behalf of the Committee by the Social Security Directorate (Studies and Financial Forecasts Sub-Directorate).

2.1. TURNOVER PROGRESSION

2.1.1. Sales excluding tax

The turnover excluding tax realised in pharmacies in 2002 totals €14,930 million, an increase of 4.2% compared with the 2001 turnover of €14,330 million or an increase of €600 million.

This growth has been achieved through developments of the same kind as those noted in 2001, according to which the volume of sales decreased in the first, second and third quarters and recovered in the fourth. In terms of turnover, the developments are offset by changes in the average price of packages sold, which in addition to the general tendency of prices to increase over time, increases when available volumes fall and adjusts itself to compensate for fluctuations in volume. Seasonal variations in the average price of packages sold correspond to a relative concentration of summer sales in favour of patients being treated for chronic conditions with medicines of a higher unit cost.

Table 1: Quarterly developments in ambulatory sales of medicines, 2002

Indices	1st quarter	2nd quarter	3rd quarter	4th quarter
Volume	100	99.1	89.4	99.6
Price	100	105.3	106.5	102.7
Turnover	100	104.5	95.2	102.3

In 2002, compared with 2001, the volume of pharmacy sales (measured in numbers of packages) increased by 0.7%, while the average tax-exclusive manufacturer's price (PFHT) for packages sold increased by 3.4%. The combination of increased volume and average price

for packages has led to the observed increase in turnover at tax-exclusive manufacturer's sale prices (CAHT) of 4.2%.

Table 2: Changes in figures for reimbursable sales of ambulatory medicines, 2001-2002

	Packages (billion)	€ (billion)		Average pack price (€)	
Year	Volume	CAHT	CATTC	PFHT	PPTTC
2001	2.71	14.33	21.20	5.29	7.83
2002	2.73	14.93	22.00	5.47	8.07
Rate of change 2002	0.7%	4.2%	3.8%	3.4%	3.1%

2.1.2. Sales inclusive of tax

In 2002, compared with the 4.2% increase in manufacturers' tax-exclusive turnover, the increase in tax-inclusive public price turnover (CATTC) has been less significant, coming out at 3.8%. Overall, in 2002 the average total mark-up (calculated on the basis of the (CATTC-CAHT) / CAHT turnover) was 47.4%, a decrease of 0.5% compared to the previous year in which it totalled 47.9%. This variation has been caused by a shift in the market towards more costly products, whose PFHT in 2002 was on average 3.4% higher than in 2001, but whose mark-up rate, thanks to the phenomenon of degressivity[2], is less. This has led to a lesser increase, of 3.1%, in the tax-inclusive public price (PPTTC) charged for the package.

This reduction in average mark-up rate has however been slowed by the great increase in generic medicine sales, and is therefore less pronounced than the increase in the average pack price might suggest. This is because the mark-up for generic medicines, at the same PFHT price level, is higher than the mark-up for patented medicines. In 2002, this phenomenon was exacerbated by the appearance of more costly generic medicines, more costly sometimes than the non-generic medicines sales which decreased at the same time. Part of the structural effect (see 2.4 below) was therefore supplied by these higher-priced generic medicines which, in terms of overall consumption, have replaced[3] low priced non-generic medicines.

2.2. THE GENERICS MARKET

Overall, in 2002, generic medicines accounted for 8.4% of sales by volume and 4.1% of the total tax-exclusive turnover. From one year to the next, the turnover in generic medicines increased by 37.5%. The increase in generic sales rates occurred during the second half of the year, following the agreement between doctors and sickness insurance funds dated 5 June 2002 (increased consultation fees and the undertaking to prescribe generics).

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[2] The retail mark-up consists of a fixed part, which is identical regardless of the tax-exclusive price of the medicine, and a proportional part of 26 % up to a tax-exclusive price for the medicine of €22.9. Above this price, the applicable mark-up will be 10%.

[3] We are not looking here at replacement of generic medicines with the original branded drug but at a hypothetical situation in which the overall consumption of inexpensive products is replaced by more expensive generic medicines with higher mark-ups. This hypotheses can be illustrated in the example of non-reimbursement of products with an average price of €2.5 and an average mark-up of 50%, to be compared with the development of sales of generic medicines with an average price of €3 and an average mark-up of 70%. In this case, the increase in the CATTC and the increase in the average tax-inclusive TTC pack price would be more rapid that the increase in the CAHT and the average tax-exclusive pack price.

Table 3: Development of the generic medicines market in 2002 – units (million) / value (million €)

Market share	2001*		2002**	
	Units	Value (no tax)	Units	Value (no tax)
Generic groups market	543	1,985	575	2,190
Generics market	182	443	230	609
Generic groups market / total market	19.9%	13.9%	21.1%	14.8%
Generics market / generic groups market	33.5%	22.3%	39.7%	27.8%
Generics market / total market	6.7%	3.1%	8.4%	4.1%

* Corresponds to the AFSSAPS list published in the JO on 21 June 2001.

** Corresponds to the AFSSAPS list published in the JO on 27 October 2002.

On these bases, given that generic medicines have been substituted for their branded versions that had a tax-exclusive price 50% higher on average (that is, the generic price is on average 33% less than the branded product price), the effect of the increases in generic sales on growth in the tax-exclusive market in 2002 can be estimated at €83 million, that is, 0.6 growth points less than tax-exclusive ambulatory sales in 2002.

From 2001 to 2002, the CAHT for generic products has increased by 37.5%, while the corresponding CATTC has increased from €780 million to €1,060 million, an increase of 34.7%; this corresponds to a reduction in mark-up from 76.8% to 73.3%. The average tax-exclusive sale price of a generic pack increased from €2.43 to €2.65, that is by 8.8%, while the average tax-inclusive price of the pack increased by 6.6%, from €4.30 to €4.59. The increased prices and reduced mark-ups indicate changes in generic sales levels in keeping with the list of substitutable products, which was expanded to include several higher-priced classes from 2001 to 2002.

2.3. THE EFFECT OF PRICE REDUCTIONS IN 2002

According to the estimates of the Economic Committee for Health Products, the price reductions in 2001, whether they were related to insufficient medical benefit (SMR) ratings or reductions for products for which the SMR was not disputed in high-volume or high-price classes, had the effect of bringing about a 1.5-point reduction in growth of tax-exclusive sales in 2002. The insufficient SMR reductions in 2002, brought in at the end of the first quarter (for a total estimated at €90 million for a full year) brought about a reduction in growth of 0.3 points in relation to medicines the market for which was going down.

2.4. THE COMPONENTS OF GROWTH

The 4.2% increase in turnover can be analysed in terms of:

- A 1.6% drop in unit pack price in comparison with the previous year (price effect).
- A 0.7% increase in the number of packs sold for 2002 over 2001 (container effect).
- An average price rise of 5.1% for unit-priced packs continually available (structure effect). This structure corresponds to a distortion in sales structure towards the most costly available products, whether a shift in sales towards therapeutic classes with a higher price is involved, or whether there has been a shift in consumption within the same therapeutic class towards medicines marketed at higher prices.

Table 4: The components of ambulatory sales growth

Year	Price effect	Package effect	Structural effect	Total growth
2002	-1.6%	+0.7%	+5.1%	4.2 %
2001	- 1.3%	+1.2%	+7.3%	7.2%
2000	- 0.9%	+2.9%	+6.8%	8.9%
1999	- 0.7%	+1.8%	+5.5%	6.6%

The price effect, which is negative as in previous years, has however been more pronounced (see 2.3 above). The package effect is relatively insignificant at +0.7%. Most of the change in retail pharmacy sales in 2002, as in previous years, is attributable to the structural effect; it is however much less pronounced than before.

2.5. THE PRICE OF MEDICINES

2.5.1. The INSEE price indices

INSEE makes an annual calculation of prices indices for reimbursable and non-reimbursable drugs. The following table traces the changes in these indices across the past five years, with a base of 100 for the 1998 annual average[4].

Table 5: Price indices for pharmaceutical products

Year	Reimbursable products		Non-reimbursable products	
	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
2002	95.7	96.0	110.5	109.4

Source: INSEE

The prices used in the calculation of the indices (followed by a sample of 7,000 available products periodically updated) are the pharmacy prices, including all taxes and mark-ups. With regard to reimbursable products, they therefore include variable elements such as mark-up and tax liability, which lead to specific variations over and above the tax-exclusive manufacturer's price. In addition, there is still a continued downward movement in the reimbursable products index, which is more noticeable in 2002 because of the full-year effect of the 2001 price reductions, the continuation of the downward movement in 2002 on the basis of medical benefit rendered, and developments in the generic market. However, in its structure the INSEE index only takes account of continued market sales; products that were sold in the previous year but cease to be marketed in the following year are not taken into account, and neither are any newly marketed products. The effect on prices of the replacements made available for consumption following the disappearance of old medicines or the arrival of new replacement products, in terms of replacing less expensive products with more costly ones (see 2.4 above: The Components of Growth – Price Effect and Structure Effect) is therefore concealed in the INSEE index.

[4] INSEE, Monthly Statistics Bulletin, February 2003, No. 2.

Logically, the result produced by INSEE, that is, a 2002 index 1.5 points lower than the 2001 index, is almost the same as the –1.6% price effect calculated above, according to a method that also takes account only of continuous market sales. The results of the INSEE procedure and the calculation of the price index bear each other out but do not accurately show the actual developments in prices across the whole of the medicines market.

The Committee is therefore interested in changes in *average* pack prices.

2.5.2. The average pack price

The average price of "packages" sold is obtained by dividing the annual tax-exclusive turnover by the number of units (packages) sold in the same year. It concerns all the products sold in a given year, regardless of their market share, and therefore includes not only prices and price variations but also the structural effects (see 2.4, The Components of Growth, above).

Table 6: Changes in the average tax-exclusive manufacturer's pack price between 1998 and 2001

	1998	1999	2000	2001	2002
Average tax-exclusive "pack" price	€4.48	€4.69	€4.98	€5.29	€5.47
Changes / year n-1 (tax-exclusive price)	-	+4.7%	+6.2%	+6.2%	+3.4%
Tax-exclusive index 1998 = 100	100	104.7	111.2	118.1	122.1

Prices calculated in this way do not allow isolation of the effect caused by changes in packaging. For example, when for a given specialist product a 28-tablet pack is replaced by a 14-tablet pack, the average pack price increases without effect (except for possible mark-up effects) on general price levels or on costs. It can however be estimated, in the absence of carefully ordered movement and any changes to the size of packaging, that this effect will play no more than a marginal role in 2002 and in previous years.

The full-year impact of price reductions generated in 2001, plus the reductions generated in 2002, combined with the increased sales of generics in 2002, are the causes of the relative moderation in 2002 of the average pack price increase. This increase totalled 3.4% in 2002, compared with 6.2% for the previous two years.

2.6. EVOLUTION ACCORDING TO THERAPEUTIC CLASS

In 2002, over three-quarters of the €600-million increase in sales can be attributed to the ten classes or groups of classes whose turnover showed the greatest increase.

Table 7: Contribution by class to the increase in sales

million €

Class	CAHT 01	CAHT 02	Diff.	Growth
A02B2: Proton pump inhibitors	704	831	127	18%
C09C,D: Single/ combined angiotensin antagonists	387	453	66	17%
B01C: Platelet anti-coagulants	226	280	54	20%
R3: b2 stimulants, inhaled corticosteroids, combinations	549	602	53	10%
C10A1: HMG-CoA reductase inhibitors	776	813	37	5%

N2B: Non-narcotic analgesics, anti-pyretics	570	601	31	5%
M5B: Bone calcium regulators	86	128	27	49%
N5A1: Atypical anti-psychotics	124	150	26	17%
N6A: Antidepressants	545	569	24	4%
N7D: Anti-Alzheimer's drugs	81	102	22	27%
Total	4,048	4,529	467	12%

This table brings together the ten classes or groups of classes with the greatest positive difference in turnover compared to 2001. The table shows them in decreasing order according to the magnitude of the difference in turnover between 2001 and 2002.

The growth noted in these classes, which account for about 30% of the total market, is about 12%.

In contrast, the following table brings together the classes that showed the greatest negative difference in turnover between 2001 and 2002.

Tableau 8: Classes showing decreases

million €

Class	CAHT 01	CAHT 02	Diff.	Decrease
J1 ex. J1M: Antibiotics	967	876	-91	- 9%
C4, N6D: Vasodilators, nootropics	341	312	-29	- 8%
C5C: Varicose therapy, systemic	384	368	-16	- 4%
C1D: Coronary therapy	180	168	-11	- 6%
A2B1: H2 receptor antagonists	72	61	-11	-15%
Total	1,944	1,785	-158	- 8%

For Class J1 (except J1M), the class grouping used in the presentation of this table brings together all the ambulatory antibiotics available on the French market. The overall drop noted in 2002 for this group is 9% in terms of value and 10% in terms of volume, and has occurred suddenly. After increasing sharply in January 2002, with a turnover 11% greater than that realised in January 2001, the sudden drop in sales of antibiotics started in February 2002 and by the end of the last quarter of that year sales levels had dropped to 15% below the figure for the last quarter of the previous year.

3. INCREASE IN SALES AND EXPENSES

According to statistics compiled by the National Sickness Insurance Scheme for Salaried Workers (CNAMTS), the 2002 increase for medicine reimbursements under the *régime général* will be 6.8%.

For all the sickness insurance regimes, according to the observation that *régime général* reimbursements regularly increase at a greater rate than under the others, the increase in reimbursements will probably be about 6.5%, that is, 2.3 points higher than the growth in the retail pharmacy market calculated according to tax-exclusive manufacturers prices (CAHT) and 2.7 points higher than the growth in the retail pharmacy market calculated according to tax-inclusive manufacturer's prices (CATTC), to which it should be compared (see Table 2).

This difference between increases of ambulatory sales and reimbursements under the compulsory sickness insurance scheme begs explanation. The Committee has sought an

explanation for the difference, taking account of reimbursements relating to the *rétrocession hospitalière* and the effective rate of reimbursement under sickness insurance schemes.

3.1. *LA RÉTROCESSION HOSPITALIÈRE*

Medicines covered by the *rétrocession hospitalière* are dispensed by a hospital pharmacy to out-patients. The cost of these medicines is not included in the hospital's overall budget, but instead is included in ambulatory reimbursement expenditure. Reimbursement of these medicines is included in the compulsory sickness insurance scheme costs but not in the turnover of the laboratories, which allocates the sales back to the pharmacies. Therefore, to analyse reimbursements under sickness insurance, it is a good idea to use as a basis the total retail pharmacy sales and sales corresponding to *rétrocession hospitalières*.

