The Economic Committee for Health Products

Activity Report 2004

July 2005

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The Economic Committee for Health Products

Activity Report 2004

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

The present report deals with the main activities of the Committee during 2004.

The first part deals with trends in the legislative context, in application of the Social Security Finance Law for 2004 and the Law of 13 August 2004 concerning sickness insurance and its effect on the committee in terms of skills, tasks and activity during 2004.

The second part relates to medicines and deals successively with the medicines market in 2004 (Section I), regulatory activities carried out in 2004 (Section II), and the methods by which the committee fixes prices (Section III).

The third part relates to health products other than medicines. Section I is given over to a description of the cost of medical devices and the changes in those costs. Section II deals with the administration of medical devices on the basis of the committee's advice and the determination of prices and tariffs for products and services defined by Article L.165-1 of the Social Security Code.

PART ONE – CHANGES IN THE LEGISLATIVE AND REGULATORY FRAMEWORK

Since the last annual report, the legal framework in which the committee operates has been substantially modified through two laws: the Social Security Finance Law for 2004 and the Law of 13 August 2004 relating to sickness insurance. These alterations have affected both the basic rules applicable to the medicines sector and to medical devices and the methods by which the committee operates.

SECTION 1 – BASIC RULES

Some of the new rules are aimed at facilitating better use of medicines or medical devices; others are aimed more directly at providing economic regulation.

1.1 Measures in favour of rational usage

1.1.1. THE MEDICAL VISIT QUALITY CHARTER

The new Article L.162-17-8 of the Social Security Code, introduced by the Law of 13 August 2004, provides for a professional practice quality charter for persons responsible for promoting pharmaceutical products through prospecting and canvassing. The charter is concluded between the committee and one or more syndicates representing the drug companies. The law also provides that the long-term agreements concluded between the committee and the companies include an obligation on the companies to respect the charter and have the quality of the medical visit organised or commissioned by the companies assessed by approved bodies under the supervision of the Health Authority for Health.

The discussions held from late summer between the CEPS (Economic Committee for Health Products) and Drug Companies (LEEM) culminated in the signature of the medical visits charter on 22 December 2004.

The charter, aimed at ensuring that medical visits make a positive contribution to the better use of medicines, while avoiding any possible misuse, recalls and completes in some areas the rules applicable to companies providing information on medicines to doctors. Specifically, it prohibits the distribution of samples by medical representatives, as well as the recruitment and payment of doctors by these representatives for study purposes. It reinforces the prohibition on gifts of all kinds, laid down by Article L.4113-6 of the Public Health Code.

Especially, it gives pharmacist-managers a central role in the definition and internal control of the promotion of medicines.

Finally, the charter creates a tripartite supervisory committee, containing representatives of doctors, LEEM and the committee.

1.1.2. THE CONTEXT OF USE OF CERTAIN HEALTH PRODUCTS

It is a common occurrence in the field of medical devices for the achievement of the intended result, in terms of the benefit-risk ratio, to depend as much on the conditions under which the device is used as on its actual performance. In its 2002 report, the committee noted that the then rules were unsuited to the creation of such conditions and to making them opposable. This difficulty, in particular, created a long-term obstacle to reimbursements for implantable cardiac defibrillators.

The problem was removed by Article 24 of the Social Security Finance Law for 2004, which completed Article L.165-1 of the Social Security Code. These new provisions allow the use of certain products or services to be subjected to "conditions relating to the method of provision of care or to the qualifications or skills of practitioners in health establishments using these products or providing these services". When such conditions are laid down, they may be applied in one of two ways: either directly, in which case the sickness insurance must monitor compliance with the conditions when the patient is cared for, or by registration, a process entrusted to the directors of regional hospital admission agencies according to the skill and experience of the teams. The establishment provides the right to care on the basis of limited lists "in view in particular of the hospital capacity needed to satisfy the needs of the population as well as their implantation or experience in the field of care concerned".

It was this second way that was chosen for the registration of implantable defibrillators and three-chamber pacemakers.

Article 128 of the Public Health Policy Law dated 9 August 2004 introduces a similar provision for medicines. It alters Article L.162-17 of the Social Security Code and Article L.5123-2 of the Public Health Code by providing the possibility of combining the registration of a medicine with conditions relating to the qualifications and skills of the prescribers, the technical environment or organisation of care, and a method of monitoring patients treated.

1.2 Measures aimed directly at economic regulation

1.2.1. PROMOTING THE GENERICS MARKET

Three significant steps were taken during this period, their common objective being to amplify and speed up the growth of the generics market and therefore make the savings that this growth could provide for sickness insurance.

The first, arising from Article 19 of the LFSS (Social Security Finance Law) for 2004, provides that a marketing authorisation for a generic medicine can be delivered before expiry of the intellectual property rights attached to the reference speciality. This provision puts an end to an abnormal situation in which, in application of Council of State case law, the AFSSAPS was assumed to ensure, before authorising a generic product, that its marketing is not likely to infringe a patent. This was of course a mission impossible for the AFSSAPS which, in order to avoid the risk of being implicated in a counterfeiting process, was reluctant to authorise any generic product for which the owner of the first version asserted any form of right of ownership.

In fact, the marketing of generics for several important molecules was significantly delayed.

Now, the AFSSAPS is judge of equivalence only, while the generic products are marketed under the supervision of their owners, under the control of the patents judge.

The same article provides that inclusion in the substitution list occurs two months after the holder of the original version is notified of the marketing authorisation for the generic product; and the article organises, through the AFSSAPS, availability to the public of the intellectual property rights.

The second measure arises from Article 30 of the Law of 13 August 2004, which extends the definition of "generic" in accordance with the definition given in European legislation, indicating that "the various salts, esters, ethers, isomers, isomer mixtures, complexes or derivatives from the same active principal are considered to be the same active principal, unless they present significantly different properties in terms of safety and efficacy".

This measure may prove decisive in the fight against numerous companies bypassing patent expiry through developing derivatives of molecules already on the market for a long time, often without real additional benefit for patients.

The third measure, the regulatory transcription of which only appeared in the Decree of 18 February 2005, was the reversal, in a July 2004 decree, of a Council of State case law according to which the generication of a new dose of product otherwise genericable could not be made less than ten years after the marketing authorisation for that new dose. Several high-turnover medicines were affected by this prohibition.

According to the new rule, the marketing authorisations issued for changes of dose, form, method of administration, activity, bioavailability or pharmacokinetic properties, as for the introduction of a dose, pharmaceutical form, method of administration or additional activity, are considered to form part of the same overall marketing authorisation. The effect of this concept will be that these extensions to ranges of medicines already authorised will not be the subject of additional data protection periods, and will thus accelerate the marketing of generic versions of these products.

1.2.2. HOSPITAL PRICES

The prices of medicines or medical devices purchased by health establishments are freely negotiated, in accordance with the procurement contracts code where applicable. They remain freely negotiated in principle and in practice in all cases where these purchases are financed from the establishments' resources.

The LFSS for 2004, however, made decisive changes to these rules in order to respond to the abnormal situation that had for a long time faced medicines dispensed by hospital pharmacies to outpatients and charged to the patient's insurer (*rétrocession*), and to deal with the new situation produced by the implementation of DRG-activity tariffs (T2A). One significant aspect of T2A provides that costly medicines or devices included on lists compiled by the Ministry of Health are directly reimbursed by the sickness insurance and do not therefore impinge on the establishments' ordinary resources.

The situation regarding *rétrocession* medicines was in fact unjustifiable, as the hospital purchasers, in the many cases where *rétrocession* represents most of their purchases of a given medicine, were deprived of any incentive to obtain more beneficial prices or attempt to limit volumes, as the sickness insurance reimbursed everything without the possibility of control, and in addition was unable to obtain sufficient information on prices applied elsewhere, especially elsewhere in Europe. As the committee subsequently verified, the result was prices that were sometimes very high in relation to those applied by our near neighbours, as well as quantities not subject to any form of regulation.

Undoubtedly, without the new law, this situation would have recurred for the costly T2A products if they had been reimbursed on invoice.

The law (new Articles L.162-16-5 & L.162-16-6 of the Social Security Code) therefore introduces two parallel mechanisms for fixing prices (for *rétrocession*) or tariffs (for T2A), which constitute limits for reimbursement for medicines by the sickness insurance. The committee publishes these prices on the basis of prices declared by the companies, unless the committee specifically opposes, in which case the price or tariff published is that decided upon by the committee. These prices or tariffs are therefore opposable by the sickness insurance against the health establishments, but not against their suppliers. It may be expected, however, that generally they will be respected.

The law provided that the methods for applying these new mechanisms would be specified in an agreement to be concluded between the pharmaceutical industry representatives and the committee. This agreement, termed the "hospital framework agreement", was signed on 30 March 2004 (see annex 2) and implemented in the same year.

In fact, the draft *retrocession* and T2A lists were published in the Journal Officiel on 28 July 2004 and 22 August 2004, respectively. The "definitive" *rétrocession* list was signed on 17 December 2004. The prices relating to *rétrocession* products were published in the Journal Officiel on 24 December, and the prices relating to T2A list products was published in the Journal Officiel on 31 December 2004.

For applying the T2A to costly medical devices, the provisions adopted by the LFSS did not entail any new activity for the committee, as it was provided that their tariff was the one fixed in the context of their registration in the LPPR.

1.3. The annual financial regulation of medicines

The Law of 13 August 2004 fixes at 1% the K-rate used for calculating the contribution due from companies for 2005, 2006 and 2007.