For 2001, the Directorate-General of Public Accounting (DGCP) assessed sales linked to *rétrocession hospitalières* at €945 million. For 2002, according to provisional DGCP figures, the increase in these sales will total 31.9%. This provisional figure is approximately equal to the 30.7% increase in *rétrocession hospitalière* reimbursements recorded by the *régime général*[5]. On the basis of this rate of increase, 2002 sales can be estimated at €1,246 million. The following table sets out the figures shown in Table 2, including those estimated above for the hospital reimbursement system.

Table 9: Estimated evolution of the reimbursable medicine market in 2002

billion €

	Turnover, tax-inclusive public prices (CATTC)		
Year	CATTC ambulatory	*Rétrocession* TTC	Total CATTC
2001	21.195	0.945	22.140
2002	22.004	1.246	23.250
Rate of change, 2001-2002	3.8%	31.0%	5.0%

Including the *rétrocession hospitalière* allows the growth in tax-inclusive turnover between 2001 and 2002 to be estimated at 5%.

3.2. EFFECTIVE RATE OF SICKNESS INSURANCE REIMBURSEMENT

The average effective reimbursement rate calculated by the CNAMTS for the *régime général* is 74.8% in 2002[6] compared with 73.9% in 2001[7]. The effective rate of reimbursement is equal to the ratio between the reimbursements made by the *régime général* and the tax-inclusive value of medicines presented for reimbursement. The calculation of this effective reimbursement rate includes reimbursements made in relation to the *rétrocession hospitalière.*

Direct application of the effective rate of reimbursement under the *régime général* (CATTC) does not allow for the non-presentation for reimbursement of a certain number of medicines to be taken into account, and the extrapolated rate observed for the *régime général* for all reimbursements will show a number of discrepancies from the other regimes. The result obtained therefore corresponds, provided all things are equal, to potential reimbursements

[5] CNAMTS, Directorate of Statistics and Studies, Economic Circumstance Point, April 2003, No. 12.

[6] CNAMTS, Directorate of Statistics and Studies, Monthly Statistics, Results as at end December 2002.

[7] CNAMTS, Directorate of Statistics and Studies, Monthly Statistics, Results as at end December 2001.

(potential in the sense that not all medicines sold are presented for reimbursement) under the sickness insurance schemes. On these bases, the total potential reimbursements under the compulsory sickness insurance scheme will show an increase of 6.3% for 2002 over 2001.

Overall, the inclusion of *rétrocession hospitalière* on one hand and the increase in the effective rate of reimbursement on the other hand, could explain most of the difference between the increase in the rate or compulsory sickness insurance reimbursements (6.5%) and that of tax-exclusive rates through pharmacies (4.2%). The residual discrepancy of 0.2% between the estimate submitted and the global results may be explained by the reduced reliability of the estimates and the methods for calculating them, by differences between the effective reimbursement rates for the *régime général* and for other regimes. There is in fact little reason to suppose that the rate of presentation of medicines for reimbursement will change suddenly between 2001 and 2002 or that there might be differences in the number of reimbursements such as could lead to such a difference.

A change in the effective rate of reimbursement is caused by changes in the rate of division of medicine sales according to their rate of reimbursement, in the population totals 100% covered by the system, and in changes in its medicine consumption levels.

3.2.1. Theoretical reimbursements

The total of theoretical reimbursements is calculated on the basis of the reimbursement rates of 35%, 65% and 100% applicable to the various medicines and their tax-inclusive turnover.

Depending on how the division of sales changes according to the three reimbursement rate categories (taking account of the *rétrocession hospitalière* considered to come under the category of 100%-reimbursed categories), the average theoretical reimbursement rate, which totalled 62.8% in 2001, reached 63.3% in 2002, thus showing a 0.5-point increase.

This increase in the theoretical reimbursement rate explains part of the increase in the effective sickness insurance reimbursement rate: the part that corresponds to the reimbursements made in favour of the patient population paying the “moderator ticket”. As an initial approximation[8] (the reimbursements made in favour of this category of patients corresponds to about 50% of reimbursements for medicines under sickness insurance), the increase in the theoretical rate could explain, to the tune of 0.25 of a point (or one half of the increase in the theoretical rate) part of the increase in the effective reimbursement rate.

The balance of the increase in the effective reimbursement rate is therefore accounted for by changes in medicine consumption by the 100%-covered population.

3.2.2. Patients covered at 100%

Patients being treated for long-term conditions (ALD) benefit from 100% reimbursement for medicines prescribed in relation to these conditions, regardless of their theoretical reimbursement rate. The vast majority of 100%-covered patients fall into this category. For the *régime général*, the CNAMTS noted that in 2002 there was a sharp increase in 100% reimbursements linked to the ALD population, arising from both the size of that population

[8] Assuming that the structure of medicine consumption according to the rate of reimbursement is the same for patients paying the “moderator ticket” and for those who are 100% reimbursed.

and its medicine consumption levels[9]. On the basis of this observation, and the analysis conducted by the CNAMTS Statistics Department, it can be considered that almost all the balance of the increase in the effective reimbursement rate is linked to changes in reimbursements linked to ALD patients, who now account for 50% of all reimbursements under the *régime général*.

SECTION II – REGULATIONS GOVERNING AGREEMENTS

After 2001, during which the very rapid growth in reimbursable medicine sales justified the implementation by the Committee of rigorous regulation measures, in terms of both price reductions and agreement discounts, the slowdown noted in 2002 led to a much more restricted use of these instruments.

1. PRICE MODIFICATIONS

2002 saw the third and final stage of the price reduction plan for medicines whose medical benefit rating (SMR) has been declared insufficient by the Transparency Commission.

The 2002 reductions were finalised in the context of continuing the reductions applied in previous years, using the same process. In the same way, with the agreement of the authorities responsible for registration, the Committee agreed on the delistings proposed by companies as the risk of reimbursable prescriptions being carried over was low.

Compared to the quantities sold in 2001, the full-year impact of these measures accounted for €90 million, €30 million of which related to delistings.

Two thirds of companies active in the reimbursable medicines market were affected by these reductions, but some in a very limited way.

In accordance with Article 14 of the Sectorial Agreement, the accepted conventional reductions, that is almost all of them, could be deducted to the tune of the loss of turnover assessed on the basis of sales for the previous year, and the additional discounts owed by companies.

With regard to other medicines, the price reductions have been few, their total effect being worth €17 million. Most were approved in application of previously existing agreement clauses, and only very rarely did the Committee take the initiative of requesting a further reduction, usually in instances of re-registration.

On the other hand, the Committee approved a few increases in price for old medicines, without alternatives, whose prices no longer allowed operation under normal circumstances. The overall impact of these increases is however very small, as they relate in all cases but one to medicines with very low sales volumes at reduced prices.

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[9] CNAMTS, Directorate of Statistics and Studies, Economic Circumstance Point, September 2002, No. 4-5. The increase in the average rate of medical care cover.

2. PRODUCT-SPECIFIC DISCOUNTS

The product-specific reductions paid by companies in application of agreement clauses particular to a product, accounted for a significant proportion of the total discounts paid by companies in relation to 2002, in view of the small total covered by the safeguard clause (see below). They related mainly to the application of clauses covering daily treatment costs (CTJ) for ranges or doses, and in a few cases to volume clauses.

3. END-OF-YEAR EXEMPTION CONTRACT

The law provides that "the contribution provided for by Article L.138-10 shall only be payable by companies that have concluded (…) an agreement with the Economic Committee for Health Products (…) still valid on 31 December of the calendar year for which the contribution is due".

Just before the beginning of the 4th quarter, therefore, the Committee sent all companies a proposed amendment to the agreement, relating to the method of calculating the end-of-year quantitative discount. Acceptance of this amendment conditioned the exemptive nature of the agreements for 2002, without prejudice to the specific provisions to be negotiated between each company and the Committee.

The principles of end-of-year agreement negotiation were identical in every respect to those applied in 2001, in accordance with the Sectorial Agreement. As this is now the fourth year for which this agreement has been applied, the procedure has become well known and understood in the three years in which it has been used so far. However, because of the signs of a slowdown in growth noticed in the autumn, the Committee decided to reduce the rate of discounts payable according to class and reduce the contributions made in relation to turnover.

3.1. DISCOUNTS ACCORDING TO CLASS

Discounts according to class are linked to the overall changes in sales in pharmacotherapeutic classes. They are the essential element of the end-of-year agreement.

The 2002 table for the thresholds for inception of discounts according to class (Annex 3), drawn up after discussion with companies, was attached to the proposed amendment sent at the beginning of the agreement campaign.

To recall, only minor alterations were made to the 2001 table, most notably because of the inclusion of an additional year with the aim of keeping the table legible over a four-year period, and because of the revision of certain inception thresholds, either to include the arrival of new medicines or to take account of actual sales in 2001, particularly when these sales greatly exceeded the thresholds laid down and thus justified alteration of the base.

In order to take account of the shift in sales trends at the end of the year, the rate of call for discounts was altered from 35% to 28% of the excess noted within the class. Finally, the division of class discounts between the part based on the turnover realised within that class (65%) and the part based on the increase in that turnover (35%) has been kept at the same level as in the previous year.

In application of the rules of the agreement, ASMR I and II products were exempted from the class discounts, as were paediatric medicines, generic medicines and medicines sold at generic prices.

Beyond the strict application of the agreement rules, the Committee systematically altered the class discounts payable:

- for medicines that also gave rise to payment of a specific discount, in order to take account of the net turnover realised by the business;
- for medicines launched in 2002 or late 2001, for which the method of calculating the discount led to an unusually high contribution because of the growth noted from one year to the other.

3.2. DISCOUNTS ON TURNOVER

With regard to discounts on turnover, the agreement amendments were agreed as in previous years with the safeguard contribution required to be paid by each business in the absence of an agreement taken into account as an indicator. The use of the indicator was however a particularly sensitive issue in 2002, given that the slowing of growth in the last quarter at a level not far from the contribution inception threshold necessitated a substantial alteration in the forecast for the amount expected to be paid by way of contribution.

As before, the indicator was systematically rectified for those companies whose growth in the ambulatory market in 2002 was the result of increases in their generic sales or of the transition to the ambulatory sector of previous hospital medicines.

3.3. DISCOUNT CEILINGS

Still more frequently than in 2001, companies have wished for discount ceilings to be fixed in agreements, either for the total discount or for discounts on turnover alone. It was mostly large companies who wanted a total discount ceiling, in order to make the calculation of their provisions for their annual accounts reliable. In most cases, the Committee accepted a ceiling a little higher than the anticipated income from the discounts as it would be assessed at the time of the negotiations.

It has been possible to fix turnover discount ceilings, especially in the event of disagreements between the company and the Committee on the 2002 sales estimates, the Committee's forecast being lower than the company's. In these cases, the threshold was fixed at a level that allowed the anticipated output to be reached if the Committee's lower estimate was borne out, and the discount limited to the ceiling if the company's estimate was realised or exceeded.

In total, over half of the 81 businesses not covered by a simplified agreement have signed an agreement that provides for the fixing of a discount ceiling. Only in four cases did the fixing of the ceiling relate to the turnover discount only.

4. OVERALL RESULTS OF THE REGULATION

4.1 SIGNATORIES

Of the total 179 companies involved in the retail pharmacy reimbursable market in 2002, 173 were signatories to the agreement amendment negotiated with the Committee. The six businesses from which the Committee was unable to secure return of the signed agreement amendment prior to 31 December 2002 were all very small businesses to which a simplified agreement had been suggested.

The Committee in fact maintained the simplified agreement regime set up in 1999 in favour of the small laboratories. Its main advantage for these businesses, as well as the simplicity of form of the agreements, is the fixing of the discount ceilings according to turnover. In 2002, 92 out of a total of 98 laboratories likely to fall within the scope of this regime signed the simplified agreements.

4.2. FINANCIAL RESULTS

The total discounts effectively paid to ACOSS by pharmaceutical companies in relation to 2002 is €129 million. This total, which is net of the useable discount credits available to the companies, includes both the end-of-year quantitative discounts and the product-specific discounts. It is believed that these latter discounts account for more than half of the total, although it is not possible to make a division within the overall total between what relates to product-specific discounts and what relates to end-of-year quantitative discounts. In fact, the undifferentiated total of discount credits deducted from part or all of the end-of-year or specific discounts does not indicate what arises from one type of discount or the other, except in an artificial and therefore insignificant way. In this case, the total discount credits acquired previously by the companies and used to reduce the end-of-year and specific discount totals was €75 million.

Price reductions and voluntary removals from reimbursement totalling €107 million are to be added to this total. To recall, the 2002 safeguard contribution would have totalled €100 million.

SECTION III – DETERMINING THE PRICE OF MEDICINES IN 2002

The main task of the Economic Committee for Health Products, and the most important aspect of its activity, is to negotiate and determine prices of medicines. This activity can be retraced by counting the files sent, examined and processed by the Committee in 2002 and the file treatment period, all based on the characteristics of the files. With regard to the methods used by the Committee to determine the prices, the corresponding exposition, set out already in the previous reports, is reproduced in Annex 2. These methods of negotiation did not in fact change greatly during 2002.

The distinguishing feature of 2002 was a sharp drop in the number of files submitted to the Committee, combined with a reduction in its activity in terms of numbers of files processed. The result, compared with the previous year, is a dramatic reduction in the number of files not finished at the end of the year. The overall file processing times have however extended,

albeit only because of the reduction in stocks related by definition to files previously submitted. There are still difficulties, which have further increased the time taken to process the files, not all of which can be dealt with by the Committee alone.

What follows, in succession, is a schedule of activity in 2002, an analysis of the processing times and an analysis of the stock of files being worked on at the end of the year.

1. SCHEDULE SHOWING THE MEDICINE DEPARTMENT'S ACTIVITIES IN 2002

1.1. APPLICATIONS SUBMITTED TO THE COMMITTEE IN 2002

1,162 applications were submitted to the Committee between 1 January and 31 December 2002[10]. Compared with the previous year, this is a 35% drop in the total of applications.

Table 10: Changes in the number of applications submitted

Year	1999	2000	2001	2002
Number of requests	1,364	1,649	1,785	1,162
Difference (year n) – (year n-1)	288	285	136	-623
Rate of change (year n / year n-1)	+27%	+21%	+8%	-35%

The sharp drop in requests in 2002 relates mainly to re-registrations. The alteration of the re-registration period from 3 to 5 years in 1999 is the reason for this downward trend, which from April 2004 onwards should be compensated for by a huge return of new re-registration requests. The other categories of applications have all shown a drop, although the drop has been less significant than for re-registrations: 20% for initial registrations, 7% for price alterations and one-third for indication extensions.

Table 11: Characteristics of applications submitted in 2002

	1st registration	Re-registration	Price alteration	Extension of indication	Total
Number of applications	507	406	165	84	1,162
of which are generics	250	129	37	0	416

In 2002, the 416 applications relating to generic presentations accounted for 36% of applications submitted. They were down on 2001, when a total of 557 applications were submitted.

1.2. CASES CLOSED IN 2002

In 2002, 1,688 files were successfully concluded, leading to agreement between the company and the Committee with a subsequent decree publication in the *Journal Officiel*, rejection or abandonment. The total number of files was 12% up on 2001, during which year 1,508 files were successfully concluded.

[10] This breakdown does not include deletion applications.

Table 12: Number of applications concluded in 2002 according to nature of application and decision

	1st registration	Re-registration	Price alteration	Extension of indication	Total	Average time taken (days)
Agreement	533	793	107	87	1,520	234
Abandonment*	12	11	25	-	48	140
Notification**	-	81	-	-	81	392
Rejection	12***	3	24	-	39	208
Total	557	888	156	87	1,688	243

* Abandonment is noted by the Committee if the company in question explicitly withdraws its application, or in rejection of the Committee's proposal, fails to answer for a long period.
** Notification is given to re-registrations observed after the expiry of the 180-day deadline.
*** For the 12 initial registration applications (corresponding to four specialities) that were rejected, the average period noted was 493 days.

The applications dealt with by the Committee in 2002, corresponding to 1,688 presentations, were submitted by a total of 142 different laboratories, that is, 80% of the laboratories involved on the French market.

In 2002, the number of applications successfully concluded exceeded the number of applications sent to the Committee during the year by 526. This difference shows in an equal reduction in the number of presentations in progress at the end of the year (see 3. below).

This result is caused both by a reduction in the flow of applications submitted and more sustained activity on the Committee's part in relation to applications in progress at the beginning of the year. Also, most notably with regard to initial registrations, with the processing of 557 applications against a figure of 507 applications submitted, the Committee has been able to make good some of the delay noted at the end of 2001.

2. CASE PROCESSING TIME

Article R.163-7-I specifies that for a medicine to be registered, "the decisions (…) must be taken and notified to the company making use of the medicine within a period of one hundred and eighty days from receipt of the application (…). Registration of the medicine on the list must be published, together with its determined price, in the *Journal Officiel* within that period". For price alteration applications submitted by businesses, the Committee is required to take a decision within 90 days.

The following presentation analyses the case processing period, according to the nature of the application and the decisions taken by the Committee, from submission of the file to publication of decrees or advices in the *Journal Officiel* where applicable (abandonment or rejection is not published in the JO). It therefore covers the time taken by the Committee to process the requests and the time taken by the Transparency Commission to examine the files.

2.1. OVERALL TIME TAKEN

2.1.1. Total period according to type of application

The average time taken to process each of the 1,688 applications concluded in 2002 was 243 days, that is, 20% longer than the period of 202 days noted in 2001. This result, rather unsatisfactory in the continuation of the 2002 activity, is the result of the self-same activity, which took the form of a major reduction in the stock of files in progress at the beginning of the year. In fact, there is good reason to believe that the proportion of files in progress over the total number of files processed was higher in 2002 than in the previous year. In other words, with regard to files older than those deposited in the same year, the average processing time has increased by the same amount.

The following table sets out the time taken according to the type of application submitted.

Table 13: Average processing time according to application category

number of days

Type of application	Average time	Median time	Standard diff.	Maximum time
1st registration	221	159	183	1,047
Re-registration	269	258	121	685
Alteration of price	96	88	56	415
Extension of indication	337	350	183	726
Total	243	223	155	1,047

With regard to the length of time taken to process applications for re-registration, it should be pointed out that it is partly because in every case, the publication of the corresponding decision is at least adjusted on the due date for re-registration, while a company may have submitted a request for re-registration more than 180 days before the due date.

The shortest average and median processing times are noted for price alteration applications, for which regulations require the Committee to issue a judgement within 90 days. The average total time, in fact, covers applications and decisions of differing natures. In this way, when the application is rejected, the period observed before a decision was made was 62 days, while the average period observed for files given an approval, including the additional time required for signature and publication of advice subsequent to the Committee's decision, is 102 days. In addition, for a few files opened at the Committee's request, the 90-day period is not opposable; this was the case most often with price alterations for generic medicines in the light of price reductions for corresponding branded drugs.

2.1.2. Total period according to type of drug

The average period for processing a file relating to generic medicines was 135 days, slightly less than the 141-day average period noted for 2001. This average figure corresponds to 98 days for initial registration applications, 173 days for re-registration applications and 103 days for price alteration applications, most of which are issued by the Committee.

The processing period for single applications relating to generic medicines accounts for just 50% of the average processing time for applications relating to non-generic medicines. In essence, this difference is caused by the fact that generic medicine files no longer have to be examined by the Transparency Commission.

2.2. ANALYSIS OF INITIAL REGISTRATION APPLICATION TIMELINES

The analysis of the interim periods relates exclusively to initial registration requests that led to a publication in the *Journal Officiel*. The analysis therefore excludes abandoned applications and rejections, which are not published[11].

The total time taken to process an initial registration file was broken down into five phases: the submission of the file, transfer of the Transparency Commission's advice to the Committee, transfer to the first sitting of the Committee (Investigation), the period from the Committee's first to last sitting for the same file (Negotiation), the period from the last sitting to the signature of the agreement amendment (Agreement), and the period from signature of the amendment by both parties to publication of the registration decree and price advice in the *Journal Officiel*.

2.2.1. Initial registration periods (all medicines)

The average period for the 533 initial registration files is 216 days between the date of submission and the date of publication of the registration decree and price advice in the *Journal Officiel*. The median is 155 days. The proportion of files processed in 180 days or less is just 55%. One third of the applications (181) were examined over several sittings of the Committee. The average number of sittings per file is 2.1, and the maximum number 11.

Table 14: Processing times[12] for initial registration applications published in the *JO*

Time taken	CT	Investigation	Negotiation	Agreement	*JO*	Total
Average	60	39	42	29	46	216
Median	*	28	0	20	37	155
Maximum	411	245	448	179	640	1,047
St. diff.	*	39	88	29	48	176

* Not significant, as not all registration applications are submitted to the Transparency Commission.

2.2.2. Initial registration periods for generic and non-generic products

Table 15: Average intermediate processing times for initial registration requests published in the *JO*, according to categories of medicine

number of days

Medicine	CT**	Investigation**	Negotiation	Agreement	*JO*	TOTAL
Non-generic	115	48	80	34	48	**325**
Generic	2*	29	2	23	43	**99**
Total	**60**	**39**	**42**	**29**	**46**	**216**

* 6 generic product files concluded in 2002 were subjected to examination by the CT.

The difference is 226 days between the average processing time of 99 days for applications relating to generic medicines and the 325-day period taken for non-generic medicines. The

[11] The interim period analysis covers the 533 registration applications that led to a publication in the *Journal Officiel* and whose average processing time, 216 days, is less than that for all initial registration requests, namely 221 days (see Table 15), most notably because of the non-inclusion of rejections and abandoned applications not observed until a much longer average period has passed (average 350 days in 2002).

[12] The average CT period corresponds to all the presentations submitted to the CT divided by the total number of presentations that lodged a registration application ; it therefore includes the generic medicines that are not, except in a few cases, subject to CT advice.

difference is attributable not only to the steps taken by the Committee to increase the speed of processing of applications concerning generic medicines, but also the fact that the Transparency Commission does not examine the files as a third party, and the very short negotiation period for generic medicines compared to the period for other medicines. When the price request for the generic medicine is located in the price zone 30% or 40% below the branded product price, the application is accepted.

For non-generic medicines, the very long registration period noted for 2002 is mostly caused by medicines that benefit from an ASMR.

Paradoxically, this category of medicines produces periods significantly longer for each phase in the procedure, including the phases whose duration is not dictated by the requirements of the Committee. Two products registered for reimbursement in 2002 were registered, following inclusion of the corresponding documents in the general professional documents nomenclature or NGAP, after 850 days for one and 1,050 for the other. In other cases, with a still greater effect on the period in view of the sometimes high number of presentations for the specialist products concerned, the companies, whether they advised of difficulties in supplies or were satisfied with the economic conditions (volumes and price) associated with marketing under a temporary use authorisation (ATU) showed little inclination to speed up the ambulatory registration process.

2.2.3. Intermediate periods during initial registrations

2.2.3.1. Phase One: The Transparency Commission

Files must be submitted simultaneously to the Economic Committee for Health Products and the Transparency Commission. This initial phase corresponds to examination of the application by the Transparency Commission and the transfer of the CT's advice to the Committee. The examination relates to non-generic medicines only. For the files concerned, the CT's advice is issued after an average period of 86 days from the submission of the file. On average, it is sent to the Committee 29 days later, making a total Transparency Commission examination period of 115 days for these files.

In total, the average duration of this initial phase is 139 days for applications relating to medicines for which the CT grants an ASMR and 110 days for medicines without an ASMR.

2.2.3.2. Phase Two: Rapporteurs' Instructions

This phase, which extends from the date on which the Committee receives the CT's advice to the date on which the presentation is first examined at a sitting of the Committee, includes investigation of the file by the rapporteur working with the company and the period required for entry in the Committee's agenda (at least one clear week following communication of the report to the members of the Committee).

Between the submission of the file (in relation to generic medicines) or transfer of the Transparency Commission's advice (for non-generic medicines), and the examination of the file at a sitting of the Committee, an average of 39 days passes.

This period is 29 days for generic medicines in relation for which the Committee sets up a simplified investigation procedure and 48 days for all non-generic medicines (account is taken

of this investigation and of the time required for sending the Transparency Commission's advice when calculating this period).

2.2.3.3. Third phase: Negotiation

The period between the first and last examinations during sittings of the Committee relates in part to the time required for the Committee to adjust its proposals if they are not finalised in one siting, and the time required for the negotiation phase between the Committee and the company. If the company rejects the Committee's proposal, time will be required to examine the company's counter-proposals following discussions with the rapporteur. The average periods noted in 2002 were 2 days for generic products but 125 days for medicines benefiting from an ASMR and 70 days for other medicines.

Table 16: Negotiation periods

Type of drug	per drug			Negotiation period
	Number	Average. no. of sittings	more than one sitting	
Generic	258	1.1 sittings	16 (6%)	2 days
Non-generic	275	3.0 sittings	165 (60%)	80 days
Total	533	2.1 sittings	181 (34%)	42 days

60% of applications relating to non-generic medicines led to more than one examination in a sitting, while this was the case for just 2% of registration requests for generic medicines. Overall, the average negotiation period for non-generic medicines is 80 days.

Only on paper is this third phase of negotiation with the company dissociated from the next phase, which also includes a subsequent negotiation on the precise terms of the agreement and its acceptance by the laboratory.

2.2.3.4. Fourth phase: Agreement

This is the period running between the Committee's last sitting for a file and the signature of the corresponding agreement amendment. It is a time for adjusting the amendment, which may give rise to several exchanges between the Committee and the company, but is also the logistical period required for both parties to sign the documents. The phase may be longer or shorter depending on the degree of urgency felt by the business for the marketing of its product and also on the time taken to get the agreement signed. The fourth phase, in fact, includes a subsequent negotiation period that is difficult to dissociate from the logistical periods. On average, the period totals 20 days. It is believed that the 11-day difference between the 23 days required for generic medicines and the 34 days required for non-generic medicines relates to a final negotiation period that may relate in particular to the precise terms of specific clauses (volume, CTJ, study etc) that may appear in some agreements.

2.2.3.5. Fifth phase: Signature and Publication in the Journal Officiel

This final phase includes the preparation and signature by the Committee of the price advices and registration decrees for reimbursement by the relevant authority within the Ministry for Employment and Solidarity, and the submission to the *JO* and publication therein of the registration decrees and price advices. On average, the period lasts 46 days and is practically the same regardless of the category of medicine involved.

3. APPLICATIONS PENDING

The flow of "files out" created by the number of applications concluded during 2001 (a total of 1,688) must be compared with the flow of files submitted during the same year, a total of 1,162. The difference between these two figures, totalling 526, has led to an equivalent reduction in the number of applications in progress, which totalled 793 at the end of 2002 (the total number of applications in progress on 31 December 2001 was 1,319).

For 76 of the applications in progress on 31 December 2002, the decision was finalised and the Committee's proposals for signature by the company, or the decrees corresponding to the signature or in the publication circuit of the *JO*. *338* other applications had already been examined at least once by the Committee, before the end of 2002.

For initial registrations only, the number of applications not concluded by 31 December 2002 totalled 384. 201 applications, that is over 50%, had already been examined at sittings of the Committee, and a decision drawn up for 33 of them. For 99 of the 183 applications that had not yet been examined at a sitting, the Committee had not received advice from the Transparency Commission by 31 December 2002.

PART TWO – MEDICAL DEVICES

SECTION I – EXPENDITURE ON MEDICAL DEVICES

For 2002, given that the turnover for the medical equipment market that represents a very large portion of the total market developed very little, and working on the hypotheses that the rest of the market for reimbursable products and services listed in Article L.165-1 of the Social Security Code has seen growth of the same order as that shown by sickness insurance reimbursements (a number of these products are reimbursed at 100% of their tariff), the Committee estimates a figure of about €6,300 million for public tax-inclusive price sales of the said products and services. These sales, which correspond to reimbursable costs, therefore include the sums remaining payable by patients or through their additional insurance policies. These reimbursable costs gave rise to a total of €3,450 million in reimbursements[13] in 2002 (see 2 below). The major difference between the estimated sales and the estimated reimbursements indicates the difference there may be for certain product categories (medical optics and hearing aids in particular) between applied public prices and reimbursement rates.

Overall, the medical equipment sector has enjoyed sustained healthy growth for a number of years, and this is evident from the changes in compulsory sickness insurance reimbursements.

The following tables have been compiled on the basis of data processed following collection by the CNAMTS[14] (Table 17). The inclusion in each section of the ratio between expenses under all the compulsory sickness insurance regimes and those under the general regime only[15] allows an all-regimes figure to be calculated (Table 18), as well as the total reimbursements paid in 2002 and their division according to title and section.