This exceptional measure, which accompanies the sickness insurance reforms, sets the contribution expected for medicines in order to balance the accounts. In addition to its mechanical bearing on the total rebates payable by the companies, it is a true objective consistent with the steps taken in the context of the medicines plan and with the efforts made to master expenses on the basis of prescription control.

SECTION 2 – THE FUNCTIONING OF THE COMMITTEE

The Law of 13 August 2004 marks a decisive stage in the organisation and function of the committee in the three areas of its position, composition and authority.

At the end of a lively open debate, the law initially reaffirms the position of the committee as a State administrative authority, subject to the directions decided upon by the ministers; it is therefore an instrument of the policy pursued by the Government. This position shows a clear conception of the committee's task within its principal activity of negotiating and fixing prices or tariffs: the purchasers' "representative", called upon as such to seek the most competitive costs for the sickness insurance, and required at the same time to take account of the public health directions decided upon by the State and ensure that the market functions effectively, including, in the context of economic growth within the sector, fulfilling the function of regulator.

The new composition of the committee also makes clear what is expected of it, and thus serves as a pointer. On it, four representatives of the State administrative authorities and four representatives of the compulsory and complementary sickness insurance companies deliberate with equal strength alongside a President and Vice-President in each section. A representative of the hospital directorate and care organisation and a representative of the ministry of research also participate in a consultative capacity; the first illustrates the unity of the market (retail and hospital sales combined) and the medicine or medical devices, and the second illustrates the opportunity to take into account the medium-term and long-term challenges within pharmaceutical research.

The committee's new means of action also illustrate what is undoubtedly the completion of a continuous process of transfer at legal level, from ministers to the committee, of specific decisions for implementing the policy expressed in their directions. This process, initiated in 1993 with the Prime Minister's decision to create the Economic Committee for Medicines, an inter-ministerial negotiation and proposal group then devoid of clear legal powers, saw the law follow the facts quickly and consistently. The committee became an institution as a result of a 1996 law, and price agreements were an official support for ministerial decrees by the 1998 law. The agreements were given direct effect by the 1999 law; and in 2000, the Council of State recognised the committee's capacity to defend its decisions alone. Finally, the Law of 13 August 2004 gave the committee true autonomous regulatory power (reference pricing, unilateral fixing of prices or tariffs in the absence of an agreement), and the power of sanction (breaches of advertising regulations). This makes the committee a very specific part of the French institutional fabric, although it must be remembered that it cannot be considered an independent administrative authority, being subject to the directions issued by the ministers.

PART TWO –MEDICINES

SECTION I – THE REIMBURSABLE MEDICINES MARKET

1. Broad market trends

Although the consequences of the decisions taken during the reform of sickness insurance could not be noticed from 2004, the changes in sales of reimbursed medicines are, from the viewpoint of the CEPS, worrying. They refute the forecast that the CEPS issued, evidently in good faith, in its previous report, concerning the presence of a solid platform of slowing growth.

This growth, taking all pharmacy sales and sales to healthcare establishments together, has in fact reached 6.9%. Compared with 2003 (6.5%) and 2002 (5.7%), the acceleration is greater than anticipated in that 2004, like 2002, did not see any significant epidemics. On the other hand, the December 2003 epidemic accounts for an additional 0.4 growth point in that year.

The situation is more worrisome as this acceleration occurred even though there was very vigorous growth by generics, an important product was withdrawn from the market, and few new medicines with high potential appeared in the recent period.

This poor result is visible in both the retail and hospital sectors. Retail growth (6.2%) exceeded that of 2003, while transfers from hospitals were practically the same and the number of packages prescribed actually fell. This can only be the result of a very significant increase in promotion of the costliest medicines still protected by patents. In hospitals, where the rate of growth has increased to 10% while quantities sold have increased little, the arrival of new medicines explains at most one half of this growth, the remainder being due to increases in prices of medicines already reimbursed.

Total reimbursement expenses came in at €26.33 billion. The increase compared to 2003 (5.7%) is slightly less than the increase in sales because of the degressivity of the distribution mark-ups applied to increasingly costly products. However, the average rate of reimbursement has begun to climb again, following the 2003 drop caused by a number of medicines with low or moderate medical benefit being reduced to a 35% reimbursement rate. The compulsory sickness insurance expenses (all schemes) increased by 6.4% to €19.87 billion. Overall, public medicine expenditure (retail plus hospital) reached €22.7 billion in 2004, a much faster increase than that which would, for the part relating to medicines, have ensured that the overall expenses objective voted by Parliament was met.

Of course the end of the year showed a certain slowing in that growth, but it still cannot be said whether it was linked to the initial measures implementing the reforms. In any case, it still needs to be confirmed and greatly amplified in view of the objectives finalised for 2005.

2. Analysis of retail medicine sales in 2004

2.1. TOTAL SALES

2004 sales at tax-exclusive manufacturer's prices (PFHT) were €16.82 billion, an increase of 6.2% or almost €1 billion compared to 2003 (€15.84 billion). On one side, these increased pharmacy sales are the result of the transfer to retail pharmacies, in the 3rd quarter of 2003, of medicines previously reserved for hospital use. In 2004, these transfers led to an increase of €170 million in retail sales, thus providing a point of growth.

Table 1: Changes in retail sales of reimbursable medicines, 2003-2004

	No. of packs sold (billions)	Sales at tax-exclusive manufacturer prices (billions)	Sales at tax-inclusive public prices (billions)	Average tax-exclusive manufacturer price for one pack (€)	Average tax-inclusive public price for one pack (€)
2003	2.755	15.840	23.197	5.75	8.42
2004	2.722	16.819	24.307	6.18	8.93
Evolution	-1.2%	6.2%	4.8%	7.5%	6.1%

In 2004, the volume of sales measured in numbers of packs sold fell by 1.2%. At a time when the French population is increasing, and this increase is accompanied by an increase in sales volumes in the last few years, 2004 appears to show a real break, with a reduction in volumes sold for the first time. This reduction in sales is however more than offset by a very steep increase in the average prices of packs sold, which in terms of tax-exclusive manufacturer sales have increased by 7.5%, rising from €5.75 in 2003 to €6.18 in 2004. The reduction in sales volumes has therefore been accompanied by a very significant sales shift towards obviously costlier products. This movement, evident now for several years, showed remarkable acceleration in 2004.

Because of the degressivity of the mark-ups, the shift of sales towards continually costlier products has led to a 4.8% increase in sales measured in tax-inclusive public prices (PPTTC), less steep than the 6.2% increase in sales measured in tax-exclusive manufacturer prices (PFHT). The same is true for the average PPTTC increase for a pack of medicine, which increased by 6.1% to €8.93, while the average PFHT increased by 7.5%.

2.2 COMPONENTS OF RETAIL SALES GROWTH

The 6.2% increase in turnover can be broken down into:

- A 0.4% drop in unit prices for packs of medicine, compared to the previous year (price effect)[1].
- A 1.2% reduction in the number of packs sold in 2004 (pack effect).
- A 7.9% rise in the average price of a pack at constant unitary prices (structure effect). This structure effect corresponds to a distortion in the sales structure towards the costliest products, whether there has been a shift of sales towards costlier

[1] The price effect calculation is based on the tax-exclusive prices for products sold in year n and year n-1.

therapeutic categories, or whether there has been, within the same therapeutic class, a movement in consumption towards medicines marketed at higher prices.

Table 2: Components of retail sales growth (tax-exclusive sales)

Year	Price effect	Pack effect	Structure effect	Total growth
2004	**-0.4%**	**-1.2%**	**+7.9%**	**6.2%**
2003	-0.4%	+0.6%	+5.5%	6.1%
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%

In 2004 the structural effect, diminished by the price effect and volume effect that for the first time were both negative, itself explains the increase in sales. The scale and speed of the shift towards the costliest products cannot be explained alone by the arrival of new very costly products (given that in most cases carefully targeted products are involved). This begs the question as to the medical and non-medical reasons for such a shift, including de-reimbursements, alterations to reimbursement rates and their effect on the prescription of better reimbursed products, the impact of promotion, but equally improvements in care of the elderly, and more generally, improvements in medical care through more effective but also costlier pharmaceuticals.

2.3. THE GENERIC MEDICINES MARKET

2.3.1. Trends in generic medicine sales

From 2003-2004, the increase of over 50 million in the number of generic medicine packs sold (see Table 3) was not sufficient to offset the reduction in sales volumes for non-generic medicines.

Table 3: Trends in numbers of packs sold

million packs

	Volumes 2003	Volumes 2004	Change	Rate of change
Generics	311	364	+53	+17.0%
Non-generic	2,444	2,358	-86	-3.5%
Total	2,755	2,722	-33	-1.2%

In 2004, the tax-exclusive turnover of generic medicines was €1.17 billion, an increase of €0.3 billion or 35% compared with the previous year. Turnover in terms of tax-inclusive public prices rose to €1.94 billion.

Table 4: Changes in the generic medicines market in 2004

Units: million packs / Value: million €

	2003*		2004**	
	Units	Value	Units	Value
Retail sales	2,755	15,840	2,722	16,819
non-generics market	2,444	14,969	2,358	15,646

generic groups market	600	2,219	708	3,395
generics market	311	871	364	1,173
Generic groups' share in total market	21.8%	14.0%	26.0%	20.2%
Generics' share in generic groups' market	51.8%	39.3%	51.4%	34.6%
Generics' share in total market	11.3%	5.5%	13.4%	7.0%

* Corresponding to the AFSSAPS generic substitution list published in the JO of 9 January 2004 (decision dated 23 December 2003).
** Corresponding to the AFSSAPS generic substitution list dated 18 January 2005.