[13] The common law reimbursement rate for products and services is 65% of the tariff, although for certain products for ALD patients, or because the operative coefficient (KC) is greater than 50, the rate is increased to 100%.

[14] The monthly statistic "Results at End December 2001" and "Results at End December 2002" (complete results) – Directorate of Statistics and Studies, CNAMTS.

[15] The CNAMTS data for all the regimes is extrapolated on the basis of rates obtained from the health accounts.

1. EVOLUTION IN REIMBURSEMENT COSTS UNDER THE RÉGIME GÉNÉRAL

According to CNAMTS statistics, repayments under the general regime for medical devices increased by 15.4% between 2001 and 2002, rising from €2,320 million to €2,670 million. The high-volume categories with the greatest increases are mostly in Part I, which now accounts for about 55% of all general regime reimbursements.

Table 17: Changes to general regime reimbursements in 2002

million €

Description	Section	2001	2002	Change, %	Relative portion*
Home breathing assistance apparatus	1	241	288	19.5%	19.7%
Other home treatment apparatus	1, 2	306	380	24.5%	26.0%
Container equipment and apparatus	3	28	27	-3.6%	1.9%
Equipment and apparatus for other forms of treatment	1	421	508	20.7%	34.7%
Dressings	3	230	260	13.4%	17.8%
TOTAL, PART I		**1,226**	**1,465**	**19.5%**	**54.8%**
Ortheses	1	149	171	14.7%	32.8%
Optics	2	137	142	3.9%	27.2%
Electronic hearing aids for the deaf	3	39	48	21.6%	9.1%
Non-orthopaedic external prostheses	4	4	4	12.2%	0.8%
Artificial eyes / facial prostheses	5	11	11	7.8%	2.2%
Artificial legs/feet	6	43	46	7.9%	8,9%
Artificial Joints	7	76	88	14.8%	16.8%
Orthopaedic prosthesis accessories (App. Centre)		13	12	-11.3%	2.3%
TOTAL, PART II		**473**	**524**	**10.6%**	**19.6%**
Internal prostheses (inert)	1,2,3	492	550	11.8%	87.2%
Internal prostheses (active)	4	77	81	5.1%	12.8%
TOTAL, PART III		**570**	**631**	**10.8%**	**23.6%**
PART IV, VEHICLES FOR DISABLED		**49**	**55**	**12.0%**	**2.1%**
TOTAL, PARTS I – IV		**2,318**	**2,674**	**15.4%**	**100%**

* Relative portion in 2002: for sections, in relation to part; for parts, in relation to total reimbursements.

According to CNAMTS statistics, these reimbursements account on average for 90% of the tariff for the product and corresponding services. The average rate of reimbursement has remained practically unchanged from 2001 to 2002.

2. EVALUATION OF REIMBURSEMENTS – ALL HEALTH INSURERS

The following table is obtained by applying the ratios previously observed for each heading to the 2001 and 2002 all-regime and general regime reimbursements on the hypotheses that these ratios are stable. This extrapolation leads to an estimated reimbursements for all regimes combined of €3,450 million – an increased of 15.7% in comparison with 2001.

Table 18: Estimated reimbursements – all compulsory insurance regimes

Millions €

Description	Sec.	2001	2002	Relative portion 2002*
Home breathing assistance apparatus	1	327	390	20%
Other home treatment apparatus	1,2	410	510	27%
Container equipment and apparatus	3	37	36	2%
Equipment and apparatus for other forms of treatment	1	551	665	35%
Dressings	3	263	299	16%
TOTAL, PART I		**1,590**	**1,903**	**55.1%**
Ortheses	1	188	216	33%
Optics	2	173	180	27%
Electronic hearing aids for the deaf	3	50	61	9%
Non-orthopaedic external prostheses	4	5	6	1%
Artificial eyes / facial prostheses	5	13	14	2%
Artificial legs/feet	6	54	59	9%
Artificial Joints II	7	95	110	17%
Orthopaedic prosthesis accessories (App. Centre)		13	12	2%
TOTAL, PART II		**591**	**658**	**19.1%**
Internal prostheses (inert)	1,2,3	640	715	87%
Internal prostheses (active)	4	99	104	13%
TOTAL, PART III		**739**	**819**	**23.7%**
PART IV, VEHICLES FOR DISABLED		**65**	**73**	**2.1%**
TOTAL PARTS I, II, III, IV		**2,985**	**3,453**	**100%**

* Relative portion in 2002: for sections, in relation to part; for parts, in relation to total reimbursements.

According to this estimate, sickness insurance reimbursements totalled €3,450 million in 2002, an increase of 15.7% compared with 2001. This is a much faster rate of growth than the 13% recorded in the previous year.

3. BREAKDOWN OF COSTS

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

This covers most of the reimbursements (55.1%) relative to the reimbursable products and services that have increased by about 20% over 2001 after enjoying growth of similar magnitude in the previous two years. Within this heading, the greatest increases, of over 20%, relate to Sections 1 and 2 (equipment and apparatus for various forms of treatment at home, including respiratory apparatus. These two sections account for 44% of all reimbursements.

The growth, which in this heading relates mostly to home care apparatus for patients, can in the main be explained by an increase in numbers of elderly people and the development of the policy of “return home and home care”. In addition, the steps taken in 2000 to improve the use of insulin pumps and internally administered nutritional products continued to make themselves felt during 2002.

3.2. PART II: ARTIFICIAL JOINTS AND LIMBS

This accounts for 19% of expenses connected with reimbursable products and services, with an increase of 11% over 2001. Most of the growth has been under Section 3 (electronic hearing aids for the deaf), following the development of stereophonic equipment early in 2002.

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

This covers the second largest reimbursement section (23.7%), with an increase of 11% over 2001. Although more vigorous than in 2001 (7%), the rate of growth remains below the average.

3.4. PART IV: VEHICLES FOR THE PHYSICALLY HANDICAPPED, FOR PURCHASE

This accounts for about 2% of reimbursements, and increased by 12% in 2002 compared with 19% in 2001 and 13% in 2000. This increase may be due not so much to an increase in volume as to an increase in purchases in relation to location and the inclusion on the list of more efficient, electric and/or vertical, and therefore more expensive, chairs.

SECTION II – REIMBURSEMENT UNDERTAKING FOR MEDICAL DEVICES

1. MANAGING THE REFORMS: CONTINUED

2001 was the year in which the reform of the registration procedures for reimbursement for medical equipment was instituted; it became effective when the applicative decrees were published on 26 March 2001. Most of the questions of principle and practical difficulties raised by the application of the new provisions have now been settled (see the Committee's 2001 Report). Not all, however. In 2002, therefore, the Committee helped out the authorities responsible for registration for reimbursement or worked under them, together with the Products and Services Evaluation Commission (CEPP), continuing to reflect on how the system is operating.

This reflection was based on four main themes:

- The direction and scope of the various levels of improvements to services provided (ASR).
- The building of new generic lines.
- The issue of authorising implant centres.
- The issue of the scope of the list.

1.1. THE DIRECTION AND SCOPE OF THE VARIOUS IMPROVEMENT IN BENEFIT

The separation of the evaluation and pricing bodies, which is the central element of the reforms, assumes that the messages sent by the valuer to the price authority are fully understood by the authority. The CEPP and CEPS have therefore held discussions on this

matter and on the scope of the various levels of ASR allocated to the innovative equipment submitted by the CEPP. What the Committee needs in fact, in order to apply the rule that dictates that registration of a new item of apparatus may only attract an additional cost if it carries an ASR, is to be able to compare this item with the best apparatus already registered in its category. This comparison is not always easy to make in the medical equipment sector, where the speed at which ranges of products are renewed generally prevents the CEPP from obtaining elements of direct comparison between innovations issued at similar times. Instead, it is easier for the CEPP to assess the ASR in relation to minimum technical specifications or on the basis of older comparisons. The reciprocal effort made in 2002 to arrive at a better understanding between the CEPP and the CEPS therefore needs to be continued.

1.2. NEW GENERIC LINES

The Committee's report for 2001 shows that the CEPP had grasped the situation in relation to new texts for a large number of generic nomenclature lines referred to as "approval number lines". In anticipation of the advice to be issued by the CEPP, it had been decided to have the products registered under a brand name.

In 2002, following the CEPP's advices, the Committee suggested creating five new generic categories for adult electronic hearing aids, blood sugar readers, implantable catheter mechanisms, ortheses for stabilising the ankle, and vehicles for disabled persons (VHP). With the exception of the VHP, the products all had identical tariffs and had previously been registered under a brand name for which technical specifications and adapted quality control methods already existed. In other words, the categories of products fulfilled the criteria for creating a generic group.

As the scale of the evaluation required did not allow the CEPP to pronounce on all the former "approval number" categories during 2002, there was the problem of re-registering items of equipment in categories that were not yet processed but were due to be registered. In every case where it seemed likely that it would be decided to create a generic line, the Committee proposed postponing the registration deadlines so that the businesses would not have to compile complex files.

1.3. AUTHORISING CENTRES

In the medical equipment centre, obtaining the anticipated result in terms of the profit-risk ratio frequently depends as much on the conditions under which the item is used as on its actual performance. It is against this background that Article L.165-1 of the Social Security Code specifies that "inclusion in the list may be subject to compliance (…) with certain conditions of registration or use".

It is with the same object in mind that the new Article L.1151-1 of the Public Health Code provides for the possibility of submitting acts and techniques and the prescription of certain medical equipment to rules concerning the training or qualification of professionals able to prescribe or operate the equipment and to technical conditions for fulfilling these rules.

The difficulties, especially of a legal nature, posed by the application of that article prevented the successful implementation of its applicative decrees during 2002. This in turn created a barrier, especially to the registration of implantable cardiac defibrillators and three-chamber stimulators. For these items, the CEPP had proposed conditions for reimbursement based on

qualification of teams and the equipping and operation of authorised centres for reimbursable implants of these devices.

1.4. THE SCOPE OF THE LIST

The Committee's 2001 report stated that the sole aim of the reform, which was first and foremost procedural, was to increase the scope of products and services covered by the list in contrast to other forms of reimbursement arrangement, such as the nomenclature of documents or fixed operating theatre charges.

It was also noted that on the other hand, the evaluation procedure confided in the CEPP was mostly open for the whole of the field covered by Article L.165-1 of the Social Security Code. In 2002, in fact, several personal devices valued by the CEPP were turned down for entry in the LPP register, despite having a significant ASR.

The suitability of registration for reimbursement as the choice of repayment channel was certainly not based on the Committee's assessment, but fell within the scope of competence of the ministers. In practice, however, the Committee was compelled to issue advice on the principles of registration. It considered, especially with regard to equipment that although intended for a single use fulfilled functions that could double up for those of surgical equipment or instruments, that their inclusion on the list was economically unsuitable. The effect of this inclusion was in fact to prevent any judgement on the part of care establishments between the various means that could be used to bring about a given result, as some of the means (those entered on the list) were free of charge while others (such as use of surgical equipment on a collective basis) had to be paid for. An illustration of this phenomenon can be seen in the area of mechanical sutures, included on the LPP, for which the relative proportion of use of rechargeable and non-rechargeable devices differed significantly between the private institutions, for which choice was not influenced at all by financial matters, and the public institutions, for which the expenses were allocated to their budget.

In addition, the Committee observed that inclusion of such items on the LPP created a risk, at least in principle, of unjustified expenses being incurred by the compulsory sickness insurance, which would be forced into financing the registered equipment and the fixed operating theatre charges for each individual insurer.

It remains that in practice, this situation is unsatisfactory, especially in cases where the magnitude of costs associated with the use of the new equipment is incompatible with the totals charged or methods used by private, fixed-charge care institutions. In future, an activity-based tariff is likely to provide greater fairness between public and private institutions, in relation to access to the most innovative medical equipment.

2. OPINIONS OF THE COMMITTEE

Applications for registration must be processed within 180 days of submission of the application. The absence of a decision at the end of that period shall equate to a rejection[16],

[16] In application of Article 21 of the Law of 12 April 2000 and Article R. 165-8 of the Social Security Code.

which must be justified if the manufacturer or distributor so requests (Article R.165-16 of the Social Security Code).

For alterations to prices or tariffs, the deadline shall be 90 days; if no decision is issued within this period, the tariff or price requested shall be tacitly granted.

However, if elements supplied by the manufacturer for assessment turn out to be insufficient, the ministers, the Commission or the Committee shall advise the applicant as to what additional information is required. In this case, the deadline shall be suspended from the date of notification until the date on which the information is received.

Applications for renewal of registration must be sent at least 180 days before the planned re-registration date. If no decision has been notified at the end of this period, the renewal shall be granted tacitly and the previous tariff and price shall be revised and published in the *JO*.

2.1. CASES RECEIVED

In 2002, 146 files issued by businesses were submitted to the Committee, including 91 registration files, 31 re-registration files, 12 files concerning alterations to operating company names or product denominations, and 12 revaluation files.

Of these 146 files, three were withdrawn by the businesses, the Committee issued a refusal advice for a further two, and for 11 others the CEPP considered that the service rendered was insufficient.

The other files registered included:

- 3 generic line tariff revaluation files, lodged by professional bodies commissioned by the businesses and relating to major orthopaedic appliances (GAO), artificial joints and artificial eyes.
- 3 registration files issued by the authorities following an approach to the CEPP.

2.2. CASES PROCESSED

Between 1 January and 31 December 2002, 91 decrees and 1 advice relating to medical equipment were published in the *Journal Officiel*.

The public advice announced the intention of the ministers to register a number of oral rehydration solutions.

Most of the decrees related to registration or re-registration, coupled where necessary with decrees concerning the determined public sale price limits. About two thirds of the decrees related to Part III products and services.

In the following table, the “other” category has been divided into two to distinguish between specific measures relating to product transfers or operator company name changes on one hand and general measures on the other hand. These measures are very wide-ranging and likely to relate to several products or services and even to more than one heading in the list. There are two decrees relating to price alterations following the transition to the euro; one relating to measures concerning the postponement of reimbursement arrangement end dates; one price reduction measure for certain types of suture implants and internal ligatures; a

widening of the fixed charges for fitting/removing artificial joints in lower limbs; and revaluation of GAO prices and tariffs. It is recommended that measures relating to alterations in the generic nomenclature, as mentioned elsewhere in the table, should be added to these general measures.

Table 19: Decrees published

Categories of decree	Part 1	Part 2	Part 3	Part 4	**Total decrees**
Registration	6	1	14	2	**24**
Re-registration	2	1	5	-	**8**
Revaluation	-	5	-	-	**5**
Public sale price limits	2	3	29	-	**29***
Alterations to generic nomenclature	1	2	1	1	**5**
Deletions	-	-	-	3	**3**
Other decrees of individual relevance	3	-	10	-	**12***
Other decrees of general relevance	3	5	5	3	**6***
Total per heading	17	17	64	9	**91***

* Some decrees cover more than one part.

2.3. PROCESSING TIMES

For all the decrees published in the *JO* following an application from a manufacturer or distributor, the average time between initial submission of the application and its publication was 248 days. This total average time does not however take account of deadline suspensions; in most cases, because new procedures are being introduced, files submitted by manufacturers or distributors have been the subject of additional information requests from the CEPP, and as a result deadlines have been suspended. If these suspensions were taken into account, the average file processing time would be significantly shorter.

3. DETERMINING TARIFFS AND PRICES

3.1. GENERAL PRINCIPLES

The practice of determining prices and tariffs for medical equipment is based on three rules.

Two of these relate to tariffs:

Article R.165-4 of the Social Security Code specifies that "the list provided for by Article L.165-1 may only include those products or services (…) that do not bring about an improvement to the service rendered or a saving in the cost of treatment, and are not likely to incur unjustified expense for the sickness insurance fund".

Article R.165-14 also provides that "determining the tariffs shall take account first and foremost of the service provided, any improvement in it, the tariffs and prices of comparators or services included on the list, sales forecasts and foreseeable and realistic conditions of use".

Prices shall be determined in application of the very general provisions of Article L.162-38 of the same code, according to which the fixing by decree of prices or mark-ups for products or services covered by the compulsory social security regimes “takes account of changes in the charges, income and volume of activity of the practitioners or businesses concerned”.

In practice, these rules often have to be combined by the Committee, especially when a tariff and a sales price limit are fixed simultaneously at the same amount. It goes without saying that this common total must comply with rules relating to tariffs and relating to prices.

Application of these rules to medical equipment (with regard to tariffs, the rules are identical to the current rules relating to medicine prices) however poses a number of problems, in relation to the methods of registration for reimbursement for medical equipment, the form most frequently taken in that context by the innovation, and the very varied nature of the products and services concerned. The following developments report on the solutions adopted by the Committee during 2002.

3.2. TARIFF ACCORDING TO CATEGORY

The registration of products or services that do not provide an improvement in service provided must, under Article R.165-4, provide a saving in the cost of treatment instead. This simple and important rule is, however, difficult to apply in practice in the field of medical devices. The code in fact lays down a rule (Article R. 165-3) that registration for reimbursement is made in principle through the generic description of the product or service, the exception being registration under a mark or trade name. As a result, most products or services that become eligible for reimbursement do so in the context of an existing nomenclature line, and therefore at the same tariff (although they do not have an ASR), as equivalent products or services already being reimbursed.

By way of extension, the Committee has applied a similar process to categories of equipment registered under a brand name in application of the second case of exception to the generic registration provided for by Article R.165-3. “When the effect on compulsory sickness expenses, public health requirements or monitoring of minimum technical specifications requires particular monitoring of the product”. This also applies to categories of equipment that were, prior to the reforms, placed under the approval number regime and (sometimes provisionally) registered under a mark. In these cases the Committee considered that the products in question should be treated as though they belonged to generic lines, and the newly registered products are given a tariff and (where necessary) a sale price limit identical to the tariff and limit for the products already registered in the same category.

The first consequence of this situation is that the rule of economy in treatment costs only applies specifically to new equipment without an ASR and not included in an existing generic definition, whether the anticipated level of service for similar equipment already registered is achieved through a different technology or method of operation, or whether the comparison is made with methods of treatment outside the scope of the list (surgery, medical treatment etc).

The second consequence is that the reduction over time of the average price of a category of products, obtained naturally for medicines through the successive registration of medicines each less expensive than their predecessors, can only be brought about for medical equipment (when justified) through periodic revision of the drop in the generic line tariff.

3.3. ENHANCING THE VALUE OF INNOVATIONS

For products with an ASR, the criteria explicitly laid down in the texts, although they allow the process of determining prices to be organised, are insufficient in themselves to determine the actual prices. The rule of Article R.165-4 authorises an additional cost in this case, but says nothing about its magnitude. In addition, it can be deduced that in general, a low-level ASR will not allow any major tariff-related difference from the comparator, if indeed such a product exists; this is not always the case within the field of medical equipment. In addition, recognition of an ASR is an essential condition, but is not enough to justify any additional costs, and the regulations do not therefore forbid the registration of a new product with an ASR at a rate below that of comparators already registered.

In practice, therefore, the Committee has to draw a schematic distinction between three main situations for calculating tariffs for innovative products.

In the simplest cases, it can be shown that the price proposed or agreed by the company, and therefore considered by it to be a reasonable value for its discovery, incurs for the sickness insurance fund costs that are less than, or at worst equal to, the savings made through its use (in this case, only the direct costs borne by the sickness insurance are taken into account, regardless of their nature). Registration does not then pose a problem. There is however an interest, in these cases, in having access to reliable and convincing medicoeconomic studies.

In the second case, it is standard practice in the medical equipment sector for progress in service rendered to be made in the form of so-called “incremental innovations” that have the double distinction of being both modest and fairly frequent. When it appears that the potential for growth in the new product’s market share is not a sufficient value for the innovation, and that a price advantage is needed in addition, the Committee may suggest a price briefly in excess of the price of comparators already registered. Payment for innovation is therefore assured for a period, usually short, at the end of which it will most likely be out of date technologically. This practice, applied by the Committee in fixing the tariffs for cardiac stimulators, allows the ASR to be valued and the escalation of tariffs to be avoided.

There remain the most difficult cases, those of innovations that are both critical and costly. For these, the sometimes substantial additional expenses that they incur for the community only have returns that cannot be measured financially in terms of improvements in patient care. Cost and efficacy studies may help in the decision-making process, but are usually difficult to carry out. In these situations, discussions on price levels, severely restricted by the existence of international markets, are largely replaced by the issue of limiting quantities to patient populations for whom the anticipated advantage of the innovation has been properly established. This supposes that the question of identifying and measuring the target populations and the means to be applied in treating these populations to ensure that they benefit from the innovation have been addressed. In these cases, the registration process is regularly accompanied by conventional provisions on limiting volumes and rewards payable by the businesses in the event of any excess, and on the setting up of control studies.

3.4. DIFFERENCES BETWEEN PRICES AND TARIFFS

The system for reimbursing medical devices, as opposed to that for medicines until the introduction of the fixed liability tariffs, generally allows for the establishment of differences

between the tariff, which is the basis of reimbursement for compulsory sickness insurance, and the price.

When it is judged necessary (against a background of equal access to care or to compensation for a handicap) not to allow a difference to be established, the only means open since the inception of the new texts is to fix a sales price limit (see the Committee's 2001 report). The Committee has frequently proposed the use of this means. Fixing a sales price limit, however, suggests that where necessary the question of additional prices invoiced in return for the services or the issue of accessories over and above the definition given in the list for the reimbursable product or service in question has been resolved. In particular, this is often the case in the field of external prostheses and artificial joints, where patients can request and professionals offer technical or aesthetic additions.

When these additional prices can clearly be separated from the reimbursable product or service, there is nothing to stop professionals issuing separate invoices for the additional product or service requested by the patient provided the sales price limit for the principal is not exceeded. The Committee is of the opinion that this practice, adopted in some cases, does not require any particular precaution. It is different, however, when additional products or services, especially of an aesthetic character, form an integral part of the reimbursable equipment. Here, the Committee has proposed that in the field of orthopaedic footwear, the decree that sets the sales price limit should not allow for any dispensations, even in answer to specific requests from patients. It considers in fact that the possibility of such a dispensation carries a risk of any satisfactory offer in terms of reimbursement disappearing over time, and that as a result, less well-off patients may experience difficulty of access[17].

3.5. CHANGES TO TARIFFS ACCORDING TO PROFESSION

Finally, the medical devices sector covers a number of professions, most often made up of small or very small businesses; the conditions under which these businesses operate are much more similar to those of service providers for individuals or craft industries than those of research or industrial enterprises. The tariffs and sale price limits applied to reimbursable services supplied by these professions cover salary costs, often to a considerable extent.

The question of tariffs is therefore raised in a quite different context to that of the other fields of medical equipment. In particular, the criteria laid down by Article L.162-38 for determining prices (charges, income and activity volumes) naturally predominate.

The Committee considers that it should, in the proposals that it puts together for determining and in particular for periodically revising the tariffs, ensure that two objectives are met:

- The level of tariffs and prices must be sufficient to guarantee preservation of an offer that is sufficiently plentiful and spread right across the country, with a quality level that is compatible with the anticipated level of service and justifies the reimbursement.
- This level should not however be such that it unduly favours the preservation of unproductive operation units and thus has a "windfall" effect on the more competitive businesses.

[17] In 2003, however, the Council of State ruled that the comprehensive ban on dispensations was illegal. The Committee must therefore suggest different means of bringing about the desired result.

The Committee has estimated that these objectives would be more easily reached through revision of the regular tariffs and has therefore proposed mechanisms for fixed annual revisions according to medium-term developments in costs in a number of cases. This procedure is accompanied by a periodic assessment of actual cost levels and mark-ups so that where necessary, the fixer rates adopted can be altered on the initiative of the Committee or the professional organisations concerned.

- ANNEXES -

Annex 1: Methods of negotiating medicine prices

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ANNEX 1: METHODS OF NEGOTIATING MEDICINE PRICES[18]

Article L.162-16-1 of the Social Security Code determines the rules for laying down prices of medicines reimbursable by Social Security.

> "The public sale price of each of the medicines mentioned in Paragraph 1 of Article L.162-17 shall be fixed by agreement between the company supplying the medicine and the Economic Committee for Health Products in accordance with Article L.162-17-4, or failing that, by the Ministers for Social Security, Health and the Economy, following an advice from the Committee. The process of fixing these prices shall take account principally of the improvement in medical service supplied by the medicine, the price of medicines with the same therapeutic aim, the anticipated or observed sales volumes, and the foreseeable and actual conditions under which the medicine will be used".

The law is explained by the rules of registration for reimbursement (Article R.163-5-I-2°), which specify that "medicines that do not bring either an improvement in the medical service provided, as assessed by the Committee mentioned in Article R.163-15, or a saving in the cost of medical treatment" cannot be included in the list provided for in Article L.162-17 of the Social Security Code.

These public rules are the basis for the Committee's actions. It is however worth recalling the methods used by the Committee in its relations with companies, by distinguishing the general principles from those applied for initial negotiations of prices or when they are revised upwards or downwards.

1 – The general negotiating framework

The Committee's task is to secure prices and economic conditions that are most beneficial for the health insurance system, by taking account of the global medicines market, the requirements of ONDAM, public health needs, and the need to treat companies equally.

- The principle of taking account of the global medicines market means that all specific discussions on the price of medicines should be illuminated not just through the bilateral mechanism of negotiation, but by analysis of the economic effect of the price on market developments and sickness insurance costs:
  - . the direct and immediate effect on price structures within classes,
  - . the indirect effect on relative developments within classes,
  - . the medium-term consequences when the financial effect of a reimbursement on the ONDAM has to be considered,
  - . the more distant consequences when it is possible to anticipate the future advent of medicines with the same indications.

[18] This annex reproduces that of the 2001 report word for word.

- 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 equality of treatment for companies is more a principle of equality of treatment for medicines, regardless of which companies may be marketing them. One of the specific consequences of this principle is that the Committee does not believe it is justified, regardless of the interest that it shows in research and innovation, in pre-financing research through prices for medicines that do not incorporate the positive result of the research in question. Nor does it believe, *a fortiori*, that innovative medicines should be treated differently according to the territory on which the innovation is made.

2 – Registration prices

When the price is first determined, at the initial registration stage, the rule laid down by the reimbursement decree allows just two situations to be distinguished:

- either the medicine recommended for reimbursement does not have an ASMR and its registration must lead to a saving for social security,
- or it has an ASMR and additional costs may be incurred following its registration.

The Committee is not required to discuss the level of ASMR granted by the Transparency Commission. The useful area of negotiation is therefore mapped out as soon as it issues its advices, it being added that the text does not in any way prevent the Committee from claiming a saving for social security, or at least neutrality of costs, when the medicine has an ASMR (especially a minor ASMR).

The process of fixing the price must carry a revision clause whenever the initial price is established, working on the basis of hypotheses that only time and use can confirm or refute.

2.1 – Determining the price

2.1.1 – Medicines without ASMR

The Committee must ensure that the negotiated price leads to a saving for social security. The application of this rule has four main aspects:

- First, the saving is not necessarily measured by assessing the difference in unit prices between the new medicine and the medicines to which the Transparency Commission compares the new medicine, but by assessing the saving in costs, which is the product of price differences by volumes. This means that the Committee has been able to accept prices *higher* than that of the last registered comparable medicine, when it has been evident that a lower price would, for the person providing the medicine to be registered, be a handicap in the competition to make the medicine known to the prescribers and that it would sell very little. The Committee has also considered that it may be advantageous to the health insurance system if the new competitor has the means of acquiring a significant share in the market, at a price lower than that of the medicines the more frequently sold in the class. For the same reasons, the Committee may accept a price significantly higher

than the price of less expensive comparable medicines, but very much lower than the price of the most frequently sold medicines in the class. The corresponding agreement will make mention of the consequences that may arise if the anticipated savings are not made.

- The second remark is based on the distinction between the classes within which the prescription volumes are rigid (definite diagnoses, specific and limited indications) and those in which there is a risk of an unjustified increase in volumes. In the former, the arrival of a new competitor can only have the effect of moving market shares around, and as such the product is welcome even if its price advantage is relatively low. In the latter, there is quite a different situation where the relative price advantage linked to the arrival of a new actor is likely to be compensated or even exceeded by the overall increase in volumes arising from promotional pressure on prescribers. In this case, the Committee lays down more stringent requirements.
- The third, more specific remark deals with the issue of additional ranges. Generally speaking, these new presentations do not have the benefit of any ASMR and the issue confronting the Committee is that of finding whether the right comparative product, to assess the effect of the medicine's registration on social security costs, is the range in which the new product is included and which it will be partly replacing, or the equivalents marketed, possibly at a lower price, by other companies. In 2000, the Committee most often insisted on the comparison with the less expensive competing medicines.
- Finally, the Committee has paid particular attention, in the case of new galenical products without an ASMR, to verifying that the registration of these new medicines does not have the aim or even the effect, where products whose patents are about to expire are concerned, of closing the road to the development of generic products either commercially or legally. In this situation, the Committee is able to make registration dependent on the procurement of a saving in relation to the saving that would be generated by the corresponding generic product.