From 2003-2004, the average tax-exclusive price of generic packs sold increased from €2.80 to €3.22, a 15% increase, twice the increase observed for medicines as a whole. This increase corresponds to the generication of medicines that are now costlier, but also to the general phenomenon of reductions in sales of the oldest and least costly medicines against sales of more recent and costlier medicines (in this case, medicines recently genericised).

The average mark-up in 2004 was 66% for generic medicines, compared with 43% for non-generic medicines.

Table 5: Generics and non-generics: volumes, prices and mark-ups in 2004

Market	No. of packs (10^6)	Average PFHT (€)	Average PPTTC (€)	Mark-up (€)	Mark-up rate
Generic	364	3.22	5.34	2.12	65.8%
Non-generic	2,358	6.64	9.48	2.84	42.8%
Total	2,722	6.18	8.93	2.75	44.5%

2.3.2. Generic groups with reference pricing (TFR)

The turnover for reference-priced generic groups was €250 million in 2004. Sales of generics that, within these groups, represented less than a quarter of sales when TFR was introduced in October 2003, accounted for almost half of sales in 2004. In this case, the introduction of TFR, despite the alignment at the reference level of most original versions, has not prevented the continued development of generics as manufacturers feared.

2.4. THE PRICE OF MEDICINES IN PHARMACIES

2.4.1. The INSEE price indices

Each year, the INSEE calculates the price indices for reimbursed and non-reimbursed pharmaceuticals.

Table 6: Pharmaceutical price indices

(base 100 in 1998)

Year	Reimbursable products			Non-reimbursable products	
	December	Annual average	Rate of change	December	Annual average
2000	98.2	98.8	-0.7%	105.1	104.7
2001	96.0	97.5	-1.3%	107.7	106.3
2002	95.7	96.0	-1.5%	110.5	109.4
2003	94.6	95.2	-0.8%	116.2	113.3
2004	93.3	93.6	-1.7%	118.0	117.3

Source: INSEE, Monthly Statistical Bulletin, February 2005, No. 2.

Changes in the index, calculated using a constant market (except for new generics) on the basis of public prices, shows a continued downward shift in the tax-inclusive public price (PPTTC) of reimbursable products. This movement increased greatly in 2004 (-1.7%), despite the absence of price reduction measures, through the development of the generic medicines market (now taken into account in the index) and the alignment of original version prices with the reference price level (TFR) within affected generic groups[2].

The INSEE index does not however allow account to be taken of newly registered specialities other than generics, or the movement in consumption towards these generally costlier products. On the other hand, this allows the prices of medicine packs to be examined.

2.4.2. The average price of medicine packs

The average price of "packs" sold is obtained by dividing the annual turnover by the number of units (packs) sold in the same year. It relates to the total products sold within a given year, regardless of their market share. It therefore includes prices and price variations as well as the structural effect.

Table 7: Changes from 1998 to 2004 in the average price of reimbursable medicine packs sold and their mark-ups (1998 = index 100)

	1998	1999	2000	2001	2002	2003	2004
Average PFHT of pack (€)	4.48	4.69	4.98	5.29	5.47	5.75	6.18
Change / year n-1	-	+4.7%	+6.2%	+6.2%	+3.4%	+5.1%	+7.4%
Index (100 in 1998)	100	105	111	118	122	128	138
Average PPTTC of pack (€)	6.60	6.99	7.37	7.87	8.03	8.42	8.93
Change / year n-1	-	+5.9%	+5.4%	+6.8%	+2.0%	+4.8%	+6.1%
Index (100 in 1998)	100	106	112	119	122	128	135
Average mark-up (€)	2.12	2.30	2.39	2.58	2.56	2.67	2.73
Rate of mark-up	47.3%	49.0%	48.0%	48.8%	46.8%	46.4%	44.2%

After the relatively moderate progress shown in 2002, a consequence of the price reductions for insufficient medical benefit (SMR) drugs and the targeted reductions in 2001, the increase in the average price of a pack picked up again in 2003 and in 2004, despite the development of the generics market and the price drop to the reference price level of most original versions in generic groups subject to reference prices and paracetamol products. Because it is degressive, the reduction in mark-ups observed during the last three years, and the magnitude of this reduction, explains the shift in prescriptions towards costlier medicines and possibly towards new medicines sold at significantly higher prices, and an acceleration in this shift, especially in 2004.

[2] The important disparity between the price effect (-0.4%) calculated above (2.2: components of retail sales growth) and the drop in the INSEE price index (-1.7%) can be explained, apart from the fundamental disparity in methods of calculation (calculation based on all PFHTs and quantities sold in one case and summaries of PPTTCs for each survey in the other case), by the fact that the INSEE survey takes account of the arrival of generic products in place of original versions.

2.5 SALES TRENDS ACCORDING TO PHARMACO-THERAPEUTIC CLASS

Table 8: Contribution by classes to sales increases

million €

Class	CAHT 03	CAHT 04	Disparity	Growth
Anti-cancer drugs	379	552	173	45.7%
Statins	947	1,078	132	13.9%
ACE-inhibitors & sartans	1,021	1,117	96	9.5%
Platelet anti-coagulants	345	419	74	21.4%
Proton pump inhibitors	945	1,012	67	7.1%
Immunosuppressants	78	143	65	82.6%
Medicines for osteoporosis	194	258	64	32.9%
Anti-diabetics	412	468	56	13.5%
HIV and hepatitis drugs	251	301	50	19.8%
Vaccines	213	257	44	20.6%
Total	4,785	5,604	820	16.4%

This table contains the ten classes or groups of classes[3] for which the difference in tax-exclusive turnover (CAHT) was greatest compared to 2003. They are shown in the table in decreasing order according to magnitude of difference. The steep increase in anti-cancer drug sales is noticeable. On the other hand, the inclusion of immunosuppressants is artificial and provisional as it results from the transfer of two high-turnover medicines to the retail sector.

The average growth of these classes, which represent one third of the global market, is 17.1%.

In contrast, the most significant reductions were, as in 2003, in gynaecological products (G02 & G03: -€53 million), anti-rheumatic drugs (M01 & M04: -€43 million), cough medicines and all nootropic-vasodilators. Sales of antibiotics continue to decrease, but considerably less steeply than in previous years (-2.5% in 2004 compared with –7.6% in 2003).

3. Hospital medicine purchasing

From a total of €3.66 billion in 2002, hospital purchases increased by 7.6% in 2003, reaching €3.94 billion. Data available for 2004 for a significant portion of these medicines show a growth of approximately 10% between 2003 and 2004. If one assumes that the data represent all hospital purchases, total hospital purchases for 2004 can be estimated at €4.33 billion. According to the same series of data, the increase in volumes purchased by hospitals will be 1.8% from 2003 to 2004.

The comparison of these two figures suggests an average increase of over 8% in the price of units sold in hospitals in 2004. This increase may be the result of a rise in prices negotiated in the context of contracts concluded by hospitals just before the DRG-activity tariff was set, but may also be caused by a movement towards higher priced products in hospital purchases.

In 2003, transfers from hospital usage only status, which showed up as an increase quantified as 1% of the increase in retail sales, led to a sharp reduction in the increase in hospital sales, to 8% compared with 18% in 2002. In 2004, despite a reduction in hospital expenses identical

[3] These groups are shown in Annex 5 in the table of rebate trigger thresholds for each group.

to that of the previous year, an increase in the rate of growth of hospital purchases, which increased from 8% to 10%, was noted.

4. Expenses reimbursed by compulsory sickness insurance

Compulsory sickness insurance reimburses medicines sold in retail pharmacies on the basis of their tax-inclusive public price (PPTTC), and for medicines dispensed by hospitals to out-patients (*rétrocession*) on the basis of their transfer price, when they are prescribed by a duly authorised health professional and presented for reimbursement.

Compulsory sickness insurance reimbursements depend on total medicine sales and the allocation of these sales according to the theoretical reimbursement rates of 35%, 65% and 100%, the relative importance of hospital *rétrocession* (100% reimbursed) and sales without co-payments, especially in cases of long-term conditions (ALD) for which prescribed medicines are 100% reimbursed. Compulsory sickness insurance reimbursements also depend on the submission of these tax-inclusive sales for reimbursement. It can be supposed that the rate of reimbursement will be higher for the costlier or better-reimbursed sales and likely to have increased in recent times with the rate of automation of reimbursement procedures, which is now approaching 100%.

4.1. TAX-INCLUSIVE SALES (TTC)

Between 2003 and 2004, tax-inclusive sales of medicines in retail pharmacies increased 4.8%, compared with 6.2% for tax-exclusive sales. This lesser increase in tax-inclusive sales is the result of the full-year effect in 2004 of the introduction of reference prices (TFR) during 2003 and therefore of the drop in mark-ups applicable to affected generic products and of the increase in sales volumes for the costliest products combined with degressive mark-ups.

As the costliest medicines are mostly better reimbursed, the movement in consumption towards the costliest products accompanied an increase in totals theoretically reimbursable through sickness insurance. In this way, while tax-inclusive sales increased by 4.8%, rising from €23.2 billion to €24.3 billion, the total theoretical reimbursements through sickness insurance increased more quickly, by 5.6% from €14 billion to €14.8 billion.