2.1.2 – Medicines with ASMR

Registering these medicines may incur additional expenses for social security. The question of determining the acceptable additional cost is a difficult one for the Committee, and no specimen solution can be provided. We will therefore limit ourselves to setting out the few principles that define the context of the negotiation from the Committee's point of view.

It must first of all be recalled that not all ASMRs justify a difference in price in relation to comparable medicines already registered. In many cases, especially for small or modest ASMRs, the Committee has estimated that a "sufficient benefit" provided by the company for the innovation would consist of an increase in its market share, without there being a requirement for a price advantage.

Secondly, there is no scale of acceptable price differences associated with the ASMR scale, even though it is true to say that a minor ASMR cannot justify a major price difference. Discussions on the price of a highly innovative medicine are therefore open negotiations during which the requirements of the company and the greater or lesser need or urgency, assessed in terms of meeting health needs, determine whether the medicine is registered. During these negotiations, the so-called "European" price of the medicine is considered realistically by the Committee as a legitimate constraint for the company, but is only binding on the authorities to the extent at which they estimate in addition that registration is justified

at that price. In other words, the Committee generally understands fully that a business will not accept a price too far removed from that customarily applied by it on the other major European Union markets, but this is at the risk of the medicine not being registered at all if its level of innovation is not judged sufficient in terms of benefits and health requirements. In addition, the Committee has frequently reminded that France is part of the European Union, that the French medicines market represents an important part of the European market, and that in consequence no business is able to plead a truly European price if the French reimbursement price has not been fixed.

We should add that the registration of a highly innovative medicine frequently leads to the conclusion of volume clauses, especially in those numerous cases where a strong ASMR is only granted to the medicine with restricted indications.

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 revision clauses

There are two types of price revision clause: the daily treatment cost (CTJ) clause and the volume clause. The aim of the first clause is to guarantee that the actual cost per patient of using a medicine remains consistent in the long term with the cost agreed with the business at the moment of registration. The aim of the second clause is to guarantee that the overall expense set aside for a medicine remains in keeping with the medically justified “target” for the medicine in question. The main specimen clauses are set out in Annex 6.

2.2.1 – Daily treatment cost (CTJ) clauses

The CTJ clauses can be further divided into two categories: the dose range CTJ clauses and the total dosage clauses.

2.2.1.1 – Dose range CTJ clauses

Many medicines, when a “dose effect” has been calculated for 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 cases that the best means of guaranteeing good use of the different doses of the medicine and fairness of treatment between competing businesses in the category in question at the same time, was to ensure that doses of the same medicine were sold at the same price for each galenical unit. These uniform prices would prevent the companies from having any interest in promoting specifically the highest and most expensive doses. They would also allow the cost of treatment to remain the same over time and maintain equilibrium between competing companies, as the actual price of the treatment would then be independent from the division of sales between the various doses.

When a uniform price cannot be fixed, especially for reasons of international price homogeneity, a CTJ dose range clause will be substituted in order to obtain similar effects. In

this case, what is agreed with the business at the moment of registration is in fact a daily treatment shown as a nominal price for the various doses according to a prescription division hypothesis. If it is noticed that the actual division differs in use from the anticipated division, the nominal prices will be revised in order to re-establish the conventional cost of treatment.

2.2.1.2 – Posology clauses

The aim and mechanism of these clauses are precisely the same as in the dose range CTJ clauses. What is agreed at the moment of registration is a cost of treatment based on an average dosage hypothesis (AMM dosage or dosage certified by studies carried out prior to registration, including in countries in which the medicine has already been marketed). If the dosage noted during use is different from that on the basis of which the sale price was calculated, this price will be revised in order to re-establish the agreed cost of treatment.

2.2.2. Volume clauses

The Committee has estimated that volume clauses were not justified when their principal effect was to split the markets between various competing businesses. 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 Committee believes that the end-of-year quantitative discount programme for each therapeutic class is better adapted. In fact, all clauses of this type, where they existed, have now been abolished.

On the other hand, the Committee has negotiated price-volume clauses where the ASMR for an innovative medicine is valid only for some of the indications or for a quantifiable and limited patient population but there is nevertheless a risk of the medicine being prescribed for all of its indications as a replacement for less expensive medicines and without any benefit for the patients.

These clauses also have their place, independently of all financial consideration, when for public health reasons a medicine is only used under restricted circumstances or is strictly indispensable, as is often the case for antibiotics in particular.

Finally, volume clauses have sometimes been used when highly innovative medicines are registered, when there has been considerable market uncertainty over the new product. This is so that the financial risk to social security can be limited. It has happened, when the innovation was held by two or more competing businesses, that the businesses have made a joint undertaking in the form of a mutual 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.

3 – Price Reductions

Reductions in price may arise through the application of a previously existing price revision clause, the Committee's initiative or the firm's initiative.

3.1 – Price deductions linked to the application of clauses

In this case the reductions will be automatic, to the extent at which the revision clauses are specific. The Committee has endeavoured in this respect not to enter any longer – or as little as possible – into agreements including loose conjectural clauses "in the event of such-and-such, prices shall be reviewed".

3.2 – Price reductions on the Committee's initiative

Even if there is no price revision clause, the Committee believes it is justified in proposing price reductions in application of the texts that govern its activity (see in particular Article L.162-17-4 Para 2 and 3 and Articles R.163-9 and R.163-10 of the Social Security Code). This has often been done, frequently but not exclusively when registrations are renewed.

Renewal of registration provides an opportunity to examine the position effectively taken on the market by a medicine; this position may be quite different from what was forecast at the time of registration. This is particularly the case, even if the medicine has not been improperly used when it has since its registration seen significant growths in volumes prescribed, especially following an extension of indications. A reduction in price can also be justified by the marketing of equally effective and less expensive competing medicines after the medicine was first registered.

Price reductions on the Committee's initiative may concern an isolated medicine, a group of medicines belonging to one class or every medicine in a class.

3.3 – Price reductions on the firm's initiative

These are by definition competitive price reductions, evident until now mostly in the generic product field, 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.

4 – Increases in price

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.

On the other hand, the Committee has accepted price increases for medicines essential for satisfying health requirements and registered at a price that no longer covers their manufacturing and marketing costs. These products are generally older products for which the market has progressively reduced, "orphan" medicines or medicines that could be

economically likened to such products without strictly fulfilling all the criteria for an “orphan” classification.

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 2: TABLE SHOWING DISCOUNT INCEPTION THRESHOLDS ACCORDING TO PHARMACOTHERAPEUTIC CLASS

I – Establishing the table by class

The table is put together using a process with three distinct stages:

- 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) SEGMENTATION OF CLASSES

The aim of segmenting classes is to divide all the reimbursable medicines into groups, each group constituting a market in which companies are in direct competition with each other. The criterion for segmentation is therefore one of sufficient replaceability, in the economic sense of the term, between medicines belonging to the same group.

One must be sure, especially for the classes in relation to which quantitative discounts are due, that the actual solidarity created between companies is properly justified by the state of competition that they are in as regards the sale of their products belonging to these classes, and that therefore, conversely, no business is subjected to discounts because of increases in sales of medicines that do not compete with its own products.

By exception, and with simplification in mind, some non-homogeneous classes have been maintained in the table. These classes, however, consist of medicines whose development rates are of the same magnitude. These groups are not therefore of a kind likely to cause irregularities in terms of discounts.

B) DETERMINING THE CLASSES THAT SHOULD GENERATE QUANTITATIVE DISCOUNTS

This determination process relies on a two-stage analysis. Initially, the Committee assessed the potential for normal development of sales in each of the classes. It then identified sales in the classes in which it believed discounts were justified, as well as the relative proportions in which the said discounts were justified.

1) Assessing the potential for normal sales development

The assessment of potential for normal sales development within classes includes elements of prediction but is not a forecast as such, as it assumes that developments in sales of medicines within the class will be consistent with medically justified needs. In addition, the assessment relates to changes in sales and does not prejudge the normal (or exceptional) nature of consumption levels currently observed.

The assessment is based on four criteria:

- ***Changes in prevalence of the diseases to be treated***, whatever the reasons for the changes may be: advances in detection (e.g. diabetes), ageing of the population (e.g.

osteoporosis), or changes in environment (e.g. asthma) or eating habits. The transfer to outside care of patients previously treated exclusively in hospital (e.g. hepatitis C) is also deemed to be a positive change in prevalence.

- ***The actual or possible advent of innovations*** on the reimbursable medicines market.
- ***The penetration of generic products***, which conversely, by its nature, will reduce sales totals in the classes in which these medicines are placed.
- ***Known public health priorities***, whether their aim is to increase the use of certain medicines (e.g. vaccines, painkillers) or reduce the said use (e.g. antibiotics).

2) Identifying classes that must generate a greater or lesser discount proportion

As the main aim of quantitative discounts is to reduce actual expenditure on medicine incurred by the sickness insurance fund at a given registration price, the process of determining the classes required to generate discounts involves the Committee identifying the classes in which it believes that prices, at currently observed sales levels, are too high (at least relatively, in view of the global restrictions on costs voted in by Parliament). The discounts are therefore a provisional alternative to the reductions in price dictated by the market situation, the duration of this provisional alternative itself depending on a variety of different factors.

This assessment is also based on four criteria:

- ***The medical service provided as assessed by the Transparency Commission***. The Committee believes that it is sensible for the discounts mechanism to be able to provide a reduction in costs incurred by the sickness insurance fund for medicines for which the service provided has been judged insufficient to warrant their inclusion in the list of reimbursable medicines.
- ***The marketing seniority of medicines.*** The Committee also believes that it is sensible to reduce the cost to the sickness insurance fund, in order to allow the financing of innovations with respect for overall restraints, of classes of medicines that have acquired seniority, even though they may be protected by patents and still provide a significant level of medical service.
- ***The excessive sales of certain classes of medicines in relation to medically justified needs***. This is particularly the case with medicines that undoubtedly provide a level of medical service but whose use has been promoted with a first intent of undermining equally efficacious and less expensive products, when the price of the medicines in question is only justified by the specific advantage that they bring for more restricted patient populations or in a second indent (e.g. IEC and angiotensin-II blockers with high blood pressure, inhaled corticosteroids specially indicated for severe asthma but used for all forms of asthma, new generations of antibiotics, etc).
- ***The intrinsic importance of volumes sold.*** These are classes for which the SMR is undisputed, and for which there is no reason to suppose that the volumes are not justified, but whose relative weight in the sickness insurance costs and the increases therein is considerable (e.g. statins, proton pump blockers). In these cases, the discounts provided are pure and simple quantitative discounts, justified solely by the capacity of wholesale client in the French sickness insurance system. The assessment of this criterion, as for the previous criterion, may take account of differences noted in previous years between the rates accepted by the Committee and the sales; this can explain why some rates have been reduced in relation to initial forecasts for the current year and for future years.

These criteria, like those in 1) above, can sometimes be compensated, and can also be mutually strengthened. Of course it is the Committee's responsibility to define their weighting on a case-by-case basis in order to determine the outcome.

C) THE OVERALL BALANCING OF THE TABLE

This balancing process should allow three constraints to be balanced as far as possible.

. Differences between rates accepted and potential for normal development within classes, as established in the basis of the criteria in 1), must be consistent with the analysis in 2). In other words, and for example, a class in which the criteria in 2) come together to induce the Committee to estimate that the discounts should be proportionally significant will be allocated a rate, either positive or negative, noticeably less than that for the normal sales developments. Inversely, a class for which none of the criteria in 2) justify the discounts will be allocated a rate, either positive or negative, at least equal to the rate of normal development of its sales.

. The system adopted must produce results acceptable to firms. This might be described as a restriction of realism, prohibiting the acceptance of rates that are wholly justified in application of the principles and criteria listed above but would lead to an approved business or a group of approved businesses being compelled to pay discounts that represented an excessive proportion of their turnover.

. The weighted sum of the rates accepted must be equal to the safeguard contribution trigger threshold rate. This is the main principle on which the table is constructed, and its *raison d'être.* Because of it, and especially because the rates accepted have no indisputable value as absolute figures, the Committee, in contrast, made a point of being able to justify (through the application of specifically defined criteria and on the basis of a relative approach between classes), the direction and magnitude of the differences between the rates accepted and the standard potential for sales developments in these classes. For each class of medicine, the mechanism set up produces a rate of development expressed as the difference in comparison to the ONDAM rate; this means that the developments based on each rate within each group of medicines leads to a global result equal to the ONDAM forecast. The justification for the differences in rate is the adjustment, without alteration to the nominal prices of the medicines, of the real prices (with discounts deducted) paid by the community for the various groups of medicines for their marginal use. This mechanism, coupled with the exemptions planned in favour most notably of generic products or highly innovative medicines, allows consistency to be maintained between the methods of financial settlement and the fundamental principles of the government's policy on medicines: proper use of medicines, prevention of waste, development of a generic products market and support for innovation. Secondly, this type of regulation could provide a marginal but real incentive for businesses to steer their promotion efforts towards groups of medicines for which the discount trigger threshold is higher than the spontaneous sales trend and should not therefore give rise to discounts.

II – Discount calculation methods

A) MECHANISM

1) Full discount

The total discount due in relation to a class in which sales developments have exceeded the rate shown in the Committee's table is divided between the companies marketing the products in the said class, as follows:

- 65% of the total discount is divided in proportion to sales realised during the year.
- 35% of the total discount is divided between those businesses whose sales development has exceeded the figure shown in the Committee's table, in proportion to the fraction of sales realised over and above the rate.

The aim is not to penalise the marketing of new products, including when these products do not have an ASMR and lead to a saving for social security.

2) Exemption of innovations

- Medicines benefiting from an ASMR I are exempt from discounts for three years after their initial marketing; those benefiting from an ASMR II are exempt for two years.
- For medicines granted an ASMR in relation to a specific indication or an extension of indication, the exemptions shall apply to the proportion of the turnover realised in the context of these indications, as determined by agreement.
- The exemption periods shall be calculated from the initial marketing, or for ASMRs obtained in relation to an extension of indication, from the date of the Transparency Commission's advice. When this period finishes during a calendar year, the exemption shall be calculated in proportion to the sales realised during the exemption period.

3) Exemptions for low-priced products

This exemption relates to generic products, similar products with a generic price and first products with a generic price. It is not applicable to medicines of which it can simply be said that their cost is less than the average treatment cost for the class to which they belong.