Table 9: Allocation of tax-inclusive turnover according to theoretical medicine reimbursement rates (retail pharmacy sales)

(billion euros)

	2003			2004		
Rate	Tax-inc. sales	Theoretical reimbursements	Share of reimbursements*	Tax-inc. sales	Theoretical reimbursements	Share of reimbursements*
35%	4.66	1.63	7.0%	4.80	1.68	6.9%
65%	17.69	11.50	49.5%	18.32	11.91	49.0%
100%	0.88	0.88	3.8%	1.19	1.19	4.9%
Total	23.23	14.01	60.3%	24.31	14.78	60.8%

* Compared with total tax-inclusive sales

Between 2003 and 2004, despite reductions in reimbursement rates and their full-year effect, because of the de-reimbursement measures taken in 2003 (and their full-year effect in 2004), but particularly because of the changes in sales of the best-reimbursed and costliest medicines, there is a sharp increase in tax-inclusive turnover for 100%-reimbursed products and their share in the reimbursements.

Overall, the theoretical rate of reimbursement for retail pharmacy sales increased from 60.3% in 2003 to 60.8% in 2004. This increase will only have an effect on reimbursement for sales with a patient co-payment, other sales being 100% reimbursed. This increase therefore only partly explains the increase in effective reimbursement rates, which increased from 75% to 75.5% between 2003 and 2004.

4.2. SICKNESS INSURANCE REIMBURSEMENTS

Expenses reimbursed by the three main health insurance funds (CANAM, CNAMTS and MSA) accounted for a little over 95% of the corresponding expenses for all the health insurance funds in 2004. The following table shows the changes between 2003 and 2004 for medicine expenses in all three funds, and the assessed expenses for all health insurance funds for 2004.

Table 10: Compulsory sickness insurance expenses

(million €)

	Amount reimbursable	Amount reimbursed	Effective rate of reimbursement
2003: CANAM, CNAMTS & MSA	23,660	17,754	75.0%
All health insurance funds – 2003 assessment	24,905	18,688	
2004: CANAM, CNAMTS & MSA	25,014	18,885	75.5%
All health insurance funds – 2004 assessment	26,330	19,879	
Rate of change, 2003-2004	5.7%	6.4%	0.7%

The average effective rate of reimbursement is equal to the ratio between reimbursements made and the PPTTC or *rétrocession* price value of medicines presented for reimbursement. The average effective rate of reimbursement rose from 75% in 2003 to 75.5% in 2004.

4.3. OVERALL ANALYSIS OF COMPULSORY SICKNESS INSURANCE REIMBURSEMENTS

A comparison of Tables 9 and 10 (see Table 11) suggests that the disparity between the reimbursable total in the table corresponding to total reimbursed medicine costs (pharmacy sales and hospital *rétrocession*), and the tax-inclusive sales in the other table corresponding to retail pharmacy sales only, is due to the 100% reimbursed hospital *rétrocession*. The total sales and reimbursements relative to *rétrocession*, according to this comparison, would be €1.68 billion in 2003 and €2.02 billion in 2004, that is, an increase of 20%.

Table 11: *Rétrocession* and 100% reimbursed sales to patients

(billion €)

	2003	2004	Change
1. Total reimbursable (Table 10)	24.91	26.33	5.7%

2. - tax-inclusive pharmacy sales (Table 9)	23.23	24.31	4.6%
3. - *rétrocession* (3 = 1 – 2)	1.68	2.02	20.2%
4. Total reimbursed (Table 10)	18.69	19.88	6.4%
5. - *rétrocession* (5 = 3 = 1 – 2)	1.68	2.02	20.2%
6. – retail pharmacy sales (6 = 4 – 5)	17.01	17.86	5.0%
7. Effective reimbursement rate for retail pharmacy sales (7 = 6 / 2)	73.2%	73.5%	0.3%
8. Theoretical rate of reimbursement for retail pharmacy sales (Table 9)	60.3%	60.8%	0.8%
9. Share of reimbursements for 100% reimbursed patients*	49.4%	49.7%	0.4%
10. Effective average reimbursement rate (10 = 4 / 1)	75.0%	75.5%	0.8%

* Including hospital *rétrocession*

At the same time, if one deducts the reimbursements allocated to hospital *rétrocession* from the total reimbursements, the total obtained is reimbursements made for retail pharmacy sales, €17.01 billion in 2003 and €17.86 billion in 2004, or a tax-inclusive retail pharmacy sales reimbursement rate of 73.2% in 2003 and 73.5% in 2004. Comparison of these two figures with the rate of reimbursement in Table 9 allows calculation of the share of reimbursements for hospital *rétrocession* in relation to 100%-reimbursed patients. According to this calculation, about half of the reimbursements, 49.4% in 2003 and 49.7% in 2004, were made for patients who, in one way or another, are 100% reimbursed.

In 2004, on average, each resident spent a tax-inclusive total of €400 in retail pharmacies, on 45 reimbursable packs of medicine. This total included 6 packs of generic medicines at an average tax-inclusive price of €5.3 per pack and 39 packs of non-generic products at an average of €9.5. These medicines submitted for reimbursement, and those purchased by out-patients from hospital pharmacies (rétrocession) for an estimated total of €33 per resident, gave rise to compulsory sickness insurance reimbursements of €327 per resident.

SECTION II – REGULATION IN 2004

1. Annual regulation methods

In accordance with the framework agreement, regulation in 2004 was conducted under conditions identical in every respect to those applied in 2003. The committee therefore makes reference to its previous report for the details.

The only alteration is to the rate triggering group rebates, set at 30% compared with 28% in 2003 because of potential changes in sales leading to a higher safeguard contribution than in the previous year.

2. Annual regulation schedule

2.1. SIGNATORY COMPANIES

174 of the 180 companies that operated in the retail market in 2004 registered with the conventional safeguard contribution exemption system. In this respect, they were able to benefit from the provisions of Article L.138-10 of the Social Security Code, which states that companies who conclude with the CEPS an agreement still in force on 31 December of the year during which the contribution is due are exempt from paying the contribution. It is also within the framework of this conventional system that the signatory companies have benefited from the steps provided in the framework agreement for reducing the quantitative rebates at the end of the year.

Six companies did not sign an agreement. These were small companies, three of which had ceased commercialising reimbursable medicines from before the end of 2004. In the conventional framework, these companies were required to pay a rebate of €51,000.

The total turnover not taken into account within the conventions regulation was €2.7 million, that is, less than 2/10,000 of retail reimbursable medicine sales.

In 2004, the system with a ceiling of 1% of turnover for quantitative rebates at the end of the year was applied to 84 companies whose expected turnover was less than €10 million.

2.2. FINANCIAL RESULTS

Total rebates paid to ACOSS by drug companies in relation to 2004 were €349 million.

This sum is net of the useable rebate credits available to the companies and totalling €95 million, mainly in relation to credits acquired previously and used to the tune of €32 million by 82 companies.

It combines the year-end quantitative rebates and product-specific rebates, although it is not possible to divide between what relates to which rebate within the overall total. In fact, neither the non-differentiated allocation of rebates as a deduction of part or all of the year-end rebates or specific rebates, nor the impact of the deductions of specific rebates on year-end quantitative rebates, allows any significant breakdown of rebates to be presented.

As well as these rebates, there were €60 million of price reductions (full year value), with an effect of €24 million in 2004.

As a reminder, the 2004 safeguard contribution would have been €296 million.

3. Launch of medicines plan

As an accompaniment to the sickness insurance reforms, the ministers decided on a savings plan, the implementation of much of which is down to the committee.

From 2004, therefore, the committee started initial discussions with companies in order to define with them a timetable for reducing some of their patented product prices.

At the request of the ministers, a generic products surveillance committee was created and met for the first time in October 2004. This committee brings together, as members, representatives from retail pharmacies and wholesalers, LEEM and generics manufacturers. It set itself the task of putting together a system, common to all participants, for measuring trends in the generics market and the total savings made. It is also within this framework that the criteria for establishing the TFR, and the application of those criteria, were discussed.

SECTION III – PRICING OF MEDICINES

The fundamental task of the CEPS is to determine the price of reimbursable medicines sold in retail pharmacies and, since the reforms introduced by the Social Security Finance Law for 2004, the prices of medicines to hospitals. This task is traced through an examination of the methods applied by the committee to fix the prices, and through measurement and analysis of the committee's activity in relation to the fixing of prices of medicines sold by retailers and in hospitals.

1. Methods of pricing medicines

1.1. PRICING OF MEDICINES AVAILABLE IN RETAIL PHARMACIES

The alterations to the committee's composition and decision-making power, introduced by the Law of 13 August 2004 and the decree of 17 November 2004, did not become applicable until 1 December 2004, the date on which the decree nominating the President of the CEPS was published. During the last month of the year, and with regard to the pricing of medicines sold in retail pharmacies, the committee was not called upon to exercise its new decision-making powers. During December, as in previous months, the cost of medicines sold in retail outlets was fixed in the usual manner, using methods identical to those applied in the previous year. The presentation of these methods, as detailed in the previous annual report, is reproduced in Annex 4.

1.2. DETERMINING PRICES AND TARIFFS FOR HOSPITALS

Within the field and on the bases defined by the Social Security Finance Law for 2004 and the Law of 13 August 2004 concerning sickness insurance, the hospital drug sector framework agreement concluded between the CEPS and the Drug Companies (LEEM) now sets out the procedures, formats and conditions for fixing and revising the transfer prices of medicines on the hospital *rétrocession* list and the liability tariffs for products on the T2A list.

1.2.1. Social security code criteria

Articles L.162-16-5 of the Social Security Code relating to *rétrocession* medicines, and L. 162-16-6 relating to T2A list medicines, specify that the fixing of transfer prices for *rétrocession* medicines, or of the maximum reimbursement price for medicines invoiced in addition to hospital stay costs, principally takes account of: the sales prices applied to the

product, the sales prices of medicines with the same therapeutic aim, predicted or observed sales volumes, the foreseeable or actual conditions under which the product is used, and the product's improvement in medical benefit as assessed by the Transparency Commission.

1.2.2. Criteria for hospital drug sector framework agreement

In application of the above-mentioned Social Security Code articles, Article 4 of the framework agreement of 30 March 2004 concerning medicine in hospitals sets out the criteria for opposition by the committee to the price declared by the company.

Opposition may be based on the unusually high level of the price proposed in relation to prices applied in the main European Union Member States, or when there is already a market for directly comparable products in France, in relation to prices observed on that market. It may also be based on insufficient commitment by the company if the price declared is justified only for some of the indications in the marketing authorisation and the quantities sold incur abnormally high expenditure for the compulsory sickness insurance, or if, in view of market conditions, inclusion of the medicine at the price level declared by the company on one or other of the lists generates sales volumes that call for bulk rebates.

1.2.3. Committee practices

Acceptance or opposition by the committee of the price declared by the company is therefore based on one or another of the criteria in the Social Security Code or in the framework agreement, or by a combination of these different criteria.

For all the products under consideration, the committee was principally called on to examine two sets of information. One was obtained from the processing of tax declarations sent by companies, allowing volumes sold in health establishments, average prices applied and trends in prices and volumes to be determined for recent years. The other, obtained abroad and principally from the main European "administrations", relates to the prices and sometimes the sales of some of these medicines. It is therefore on the basis of comparison of this information and the company declarations that the committee issued its pronouncement. The committee also drew on the consequences of the fact that inclusion on the T2A list could constitute a development factor in the sales of the products under consideration. Finally, it paid particular attention to avoiding any price disparities within the various groups of substitutable medicines.

- Reference to European prices

Paradoxically, this reference, adopted to guarantee companies commercialising recent innovations prices no lower than those applied elsewhere in Europe, has frequently been a reason for opposition to prices declared by the companies. In quite numerous cases, the committee noticed that prices hitherto applied in relation to French health establishments, or declared for this purpose, were higher than all other European prices, even when the quantities sold in France were often higher than elsewhere in proportion to population. Exceptionally, this reference led the committee to accept declared prices higher than those applied in France when it appeared, for essential medicines, that French prices were significantly lower than most other European prices.

- Reference to the market

Generally speaking, the committee considered that there was no justification for this new procedure constituting an opportunity for fixing prices at levels higher than those hitherto applied in France in a context of "freedom of price". Noticing in addition that the price of many medicines increased significantly in 2003 and 2004, it frequently opposed the corresponding declarations in order to return to 2003 levels.

Two particular situations need to be pointed out.

The first is that of "double circuit" products, which can be acquired by patients either through hospital pharmacies or through retail pharmacies. These are, in fact, hepatitis C and HIV drugs. For these products, the CEPS judged that the prices conventionally negotiated for sales in retail pharmacies, invariably fixed with reference to European prices, must be applied without an increase in hospitals.

The second is that of largely substitutable products included on the T2A list, and for which any difference with the price accepted by the committee would lead the companies to grant higher rebates on the basis of the higher prices from which they benefited and would lead hospital purchasers to "buy rebates", thus distorting the competition and providing a form of subsidy for the health establishments, indirectly paid by the compulsory sickness insurance. Based on this hypothesis of price difference, the committee was forced into deciding to homogenise maximum prices within each substitutable product group.

More generally, the committee considers that the difference between the tariff reimbursed by the sickness insurance and the price actually paid by the health establishments should be limited to the standard price disparities applied according to volume purchases or specific services that can be rendered to sellers.

2. Fixing prices in 2004

2.1. FIXING PRICES OF REIMBURSABLE MEDICINES SOLD IN RETAIL PHARMACIES

Analysis of activity in 2004 leads to a census, according to their characteristics, of the dossiers sent, examined and processed by the committee and the time taken to process them. This examination provides an opportunity to review the first figures for use of the price notifications procedure.

2.1.1. Census

2.1.1.1. Applications submitted to the committee in 2004

In terms of presentation numbers, 1,609 applications were lodged with the committee between 1 January and 31 December 2004. This is an increase of 33% compared with the previous year, due mainly to the resumption of re-registrations following the interruption caused by the extension of the re-registration period to five years in 1999.

Table 12: Number of dossiers submitted in 2004 *(number of presentations)*

	First registration	Re-registration	Price alteration	Extension of indication	Total
Dossiers	407 *(700)*	277 *(590)*	113 *(222)*	39 *(97)*	836 *(1,609)*
Including generic dossiers	211 *(290)*	140 *(231)*	64 *(129)*	1 *(1)*	416 *(651)*
Number of companies	91	79	54	25	140

The number of first registration dossiers increased by about 9% over 2003, while the number of price alteration or extension of indication dossiers decreased very slightly. Dossiers corresponding to generic medicines accounted for one half of all dossiers submitted.

2.1.1.2. Dossiers closed in 2004

In 2004, 492 dossiers corresponding to 793 different presentations were concluded, whether they led to an agreement between the company and the committee with a subsequent insertion in the *Journal Officiel*, or were rejected or abandoned.

Table 13: Number of dossiers concluded in 2004 according to nature of application and decision *(number of presentations)*

	First registration	Re-registration	Price alteration	Extension of indication	Total
Accepted	323 *(492)*	38 *(62)*	47 *(93)*	28 *(48)*	436 *(695)*
Abandoned	15 *(21)*	3 *(3)*	3 *(8)*	3 *(4)*	24 *(31)*
Rejected	9 *(13)*	-	21 *(43)*	2 *(6)*	32 *(59)*
Total	347 *(526)*	41 *(65)*	71 *(144)*	33 *(58)*	492 *(793)*

The 492 dossiers processed by the committee in 2004 correspond to 108 different companies, or 60% of the companies operating on the French market.

2.1.1.3. Applications not concluded at end of year

The flow of "outgoes", consisting of applications concluded during 2004, totalled 492 dossiers and is comparable with the flow of dossiers submitted during the same year, namely 836 applications. The disparity between these two figures, namely 344, brings about an increase in the number of dossiers not yet concluded, totalling 559 dossiers and corresponding to 1,128 presentations.

Table 14: Allocation of dossiers not yet concluded, and time since submission, on 31.12.2004

	First registration	Re-registration	Price alteration	Extension of indication	Total
No. of dossiers	217	233	78	31	559
No. of presentations	445	532	159	82	1218
No. of days since submission	131	91	54	188	108

At the end of 2004:

- 231 of these dossiers had already been examined at least once during a committee sitting. For 119 of them, the decision had been communicated to the company. For more than half of them, the corresponding agreed prices were awaiting publication.

- 127 dossiers currently before the committee had not yet been examined at a committee sitting. For 38 of them, the committee already had advice from the Transparency Commission. The other 99 dossiers, relating to generic medicines or to price alterations, did not require examination by the Commission.

- 201 dossiers still had not been examined by the Transparency Commission.

Table 15: Number of dossiers currently before the CEPS and the Transparency Commission

	Examined by CEPS		CEPS sittings			CT sitting	Total
	Decided	Examined	Examined by CT	Generic	Other		
Registrations	30	45	20	44		78	217
Re-registrations	54	19	14	39		107	233
Alterations	35	37		3	3		78
Extensions	0	11	4	0		16	31
Sub-total	119	112	38	86	3	201	559
Total	231		124			201	559

2.1.2. Dossier processing times

Article R.163-7-I specifies that for a medicine to be registered "the decisions (…) must be taken and notified to the company commercialising the medicine, within a period of 180 days from the receipt of the application (…). The inclusion of the medicine on the list, and its determined price, shall be published in the Journal Officiel within this period". With regard to price alteration applications lodged by companies, the committee must make a decision within 90 days.

The following presentation analyses, according to the nature of the applications and the decisions taken by the committee, the time taken to process the dossiers from the time of their submission to the publication of a decree or advice in the Journal Officiel where applicable (abandoned or rejected dossiers are not published in the JO). It therefore analyses the time taken by the committee to process the applications and the time taken by the Transparency Commission to analyse the dossier.

2.1.2.1. Total time taken

a) Total time taken according to type of application

The average time taken to process the 492 dossiers concluded in 2004 was 154 days, compared with an average of 216 in 2003. The reasons for this very rapid improvement in the average time taken to process dossiers can be described as mechanical, having to do with the number and proportion of generic medicine dossiers processed and with the consequences of the resorption of the dossier stock awaiting processing during 2003. On the other hand, the time taken by the committee and the Transparency Commission to deal with them has improved.

The increase in the proportion of generic medicine dossiers not requiring examination by the Transparency Commission has allowed the (theoretical) time taken to examine the registration dossiers to be reduced by half.

In recent years, the presence of a significant number of dossiers currently being processed led the committee to process a large number of dossiers previously lodged; this meant that the

average time taken to process them was high. The resorption of much of this dossier stock in 2002 and 2003, combined with the absence of re-registration dossiers (because the re-registration period was extended to five years), led to an increase in the observed dossier processing time during these years. 2004, however, started with a reduced dossier stock, most of them recently submitted.