B) DISCOUNT RATE

The discount rate is fixed at 35%[19] of any amount by which a rate shown in the Committee's table is exceeded. It is established, in accordance with the sectorial agreement, that the net total of discounts (for all approved businesses combined) effectively paid by way of discount per class and by way of turnover-based discount may not exceed the total contributions required to be paid by the same businesses in application of Article L.138-10 of the Social Security Code. In order to ensure that this limit is respected, the rate of 35% may if necessary be uniformly reduced for all the classes that generate payments of discounts.

[19] For 2002, the discount rate was reduced to 28%.

Table showing discount trigger thresholds for each class, period 2002-2005					
Classes	ONDAM trigger rate, 2002	2002 rate ex. ONDAM (%)	2003 rate ex. ONDAM (%)	2004 rate ex. ONDAM (%)	2005 rate ex. ONDAM (%)
A2A antacids and anti-flatulence products	-3	-6	-7	-8	-3
A2B1 H2 receptor antagonists	-3	-6	-5	-4	-3
A2B2 proton pump inhibitors	6	3	0	0	0
A2B3,B9 prostaglandins and other anti-ulcer drugs	-2	-5	-4	-3	-3
A3 anti-spasmodics, anticholinergics and gastroprokinetics (excluding anti-emetics of metoclopramide type)	0	-3	-3	-3	-3
A4A1 anti-emetics: serotonin antagonists	3	0	0	0	0
A4A9 other anti-emetics, inc. metoclopramide type (A03F)	-6	-3	-3	-3	-3
A5A1,B,C choleretics, liver protectors **+ Desintex & Desintex for children (V3A)**	-12	-15	-15	-20	-20
A5A2 anti-lithiatics	3	0	0	0	0
A06 laxatives	-5	-8	-5	-3	-2
A7A,B,F,H,X anti-diarrhoea medicines + nalcron & intercron	-2	-5	-3	-2	0
A7E intestinal anti-inflammatory drugs (exc. nalcron, intercron)	3	0	0	0	0
A9A digestive products including enzymes	-8	-11	-11	-6	-3
A10B oral anti-diabetics	10	7	5	4	3
A10C,D insulin and similar products	10	7	5	4	3
A11 vitamins (exc. A11H3)	-3	-6	-6	-6	0
A12A calcium **(exc. calcium sorbisterit & phosphoneuros)**	0	-3	-3	0	0
A12B potassium	3	0	0	0	0
A12C,A13 magnesium, other mineral supplements and tonics **(exc. medifa phosphorus & nonan)**	-3	-6	-5	-4	-3
A14 anabolics, hormones and others	3	0	0	0	0
A15 orexigens	-2,5	-5,5	-5,5	-5,5	-6
A16 various digestive equipment	-5	-8	-8	-8	-5
B1A non-injectable anticoagulants	14	11	5	5	4
B1B injectable anticoagulants	1	-2	2	4	4
B1C platelet aggregation blockers	10	7	5	3	0
B1D fibrinolytics	3	0	0	0	0
B2 anti-haemorrhagics and haemostatics	3	0	0	0	0
B3A anti-anaemia products	3	0	0	0	0
B3X other anti-anaemia products (folic & folinic acid, etc)	3	0	0	0	0
C1A+C & C6 glyco stimul card (sf dopa) & others	0	-3	0	0	0
C1B antiarrythmia products	0	-3	-3	-3	0
C1D coronary treatment sf C1E, C8 (exc. molsidomine, nicorandil)	-4	-7	-5	-3	-2
C1E nitro compounds (inc. molsidomine, nicorandil)	0	-1	-1	-1	0
C2 anti-hypertensives	0	-3	-3	-3	0
C3 diuretics	5	2	1	1	1
C4,N6D vasodilators and nootropics	-7	-10	-5	-3	0
C5A local anti-haemorrhoid products	0	-3	-3	-3	0
C5B anti-varicose products, administered locally	-4	-7	-5	-3	-1
C5C vasoprotectors, general administration	-5	-8	-6	-3	-1
C7 beta-blockers	7	4	2	2	2
C8 calcium antagonists	-2,5	-5,5	-3	0	0
C9 renin-angiotensin system modifiers	3	0	0	0	0
C10A1 HMG-COA reductase blockers	4,5	1,5	0	0	0
C10A2 fibrates	5	2	0	0	0
C10A3 ionic exchange resins	8	5	3	2	1
C10A9 other cholesterol & triglyceride blockers	-4	-7	-7	-7	-5
C10B,A11H3 anti-atheroma products, natural origin, Vit. E	-1	-4	0	0	0
D1 anti-fungal skin treatments + oral Lamisil (J2A)	1	-2	-3	0	0
D2,D3,D4,D8,D11 emollients, healing products, antipruritics, antiseptics and others (exc. rosacea products, meladinine & Aldara)	-2	-5	-3	-2	-1
D5 anti-psoriasis products + meladinin (D11)	3	0	5	4	3
D6A antibiotics + sulphonamides only	-1	-4	-3	-3	-1
D6D local anti-viral products + Aldara (D11)	3	0	0	0	0
D7A single corticosteroids	3	0	0	0	0

D7B combined corticosteroids	-5	-5	-3	-3	-3
D10 oral and local anti-acne products + rosacea prods (D11)	3	0	0	0	0
G1 gynaecological anti-infectants	0	-3	-2	-2	0
G2 oxytocin inh. prolac, labour inh., locally administered sex hormone, others	1	-2	0	0	0
G3A ovulation blockers	15	12	5	5	5
G3B androgens (exc. G03 F)	-1,5	-4,5	-4,5	-4,5	0
G3C,D,F oestrogens & progestogens (ex. G3A) + androgens (ex. G3F)	8	5	5	5	5
G3G gonadotrophins / ovulation inducers	3	0	0	0	0
G3H various sex hormones	3	0	0	0	0
G4A antibiotics + sulphas, other urinary antiseptics	-1	-4	-4	-3	-3
G4B2,B4,B9 urology (prostate, enuresis, others), **exc. Lithiagel**	-1	-4	-4	-4	-4
G4B3 erectile dysfunction	63	60	25	10	0
H1A ACTH	-9	-12	-5	-2	0
H1C GNRH analogues **+ Orgalutran (H4V)**	53	50	15	10	5
H2 corticosteroids	3	0	0	0	0
H3 thyroid and antithyroid hormones	5	2	0	0	0
H4A calcitonins	-5	-8	-3	-2	-2
H4B glucagons	3	0	0	0	0
H4C growth hormones	5	2	0	-3	-3
H4D antidiuretic hormones	3	0	0	0	0
H4V other hormones and similar products **(exc. Orgalutran)**	5	2	0	0	0
J1A,B,C,E,H,K,X2,J3A Group 1 antibiotics	0	-3	-2	-1	0
J1D,F,G,X9 Group 2 antibiotics	0	-3	-2	-1	0
J1M,J4 Rifampicin, Rifamycin, anti-tubercular, anti-leprosy products	8	5	3	2	2
J2 anti-fungal products, generally administered (exc. Lamisil)	4	1	0	0	0
J5B anti-virals except anti-HIV					
Group 1: hepatitis treatment products (Rebetol) + Zeffix (J5C)	13	10	5	0	0
Group 2: other non-HIV anti-virals	6	3	0	0	0
J5C anti-HIV-retrovirus (exc. Zeffix)	20	17	7	7	7
J6,J7(exc. J7C): sera and vaccines	8	5	0	0	0
J7C other vaccines	-10	-13	-4	-4	0
K massive solutions **+ Nonan (A12C2)**	6	3	2	1	0
L1,L2 anti-cancer prods, cytostatic hormones (exc. Novatrex)	8	5	4	3	2
L3B1 alpha-interferons	35	32	15	7	5
L3B2 beta-interferons	8	5	0	0	0
L4 immunosuppressive agents (exc. Arava)	10	7	10	12	12
M1A1 anti-rheumatics, single non-steroids (exc. Art 50, Zondar)	1	-2	0	0	0
M1A3 cyclo-oxygenase-2 blockers	3	0	0	0	0
M1C + Acadione (M5X) + Arava (L4) + Novatrex (L1B)	23	20	15	10	10
M5X other locomotive support products (exc. Acadione) + Art 50 & Zondar (M1A1)	3	0	0	0	0
M2+M6 local act. products prod (AINS, balms, repellents) + anti-infection enzymes (exc. alpha-amylase-based spec. prods)	1	-2	-2	-2	-2
M3 muscle relaxants, peripheral and/or central action + **Hexaquin (M1A2)**	-1	-4	-3	-3	0
M4 anti-gout products	0	-3	-3	-2	-1
M5B anti-osteoclastics					
Group 1: osteoclastics without indication in osteoporosis	6,5	3,5	3,5	3,5	3,5
Group 2: osteoporosis medicines (exc. THS)	23	20	15	10	5
N1 anaesthetics	7	4	3	2	1
N2A narcotic painkillers					
Group 1: narcotics, excluding substitute treatments	7	4	4	3	3
Group 2: substitute treatments	7	4	4	3	3
N2B non-narcotic anti-pyretic analgesics	3	0	0	0	0
N2C migraine treatment analgesics					
Group 1: triptans	5	2	1	0	0
Group 2: other anti-migraine products (crisis & root treatment)	3	0	0	0	0
N3A anti-epileptics	8	5	2	2	2
N4A anti-Parkinson's	7	4	2	2	2
N5A1 atypical anti-psychotics	6	3	0	0	0

N5A9 standard anti-psychotics + lithium salts + Depamide + Depakote (N06A)	6	3	0	0	0
N5B1 Group 1 hypnotics: benzodiazepine & similar products (exc. calcibronat, nopron, crataegol and homeopathic products)	-1	-4	-3	-1	0
N5B2,N5B4,C1X Group 2 hypnotics: combined non-barbiturate hypnotics, single non-barbiturates other than benzodiazepine and similar products (from N5B1) + comb. barbi. hypnos + other cardiac treatment + cimipax (NOX)	-1	-4	-3	-1	0
N5C tranquillisers	-2	-5	-4	-3	-3
N6A antidepressants (exc. lithium salts, Depamide, Depakote & Levotonin)					
Group 1: imipraminics + IMAO	-2	-5	-4	-4	0
Group 2: other antidepressants (inc. IRS)	-2	-5	-4	-4	0
N7C anti-dizziness products	-2	-5	-4	-3	-3
N7D anti-Alzheimer's products	20	17	15	15	15
N7X other SNC active products (exc. cimipax) + N6B + Levotonine (N6A)					
Group 1: rilutek, revia, aotal, nalorex, modiodal, ritalin, Cooper caffeine, levotonin	8	5	5	3	0
Group 2: olmifon, yohimbin, procaine	0	-3	-3	0	0
P: anti-parasitic products	3	0	0	0	2
R1A1,A3,A6 corticosteroids (singly or in combination) and other allergic rhinitis specialist products	0	-3	-3	-3	0
R01A4,A7,A9,B rhinol anti-infectant, cortico-s/s	-2	-5	-5	-5	-5
R02 anti-infectant decongestant for throat and mouth **(A01)**	-1	-4	-4	-4	-3
R3A, D, F B2 stimulants & c/steroids, inhaled singly or in comb.	7	4	3	2	2
R3B,C,G,J xanthins, non-ster. resp. anti-inf., b2 + anticholin, antileukotriene	18	15	0	0	0
R4,R5(exc. R5C), R3X repellents, cough relief, broncho-pulm prods, other b/chodil + alpha-amylase (M6 & R5C) + **Gomenoleo (V3)**	-3	-6	-5	-4	-4
R5C expectorants (exc. alpha-amylase)	-3,5	-6,5	-4	-3	-3
R06 anti-histamines	3	0	0	0	0
R7 breathing stimulants	0	-3	-1	-1	-1
S1A,B,C,D,F,G,H,R Group 1 eye products (exc. ophtalmine, sophtal, vita3, boroclarin, benzododecinium, martigen, sodium propionate, calming antiseptic, vitasedine, vitableu, vitargenol)	4	1	0	0	0
S1M,N,X (exc. visudyn). Group 2 eye products + ophtalmine, sophtal, vita3, boroclarine, benzododecinium, martigen, sodium propionate, calming antiseptic, vitasedin, vitableu &vitargenol.	-7	-10	-10	-7	-5
S1X1 Visudyn only	68	65	20	10	0
S1E Myotics and anti-glaucoma products	8	5	4	3	2
S1K artificial tears, eye drops	1	-2	-2	-2	-2
S2A anti-infectant ear products	1	-2	-2	-2	-2
S2C, D cort. ear products + anti-infectant and miscellaneous	-2	-5	-5	-4	0
T diagnostic products	8,5	5,5	4,5	4	4
T2 other diagnostic tests	2	-1	0	0	0
V1 allergens	-2	-5	0	0	0
V3 - V7 other medicines & miscellaneous **(exc. Desintex, Desintex for children and Gomenoleo) + phosphoneuros (A12A), medifa phosphorus (A12C), calcium sorbisterit (A12A) & Lithiagel (G4B9).**	3,5	0,5	0	0	0

ANNEX 3: STANDARD CLAUSES

1. STANDARD DOSAGE CLAUSE

Article 1

The prices shown in the following table are applicable from the date of their publication in the *Journal Officiel* (or shall take effect on (date)).

Registration

Presentation	Class	PFHT	PPTTC
CIP code, brand name, dosage (active principle), galenical form, packaging		€(…)	€(…)
…		€(…)	€(…)
…		€(…)	€(…)

Article 2

2.1 The price specified in Article 1 (manufacturer's tax-exclusive reference price $PFHT_R$) is specified subject to the condition that the observed dosage (P_C) is at least equal to (…) (reference dosage: P_R).

2.2 The dosage (P_C) is examined every year, and for the first time, the date is based on the latest DOREMA published before that date. If the observed dosage (P_C) exceeds the reference dosage (P_R), the PFHT fixed in Article 1 is altered ($PFHT_M$) so that:

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

As soon as the price has been altered for the first time in application of this clause, no new alteration may be made to the price in application of the clause unless the observed dosage exceeds the dosage that generated the previous price alteration.

If (P_C - P_R) / P_R is less than *x*%, the $PFHT_R$ will not be altered and the company must pay a discount (R) calculated using the formula shown in 2.3.

2.3 If the observed dosage (P_C) exceeds the reference dosage (P_R), the business must pay a refund (R) calculated using the formula:

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

where:

- $CAHT_C$ is the turnover observed in the GERS for the 12-month period prior to the date mentioned in 2.2;
- V_C is the volume of sales of the presentation observed in the GERS over the same period.