The following table, which also sets out the number of dossiers according to application category and type of decision taken by the committee (no.), shows the average time taken as observed in 2004, in numbers of days.

Table 16: Average time taken to process dossiers according to application category

(no. of days)

	Abandoned		Rejected		Approved		Total	
Type of dossier	No.*	**Time**	No.*	**Time**	No.*	**Time**	No.*	**Time**
First registration	15	**264**	9	**146**	323	**148**	347	**152**
Re-registration	3	**28**	-	**-**	38	**122**	41	**115**
Price alteration	3	**333**	21	**64**	47	**175**	71	**149**
Indication extension	3	**321**	2	**153**	28	**231**	33	**234**
Total	24	**250**	32	**93**	436	**153**	492	**154**

* No. of dossiers processed

The committee deems a dossier to have been abandoned either when the company clearly withdraws its application or when the company, after not accepting the committee's proposal, takes too long to state its case. This method of classification can therefore lead to significant delays, without consequence.

With regard to rejections, the legal consequences of which are more significant, the observed average time taken is shorter, generally less than 180 days and less than 90 days for price alteration applications. However, two first registration dossiers were rejected after the 180-day limit and one price alteration dossier was rejected after 90 days.

With regard to the other cases, those where the committee and company reached agreement, deadlines were frequently exceeded, as with first registrations, for which the total number of dossiers beyond 180 days was 82 (or 46%). The proportion for applications for extensions of indication was 64%.

The average time taken in relation to price alterations, shown in Table 14, includes three dossiers that took over three years. If these three atypical dossiers are not taken into account, however, the average total time taken is 109 days and the average agreement period 115 days. The number of price alteration dossiers leading to a publication in the Journal Officiel after the 90-day period is one half of the dossier total. Two remarks, however, need to be made. Firstly, the agreement between the committee and the company was reached before the 90-day deadline in two thirds of cases. Secondly, a high proportion of price alteration dossiers were opened at the request of the committee and corresponded to price reductions, for which limiting the conclusion deadline to 90 days would hardly be of any significance. The three atypical dossiers, mentioned above, are in this category. Dossiers opened on the committee's initiative account for 30% of price alteration dossiers.

b) Total time taken according to type of medicine

As generic medicines are very rarely, if ever, examined by the Transparency Commission before the committee fixes their price, the time taken to process the corresponding dossiers is reduced accordingly. In addition, the absence of negotiations on prices, given that the price proposed is 40% less than the original version price, further reduces the time taken to process these dossiers compared to the non-generic medicine dossiers.

Table 17: Average time taken according to type of medicine and application

	Generic		Non-generic		Total	
Type of application	No. of dossiers	**Average time**	No. of dossiers	**Average time**	No. of dossiers	**Average time**
First registration	215	**93**	132	**250**	347	**153**
Re-registration	37	**108**	4	**212**	41	**118**
Price alteration*	18	**114**	53	**161**	71	**149**
Extension of indication	1	**135**	32	**238**	33	**235**
Total	271	**97**	221	**226**	492	**155**

* Not taking account of the atypical dossiers mentioned above would reduce the time to 79 days for generic medicines, 119 days for non-generic medicines and 109 days for all price alterations.

Generic medicine dossiers concluded in 2004 were processed in 97 days on average. The time taken to process non-generic medicine dossiers was more than twice as long. The disparity between the two categories of medicine is particularly significant for first registrations.

2.1.2.2. Analysis of first registration times

The 347 first registration dossiers concluded in 2004 included 9 rejections (including 5 for generic medicines), notified within an average period of 146 days after the application was lodged, 15 abandoned dossiers (including 5 for generic medicines) observed within an average of 264 days, and 323 dossiers (including 205 for generic medicines and 118 for non-generic medicines) leading to the publication of an agreed price in the Journal Officiel within an average of 147 days. The analysis of the intermediate times will relate exclusively to the first registration applications leading to a publication in the Journal Officiel, with applications relating to generic medicines being distinguished within the whole. The intermediate times observed for the price notification procedures shall be subjected to a specific examination.

a) Intermediate first registration times according to type of medicine

The average time taken to process first registrations leading to a publication in the Journal Officiel showed a marked improvement compared to 2003, falling from over 160 days to 147 days. The reduction in times for both categories of medicine examined, and for almost all the intermediate times, is particularly noticeable in the time taken to examine non-generic medicine dossiers; this time fell by 10% overall, from 282 days in 2003 to 253 days in 2002. This reduction is the result of the speeding-up of the registration procedures provided for in the framework agreement, and of the use of the price notification procedure in 5% of cases in 2004.

Table 18: Intermediate times taken to process first registration applications according to type of medicine

(no. of days)

Medicine	CT	Inspection	Negotiation	Approval	JO	Total
Non-generic	109	42	42	21	39	**253**

Generic	(75*)	23***	2	23	39	**87**
Total	**(40**)**	**30**	**16**	**22**	**39**	**147**

* The average is calculated for the 8 generic medicine dossiers examined by the CT because their packaging was different from that of the original version.
** Not significant: 197 generic medicine dossiers were not examined by the CT.
*** For generic medicines, the time included is the time between the submission of the application and its first examination during a committee sitting.

b) Analysis of intermediate times during first registrations

The total time taken to process a first registration dossier has been divided into 5 phases: from the submission of the dossier, to the sending of the Transparency Commission's advice to the committee; from the sending of the advice to the first sitting of the committee (Inspection); from the committee's first sitting to its last sitting on the same dossier (Negotiation); from the last sitting to the signature of the approved agreement (Approval); and from the signature of the approval amendment by both parties to publication of the registration decree and price advice in Journal Officiel (JO).

First phase: Transparency Commission

Dossiers must be simultaneously lodged with the CEPS and the Transparency Commission. This first phase involves examination of the application by the Transparency Commission and the sending of its advice to the committee. Only in exceptional circumstances does the examination relate to non-generic medicines. For non-generic medicines, on average, the committee receives the Transparency Commission's advice 109 days after the dossier is lodged.

In 2004, eight medicines with packaging different from that of the original version were the subject of Transparency Commission advice. On average, this advice was sent to the committee 75 days after the dossier was submitted.

In 2004 there was a significant reduction in the time taken to complete the inspection and forward[4] the Transparency Commission's advice.

Second phase: Inspection by rapporteurs

For non-generic medicines, this phase, which extends from the date when the committee receives the commission's advice to when the presentation is first examined during a committee sitting. It includes inspection of the dossier by the *rapporteur* in liaison with the company, and the time taken to achieve inclusion in the committee's agenda (at least one clear week after the report is sent to the committee members) averaged 42 days (46 in 2003).

With regard to generic medicines, in view of the small number of dossiers submitted to the Transparency Commission, this phase is deemed to correspond to the period between the dossier's submission and its first examination at a committee sitting. In 2004, this period averaged 23 days for generic medicines (28 in 2003).

Third phase: Negotiation

The time between the first and last examination at a committee sitting corresponds to the time

[4] For non-generic medicines registered in 2004, the committee's definitive advice was, on average, issued 92 days after the registration dossier was submitted. On average, the advices sent to the committee in 2004 were sent 18 days after the commission had issued its definitive judgement.

needed for the committee to fine-tune its proposal if it is not finalised in a single sitting, and to a phase of negotiation between the committee and the company. When the company rejects the committee's proposal, an examination of its counter-proposals, following discussions with the *rapporteur*, is involved. The time taken, observed in 2004, was a mere 2 days for generic medicines (7 days in 2003), but averaged 42 days for non-generic medicines, an improvement of 3 days compared with 2003.

44% of registration application dossiers for non-generic medicines led to more than one examination at sittings. On average, each non-generic medicine required 2.1 examinations during sittings. Only 4% of generic medicine dossiers underwent more than one examination.

This third phase of negotiation with the company is only formally dissociated from the following phase, which also includes a final series of negotiations on the precise terms of the price agreement and its acceptance by the company.

Fourth phase: Approval

This is the period between the committee's last sitting on a specific dossier and the signature of the corresponding price agreement. It includes not only the time taken to further perfect the agreement, which may involve several exchanges between committee and company, but also the logistical time needed to obtain both parties' signatures. In addition, the duration of this phase may depend upon the urgency perceived by the company with regard to the commercialisation of its product and therefore the time taken to obtain the signature of the agreement. The fourth phase, in fact, includes a final negotiation time that is difficult to dissociate from the logistical period. On average, this period lasts 22 days.

Fifth phase: Signature and publication in JO

This last phase includes the preparation and signature by the committee of the agreed prices and of the decrees concerning registration for reimbursement by the appropriate health ministry directorates, and sending of the registration decrees and agreed prices to the government's secretariat-general for publication in the JO. This period, now slightly shortened, averaged 39 days in 2004.

2.1.3. Price notifications - schedule

The framework agreement of 13 June 2003 provides, after 18 months of implementation, namely at the end of 2004, for the compilation of a price notification procedure schedule. The following presentation shows the elements of this schedule, with activity relating to 2004 distinguished.

Following the first and only price notification dossier concerning an ASMR2 product, sent to the committee in 2003 and registered in accordance with the framework agreement procedure, 7 companies applied, in relation to 8 ASMR3 medicines, to benefit from the price notification procedure in 2004. Two thirds (6/9) of the requests correspond to medicines with European marketing authorisations.

Only for a portion, about half, of the products that could have previously benefited from such a procedure, was an application submitted.

For 2 applications, the committee had to reject the price notification application. On average, the refusal was notified within 12 days of receipt of the letter of application. In one case, the combination of restructuring and transfer of the product concerned did not allow the future

transferee to benefit from the capacity of operator in order to lodge its application less than one month after the Transparency Commission's advice. Its request was therefore considered inadmissible by the committee. In the second case, the hypothesis of a turnover in excess of €40 million in the third year could not be dismissed, in view of the target population estimated by the Transparency Commission. In both cases, these dossiers were inspected according to the standard procedure, but within periods of time very similar to those provided for the price notification procedure.

For other price notifications, publication in the JO occurred within an average of 60 days from receipt of the notification letter, if one deducts the neutralised period of three clear weeks (in two cases including that of 2003), in accordance with the framework agreement.

The following table provides a comparison, in terms of time taken, between the price notification for all registrations, the times taken between the sending of the commission's advice, and publication in the JO.

Table 19: Price notification times (number of days)

	Inspection	Negotiation	Approval	JO	Total
Price notification	16 + 7	3	10	41	76
Total	31	42	21	39	133

For price notifications, the "inspection" phase is broken down into two parts. The first (16 days) corresponds to the period between the sending of the Transparency Commission's advice to the company and the sending of the price notification application to the committee (with neutralised periods deducted). The second (7 days), corresponds to the average period between receipt of the price notification application by the committee and the first examination of the application at a sitting. Overall, the duration of this phase is one quarter less for price notification. On average, the price notification application will be examined at a sitting less than one week after being sent. The need to inform the committee members beforehand implies that the corresponding definitive advices will be sent as soon as possible, and that committee will anticipate or be informed beforehand by the company on the likelihood of a price notification application for the product concerned.

On three occasions, the committee examined the price notification application in two stages, one week apart. The other applications only required one examination at a sitting. On average, therefore, the "negotiation phase" is very brief, averaging 3 days compared with 42 for all registrations.

The logistical inconveniences of the last phase of signature and publication in the JO are the same, regardless of procedure, and therefore require almost identical periods.

2.2. PRICES AND TARIFFS FOR HOSPITALS

The draft list of products transferable by hospitals, termed the "*liste rétrocession*", was published in the Journal Officiel on 28 July 2004. The draft list of pharmaceuticals (mentioned in Article L.162-22-7 of the Social Security Code) dispensed to in-patients and liable for reimbursement in addition to hospital costs, called the "T2A list", was published in the JO on 22 August 2004.

After these publications, in accordance with the procedure specified in the hospital medicine framework agreement of 30 March 2004, the committee received price declarations from 55 companies in relation to 445 product lines. After discussions with the companies on the subject of their declarations, the committee published the medicine prices for the definitive "*liste rétrocession*" covered by the decree of 17 December 2004 in the Journal Officiel on 24 December 2004. The prices of the "T2A list" products were published on 31 December 2004.

Uncertainty over hospital mark-ups for products on the "*liste rétrocession*" precluded the fixing of a public price, as did the diversity of VAT regimes relating to the T2A list products, which prevented the fixing of maximum reimbursement public prices. All prices are therefore expressed at the manufacturer's selling price level.

The two lists were both divided into two sub-lists. One showing the prices declared by the commercialising companies and accepted by the committee, with the other corresponding to the prices (bases of calculation) decided by the committee, either after definitive opposition to the price declared by the company or in the absence of declaration for products that were nevertheless included on the lists.

2.2.1. Rétrocession list prices

32 companies are affected by the "*liste rétrocession*". On the one hand, this list contains 47 products spread over 125 product lines for which the CEPS accepted the prices declared by the companies. On the other hand, it contains 33 products spread over 111 product lines whose prices were decided by the CEPS, either after definitive opposition by the committee to the price declared by the company or in the absence of declaration by the company, or when the medicines concerned can be dispensed in retail and hospital outlets and are the subject of an agreed retail price accepted by the committee as a basis for calculating the transfer price. If the 15 products on the double circuit are removed, the number of products whose price (basis of calculation) is decided by the committee is only 18.

2.2.2. T2A list tariffs

36 companies were affected by the T2A list. For 46 products, that is 110 product lines, the CEPS accepted the health establishment sale prices declared by the companies. These prices correspond to the maximum reimbursement price. The committee decided the bases of calculation for 42 products, that is, 99 product lines.

PART THREE – MEDICAL DEVICES

Compared with the previous year, compulsory sickness insurance reimbursements for medical devices for personal use have increased by about 10%, for all risks and regimes combined. The rate is very similar to the rate for the previous year and greater than that for the reimbursements made through compulsory medical sickness insurance for the other major health expenditure categories. The increase is mainly the result of an increase in the scope for reimbursement. In contract to medicines, in fact, the average effective rate for reimbursement on medical devices, observed from one year to another for the three main compulsory sickness insurance regimes, is almost stable (89.9% in 2004). This very high average effective reimbursement rate, contrasted with a rate of 65% of devices reimbursed under common law, is because for a number of devices, the reimbursements concern patients who are 100% supported in the context of a handicap, long-term condition, operation or hospital stay.

Overall, the reimbursements applied for all compulsory medical insurance regimes in relation to medical devices were estimated to total €4 billion in 2004. This corresponds to a total reimbursable expenditure of almost €4.5 billion and real expenditure in the region of €7.9 billion, much higher than the reimbursable total because of the sometimes very large disparity for some devices, especially in Category II, between the reference price and the price actually applied.

The increase in reimbursements applied – about 10% during the last two years and 15% during the last two years before them – remains very rapid. Nevertheless, this significant increase in expenditure is one of the results of the developing policy of home care or rapid return home following a stay in hospital. In this regard, it can be considered that bearing these expenses in order to reduce the number or duration of hospital stays helps to limit immediate or longer-term expenditure increases in other fields. This is the case for a number of Category I expenses. In addition, with regard to Category III, it is observed that the taking on of new, innovative devices very often leads to a reduction in the number or complexity of sometimes costlier or more disabling operations. In addition to the improvement in life quality and life expectancy of patients treated with them, the devices bring about an immediate or longer-term reduction in health costs on other areas.

The situation is therefore noticeably different from that prevailing in the medicines sector where, apart from a few notable exceptions, it is expected that the use of an innovative medicine will sometimes provide decisive benefits for patients but rarely cause a measurable knock-on effect in other health expense categories.

After an examination of changes in medical device costs in the first section, the second section, dedicated to the administration of medical devices for reimbursement, will deal successively with committee advices, determination of prices and tariffs, and action taken by the committee to make the expected savings in the field of sickness insurance reforms.

SECTION I – SPENDING ON MEDICAL DEVICES

The only sufficiently reliable information available to enable sales of medical devices for personal use and changes in those sales to be estimated is still the information relating to compulsory sickness insurance reimbursements. This information allows the growth in 2004, leading to a total reimbursement figure in the region of €4 billion corresponding to a total reimbursable expenditure of €4.5 billion, to be estimated at 10%.

The presence or absence of limit sale prices according to LPP category or section and, where applicable, the great variability of disparities between prices applied and tariffs accepted, lead to an average reimbursement of about 5-6% of total sales in the field of optical devices, and, up to the total value relating to implantable medical devices, only allows the corresponding sales to be estimated.

The re-use in 2004 of evaluations and ratios calculated by DREES[5] has led to total LPP-related sales being re-valued at €7.9 billion in 2004, including €2.9 billion under Category I, €3.9 billion for optical devices, €2.7 billion under LPP (Section II Category II) and €2.3 billion for all ortheses, prostheses and VHP (Category II except Section 2, Category III & IV of LPP).

1. Trend in reimbursements under the general scheme

According to the CNAMTS figures, general reimbursements for medical devices increased by 10% in 2004, compared with 9% in 2003.

Table 20: Trends in reimbursements under general regime in 2004 (million euros)

Description	Section	2003	2004	Change	Rel. portion*
Home respiratory assistance devices	1	334	385	15.3%	21%
Other home treatment equipment	1,2	419	463	10.4%	25%
Support equipment and devices	3	25	23	-6.1%	1%
Equipment and devices for various treatments	1	579	655	13.2%	36%
Dressings	3	291	315	8.3%	17%
Nutrients for gluten-intolerant patients / foods intended for medical purposes		1	2	55.5%	-
Total Category I		**1,649**	**1,843**	**11.8%**	**58%**
Ortheses	1	178	190	6.5%	33%
Optical devices	2	142	146	3.1%	25%
Electronic hearing aids	3	55	61	10.4%	10%
Non-orthopaedic external prostheses	4	5	4	-14.3%	1%
Artificial eyes and facial prostheses	5	10	12	15.8%	2%
Foot ortheses	6	50	53	6.4%	9%
Artificial bones/joints	7	100	112	11.8%	19%
Prosthesis accessories / ortho support centres		4	2	-48.2%	-
Total Category II		**544**	**580**	**6.5%**	**18%**
Inert internal prostheses	1,2,3	571	629	10.1%	89%
Active internal prostheses	4	84	78	-7.0%	11%
Total Category III		**655**	**707**	**7.9%**	**22%**
Total Category IV: disabled persons' vehicles for purchase		**60**	**70**	**16.7%**	**2%**
Total Categories I, II, III and IV		**2,908**	**3,200**	**10.0%**	**100%**

* Relative portion in 2004: for sections, in relation to category; for categories, in relation to total.