2.4 The total refund payable shall be notified to the company by the Economic Committee for Health Products. The company shall pay the refund to ACOSS one month after notification from the CEPS. The company shall inform the CEPS by letter of the date and total of the

payment made. The total of the refund shall, where necessary, be deducted from the quantitative class discount basis mentioned in the agreement between the CEPS and the company.

2. STANDARD DAILY TREATMENT CLAUSE (CTJ)

Article 1

The initial registration prices (or the price alterations…) shown in the following table are applicable from the date of their publication in the *Journal Officiel* (or shall take effect on (date)).

Initial registration (or price alteration)

Presentation	Class	PFHT	PPTTC
CIP code, brand name, dosage (active principle), galenical form, packaging		€(…)	€(…)
bbb		€(…)	€(…)
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 ($CTJG_R$).by aaa, bbb, ccc etc. totals at least €(…); this is the reference daily treatment clause ($CTJG_R$).

2.2 The $CTJG_C$ is examined every year and for the first time for the 12-month period prior to (date). It is calculated on the basis of the dosage for each presentation mentioned in 2.1 and shown in the latest DOREMA published before (date), and of the 12-month sales as shown in the latest GERS published before 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 $CTJG_R$.

2.3 and following (see dosage clause).

3. STANDARD "VOLUMES IN UNITS" CLAUSE

Article 1

The initial registration prices shown in the following table are applicable from the date of their publication in the *Journal Officiel* (or shall take effect on (date)).

Registration

Presentation	Class	PFHT	PPTTC
CIP code, brand name, dosage (active principle), galenical form, packaging		€(…)	€(…)
…		€(…)	€(…)
…		€(…)	€(…)

Article 2

2.1 The price (PFHT) shown in Article 1 (reference tax-exclusive manufacturer's price or $PFHT_R$) is shown subject to the condition that the annual volume of sales (V_C) is equal to or less than the reference sales total (V_R).

2.2 The volume of sales V_C is examined every year, and the date, for the first time, on the basis of the latest GERS published before that date.

If the annual volume of sales noted (V_C) exceeds the reference volume (V_R), the PFHT is altered ($PFHT_M$) so that:

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

As soon as the price is altered for the first time in application of this clause, no new alteration to the price may be made in application of the clause unless the volume noted exceeds the volume that generated the previous price alteration.

2.3 and following (see dosage clause).

ANNEX 4: COMPOSITION OF THE COMMITTEE

1. MEMBERS OF THE ECONOMIC COMMITTEE FOR HEALTH PRODUCTS

Noël RENAUDIN, President

1.1. MEDICINES DIVISION

Jean-Paul CANO, Honorary Vice-President, died on 31 December 2002.

Representatives of the Director of Social Security – Ministry of Employment and Solidarity
Stéphane SEILLER, Deputy Director, Sub-Directorate of Care System Finance
Michèle LARREUR, Pharmaceutical Adviser, Sub-Directorate of Care System Finance

Representatives of the Director-General of Health – Ministry of Employment and Solidarity
Hélène SAINTE MARIE, Deputy Director, Sub-Directorate of Health Products Policy
Agnès MOUCHARD, Head of Office, Medicines Office
Sophie FEGUEUX, Deputy Head of Office, Medicines Office
Nathalie MANTEAU, Medicines Office

Representatives of the Director-General of Competition, Consumption and Fraud Prevention – Ministry of the Economy, Finance and Industry
Claudine SEGELLE, Deputy Director, Sub-Directorate of Health, Industry and Commerce.
Anne DUX, Head of Office, E1 Health Office.
Olivier CAILLOU, Deputy Head of Office, E1 Health Office.

Representatives of the Director-General of Industry, Technology, Information and Jobs – Ministry of the Economy, Finance and Industry
Gérard MATHIEU, Manager of Sub-Directorate of Chemistry, Pharmacy and Biotechnology
François LHOSTE, Economic Task Manager, Sub-Directorate of Chemistry, Pharmacy and Biotechnology
Catherine TRENQUE, Deputy Director, Sub-Directorate of Chemistry, Pharmacy and Biotechnology

Representatives of national sickness insurance funds
Christian MARTY, Deputy Director, Medicines Specialist with the Director-Delegate for Risks, Caisse Nationale de l'Assurance Maladie (for salaried workers)
Martine PIGEON, Manager, Medicines Division
Carine BUSIN, Task Manager, Medicines Division

Representative of the Director for Hospitalisation and Organisation of Care
Dominique LAGARDE, Task Manager with the Director for Hospitalisation and Organisation of Care.

1.2. MEDICAL DEVICES DIVISION

Dominique LECOMTE, Vice-President.

Representatives of the Director of Social Security – Ministry of Employment and Solidarity
Stéphane SEILLER, Deputy Director, Sub-Directorate of Care System Finance.
Danielle GOLINELLI, Head of Health Products Office
Eric PARPAILLON, Head of Health Products Office
Serge PAON, Health Products Office
Isabelle CHEINEY, Deputy Head of Office, Health Products Office

Representatives of the Director-General of Health – Ministry of Employment and Solidarity
Hélène SAINTE MARIE, Sub-Director, Sub-Directorate of Health Products Policy
Patrick GUYOT, Head of Office of Medical Equipment and Other Health Products
Sophie CASANOVA, Office of Medical Equipment and Other Health Products

Representative of Director of Hospitalisation and Organisation of Care
Françoise CABANE, Task Manager

Representatives of the Director-General of Competition, Consumption and Fraud Prevention – Ministry of the Economy, Finance and Industry
Claudine SEGELLE, Deputy Director, Sub-Directorate of Health, Industry and Commerce.
Anne DUX, Head of Office, E1 Health Office
Olivier CAILLOU, Deputy Head of Office, E1 Health Office
Daniel MILES, E1 Health Office
Arlette TURIER, E1 Health Office

Representatives of the Director-General of Industry, Technology, Information and Jobs – Ministry of the Economy, Finance and Industry
Gérard MATHIEU, Manager of Sub-Directorate of Chemistry, Pharmacy and Biotechnology
Marie-Claire SEBAG, Head of Medical Equipment Division

Representatives of National Sickness Insurance Funds
Pierre-Jean LANCRY, Director-Delegate for Risks, Caisse Nationale de l'Assurance Maladie for salaried workers
Christine VAULONT, Economic Studies Manager – Department of Medicines and Medical Equipment
Frédéric GIRAUDET, Legal Affairs Manager, Pharmacy and Medical Equipment Division.

2. RAPPORTEURS TO THE COMMITTEE

Mrs Michèle AUDEOUD-FAURIS,
Mrs Françoise BENOIT-CATTIN,
Mrs Hélène BOURDEL,
Mrs Isabelle CHEINEY,
Mrs Élisabeth CREPON,
Mr Bertrand DIQUET,
Mr Nicolas GASPARD,
Mrs Claire GENDRE-OGET,
Mr Jean-Marc GROGNET,
Mr Philippe LALANDE,
Mrs Régine LEMEE,
Mr Jean-François MATTEI,
Mrs Michèle MSIKA,
Mrs Marie-Françoise PENY,
Mrs Catherine PHILIPPE,
Mr Michel ROUSSEAU,
Mr Bruno STALLA,
Mr André TANTI,
Mr Bernard TEISSEIRE,
Mr Jean-Pierre YVERT.

3. DETAILS OF PERSONS WORKING ON THE COMMITTEE

Name	Duty	Telephone	Fax	E-mail
Michèle AUDÉOUD-FAURIS	Deputy to the Secretary General Manager, Medicines Section	01.40.56.75.54	01.40.56.71.79	michele.audeoud-fauris@sante.gouv.fr
Anne-Marie BOUCHARD	Compilation and publication in *JO* of decrees and price advices (medicines)	01.40.56.60.70	01.40.56.71.79	anne-marie.bouchard@sante.gouv.fr
Ghislaine BROUARD	Secretariat to the President and Vice-Presidents	01.40.56.78.64	01.43.06.30.02	ghislaine.brouard@sante.gouv.fr
Marie-Thérèse DAVID	Secretariat of the EHPC	01.40.56.69.51	01.40.56.71.79	marie-thérèse.david@sante.gouv.fr
Catherine DUFAU	Monitoring of generic medicines	01.40.56.48.05	01.40.56.71.79	catherine.dufau@sante.gouv.fr
Claire OGET-GENDRE	Deputy to the Secretary-General Manager, Medical Equipment Section	01.40.56.45.60	01.40.56.40.50	claire.oget-gendre@sante.gouv.fr
Sylvette LAPLANCHE	Secretary-General	01.40.56.46.95	01.40.56.71.79	sylvette.laplanche@sante.gouv.fr
Marie LUCET	Compilation and publication in *JO* of decrees and price advices (medicines)	01.40.56.44.27	01.40.56.71.79	marie.lucet@sante.gouv.fr
Viviane PIERRE	Administrative management (Medical equipment)	01.40.56.57.55	01.40.56.40.50	viviane.pierre@sante.gouv.fr
Françoise REVECHON	Registration of applications for prices and reimbursements (Medicines)	01.40.56.46.84	01.40.56.71.79	françoise.revechon@sante.gouv.fr
Maryvonne RICHER	Manager, database and computer files (health products)	01.40.56.53.46	01.40.56.40.50	maryvonne.richer@sante.gouv.fr
Michel ROUSSEAU	General Reporter	01.40.56.49.51	01.40.56.71.79	michel.rousseau@sante.gouv.fr
Geneviève UCHIDA-ERNOUF	International cell (health products)	01.40.56.72.14	01.40.56.71.79	genevieve.uchida-ernouf@sante.gouv.fr

Dominique de PENANSTER, Manager of the Medical Equipment Section, and Ghislaine de BENTZMANN, responsible for the administrative management of medical equipment, resigned their duties at the end of 2002.

4. DECLARATIONS OF INTEREST

NATURE OF INTEREST	
Employment contract	CT
Financial holding in the capital of a business	PF
Paid work (participation in clinical trials, studies, consultations, research etc)	TR
Other declared interests	A

4.1. MEMBERS OF THE ECONOMIC COMMITTEE FOR HEALTH PRODUCTS

Members of Committee	Nature of interest
President of the Economic Committee for Health Products *Mr Noël RENAUDIN*	**CT**: none **TR**: none **PF** : none **A**: none
Vice-President of the Economic Committee for Health Products *Mrs Dominique LECOMTE (Medical Equipment Section)*	**CT**: none **TR**: none **PF** : none **A**: none
Social Security Directorate *Mr Stéphane SEILLER*	**CT**: none **TR**: none **PF** : none **A** : none
Directorate-General of Health *Mrs Hélène SAINTE-MARIE*	**CT**: none **TR**: none **PF** : none **A** : none
Directorate of Hospitalisation and Organisation of Care *Mrs Dominique LAGARDE (Medicines Section)*	**CT**: none **TR**: none **PF** : none **A** : none
Directorate of Hospitalisation and Organisation of Care *Mrs Françoise CABANE (Medical Equipment Section)*	**CT**: none **TR**: none **PF** : none **A** : none
Directorate-General of Competition, Consumption and Fraud Prevention *Madame Claudine SEGELLE*	**CT**: none **TR**: none **PF** : none **A** : none
Directorate-General of Industry, Technology, Information and Jobs *Mr Gérard MATHIEU*	**CT**: none **TR**: none **PF** : none **A** : none
National Sickness Insurance Funds *Mr Pierre-Jean LANCRY (Medical Equipment Section)*	**CT**: none **TR**: none **PF** : none **A** : none
National Sickness Insurance Funds *Mr Christian MARTY (Medicines Section)*	**CT**: none **TR**: none **PF** : none **A** : none

4.2 RAPPORTEURS TO THE ECONOMIC COMMITTEE FOR HEALTH PRODUCTS

Raporteur	NATURE OF INTERESTS
Mrs Michèle AUDEOUD-FAURIS	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Françoise BENOÎT-CATTIN	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Hélène BOURDEL	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Isabelle CHEINEY	**CT**: none. **TR**: none. **PF**: Air Liquide. **A**: none.
Mrs Elisabeth CRÉPON	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Bertrand DIQUET	**CT**: none. **PF**: none. **TR**: Research, participation in group working on HIV infection at Glaxo Wellcome, HMR internet question. **A**: wife an employee of Aventis.
Mr Nicolas GASPARD	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mme Claire GENDRE-OGET	**CT**: Nanto. **TR**: none. **PF**: none. **A**: none.
Mr Jean-Marc GROGNET	**CT**: none. **PF**: none. **TR**: none. **A**: wife an employee of Glaxo Wellcome.
Mr Philippe LALANDE	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Régine LEMÉE-PECQUEUR	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Jean-François MATTEI	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Michèle MSIKA-BOUTIGNY	**CT**: employee of Jouveinal/Parke Davis 1991/1999. **TR**: none. **PF**: none. **A**: none.
Mrs Marie-Françoise PENY	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Catherine PHILIPPE	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Bruno STALLA	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr André TANTI	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Bernard TEISSEIRE	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Jean-Pierre YVERT	**CT**: none. **TR**: none. **PF**: none. **A**: none.

4.3 PERSONS PARTICIPATING IN MEETINGS OF THE ECONOMIC COMMITTEE FOR HEALTH PRODUCTS

Persons participating in meetings of the Committee	Nature of interests
Economic Committee for Health Products	
Mrs Michèle AUDEOUD-FAURIS	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Dominique HUON de PENANSTER	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Sylvette LAPLANCHE	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Michel ROUSSEAU	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Directorate of Social Security	
Mrs Danielle GOLINELLI	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Eric PARPAILLON	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Michèle LARREUR	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Isabelle CHEINEY	**CT**: none. **TR**: none. **PF**: Air Liquide. **A**: none.
Directorate-General of Health	
Mrs Sophie FEGUEUX	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Nathalie MANTEAU	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Directorate-General of Competition, Consumption and Fraud Prevention	
Mr Olivier CAILLOU	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Daniel MILES	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Directorate-General of Industry, Technology, Information and Jobs	
Mr François LHOSTE	**CT**: none. **TR**: none. **PF**: none. **A**: Fee received for joint creation of Laboratoires Servier medicine.
Mrs Catherine TRENQUE	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Marie-Claire SEBAG	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Compulsory Sickness Insurance Fund	
Mrs Carine BUSIN	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mr Frédéric GIRAUDET	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Martine PIGEON	**CT**: none. **TR**: none. **PF**: none. **A**: none.
Mrs Christine VAULONT	**CT**: none. **TR**: none. **PF**: none. **A**: none.