[5] National Health Accounts 2003 – DREES – Ministry of Solidarity, Health and Family Matters.

2. Evaluation of reimbursements and expenses submitted for reimbursement

With regard to tariffs accepted for medical devices, the average rate of reimbursement under the general regime has been fluctuating slightly around the 90% point for a number of years, averaging 89.6% in 2004. Knowledge of the average rate of reimbursement allows the expense presented for reimbursement under the general regime to be calculated; in 2004 it was €3.57 billion for a total of €3.2 billion of reimbursements (see Table 21). In practical terms, the reimbursement rate reached in 2004 in relation to the common law reimbursement rate of 65% indicates that over 70% of expenses presented for reimbursement were borne at 100% of the reference price through compulsory sickness insurance, patients being exempted from the *ticket modérateur*.

Table 21: Expenses presented for reimbursement – general regime (million €)

Description	Reimb.	Average rate of reimbursement	Reimbursable expense
Home respiratory assistance devices	385	90.1%	427
Other home treatment equipment	463	93.1%	497
Support equipment and devices	23	77.2%	30
Equipment and devices for various treatments	654	94.0%	695
Dressings	315	82.7%	381
Nutrients for gluten-intolerant patients / foods intended for medical purposes	2	79.9%	2
Total Category I	**1,843**	**90.6%**	**2,032**
Ortheses	190	72.3%	262
Optical devices	146	66.0%	222
Electronic hearing aids	61	70.9%	86
Non-orthopaedic external devices	4	94.9%	5
Artificial eyes and facial prostheses	12	99.2%	12
Foot ortheses	53	90.9%	59
Artificial bones/joints	112	100%	112
Prosthesis accessories / ortho support centres	2	100%	2
Total Category II	**580**	**76.4%**	**758**
Inert internal prostheses	629	99.9%	629
Active internal prostheses	78	99.9%	78
Total Category III	**707**	**99.9%**	**707**
Total Category IV: disabled persons' vehicles for purchase	**70**	**100%**	**70**
Total Category I, II, III and IV	**3,200**	**89.6%**	**3,567**

The reimbursements applied through the three main sickness regimes, namely CANAM, CNAMTS & MSA, totalled €3.79 billion in 2004, including €2.2 billion for Category I. If one considers that these three regimes account for a little over 95% of sickness insurance reimbursements, it can be estimated that the total reimbursements are €3.99 billion and €2.32 billion for Category I. On the basis of the reimbursement rates observed for each category for the general regime, the total reimbursable expenses presented for reimbursement for all regimes in 2004 can be estimated at about €4.45 million.

Table 22: Evaluation of reimbursable expenses (million €)

Description	GR reimbursements	3-regime reimbursements	Extrapolation (all regimes)	Average rate of reimbursement (GR)	Reimbursable expenses

Cat. I: home treatment equipment, life enhancement appliances, dietary foods and dressings	1,843	2,200	2,316	90.6%	2,556
Cat. II: ortheses, external prostheses	580	680	716	76.4%	937
Cat. III: implantable medical devices, human-derived or constituent implants and human-derived tissue grafts	707	829	873	99.9%	874
Cat. IV: disabled persons' vehicles (VPH) for purchase	70	82	86	100%	86
TOTAL	**3,200**	**3,791**	**3,990**	**89.6%**	**4,453**

3. Trends in sales and expenses by category

3.1. CATEGORY I: HOME-CARE TREATMENT EQUIPMENT, LIFE ENHANCEMENT APPLIANCES, DIETARY FOODS AND DRESSINGS

Category I includes devices, products and services for use in the homes of the elderly, the disabled, patients requiring post-operative care who were previously kept in a health care establishment for longer periods, and chronically sick people. It continues to increase, especially as the population ages, and provides the greatest part of the overall growth in the LPP products market. The increase in reimbursements in this category, under the three main regimes, was 11.2% in 2004 (compared with an average of 9.5% for all other LPP sections); this now accounts for 58% of all reimbursable sales (50% four years ago). This growth shows a slight fall compared to 2003 (13%) and a clear slowing in relation to previous periods 20% per year in 2001 and 2002.

In the absence of any substantial revaluation of Category I tariffs, the increase in reimbursable expenses in 2004 was probably caused by an increase in volumes of products and corresponding services.

On average in this category, almost three-quarters of expenses (73%) were reimbursed at 100% of their tariff, which almost always corresponds to the sales price. However, in a few sectors, such as support bands or oral nutrients, disparities between tariffs and prices remain.

3.2. CATEGORY II: EXTERNAL ORTHESES AND PROSTHESES

Category II represents about one fifth (21%) of reimbursable LPP expenses and less than 18% of reimbursements (general regime). This category increased by 7% in 2004, more quickly than in the previous year (4 %), the increase being mostly caused by hearing aids (10%) and artificial joints (12%).

With an overall reimbursement rate of 76%, it can be estimated that less than one third of expenses reimbursable under this category are 100% borne.

In some Category II sections, the disparity between the tariffs making up the reimbursable base and the prices applied is very significant, especially for ortheses (30-45% remaining payable), adult hearing aids, and especially Section 2: Optical Devices. For these devices, the general regime reimbursements totalled €146 million in 2004, an increase of 3% over the previous year and accounting for just 7%, approximately, of the corresponding sales total.

Because of the sometimes considerable disparities between the tariffs and prices applied in the sections most significant in terms of turnover in Category II, it is only just possible, with only the general regime reimbursement figures, to make a well-founded estimation of the level of turnover corresponding to tax-inclusive public prices for this section. It may however be assumed, on the basis of the increase in reimbursements compared with the previous year, that there will be a measured increase in the turnover corresponding to this category in 2004.

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

In 2004, reimbursements paid under Category III enjoyed a growth of 8%, twice the 2003 rate. The arrival of active-release stents on the market in late 2003 is the main reason for the acceleration. Because of an average reimbursement rate of almost 100% and tariffs equal to the sales limit prices, the reimbursement total for the category is identical to the sales total, which totalled €0.87 billion in 2004 (see Table 22).

3.4. CATEGORY IV: VEHICLES FOR DISABLED PERSONS (VPH) FOR PURCHASE

In 2004, Category IV reimbursements relating to the purchase and maintenance of vehicles for disabled persons saw an increase in growth twice that of the previous year. In the absence of any alteration to the tariff, this increase reflects the increase in volumes reimbursed, possibly due in part to replacement of hired vehicles, but also, no doubt, due to the increase in the average price of wheelchairs, which contain more accessories. This is a sector where 100% of the tariffs are borne, with a public price similar to the LPP tariff for manual wheelchairs (90% of the market by volume). For other chairs and vehicles, there can be very significant disparities between tariffs and price: a ratio of 1:2 for electric wheelchairs, 1:4 for vertical electric chairs, etc.

Overall, the corresponding market can be estimated at €140 million (purchases only).

SECTION II – REIMBURSEMENT UNDERTAKING FOR MEDICAL DEVICES

1. Opinions of the committee

Applications for registration must be processed within 180 days of the application being lodged. In application of Article 21 of the Law of 12 April 2000, the absence of decision within this time is tantamount to a rejection, justification for which must be given if requested by the manufacturer or distributor.

For alterations to price or tariff, the period is 90 days. If a decision is not made within this period, the tariff or price requested is granted tacitly.

However, if the elements of assessment sent by the manufacturer are insufficient, the ministers, the committee or the Transparency Commission shall advise the applicant that

additional information is required. In this case, the deadline shall be extended by the period from the date of notification to the date of receipt of the information.

Registration renewal applications must be sent at least 180 days before the planned re-registration date. If at the end of this period no decision has been notified, renewal shall be granted tacitly and the tariff and price previously applied shall be renewed and published in the Journal Officiel.

1.1. DOSSIERS FILED WITH THE COMMITTEE

During 2004, 129 applications (131 in 2003) issued by companies were lodged with the committee. One of these applications had a twofold subject; one other had a threefold subject. A total of 107 first registrations, 8 registration renewals, 12 alterations to registration conditions and 5 price alterations were submitted.

1.2. PROCESSING OF DOSSIERS

Altogether, 108 dossiers lodged with the committee were processed during 2004, including 78 registration applications, 4 deletions, 6 revaluation applications, 15 re-registrations and 5 alterations of various types. The average age of these dossiers at the moment of notification or publication of the decision concerning them was 376 days. For dossiers leading to a publication in the Journal Officiel, the period was 423 days.

Ten of the 78 registration applications were refused. The committee considered that 15 of these applications related to a generic line registration, and the others were the subject of decrees published in the JO. Of the 6 revaluation applications, 2 were accepted. Two re-registration applications were refused, 3 were re-registered in a generic line, and 10 were the subject of a decree published in the Journal Officiel.

Table 21: Decrees published

Subject	Cat. I	Cat. II	Cat. III	Total
Registration	10	3	12	25
Re-registration	4	2	2	8
Revaluation		1	2	3
Public sale price limit	1	3	15	19
Alteration	14	3	16	33
Deletion			2	2
Total per category	29	12	49	90

In addition, 11 advices announcing planned alterations to registration conditions, technical specifications, tariffs and sales price limits were published in the Journal Officiel. With regard to these projects, the manufacturers and distributors concerned have 30 days in which to present their written observations, request a hearing with the CEPS or make written comments on planned prices and tariff before the CEPS.

2. Fixing tariffs and prices

Because of the publication of applicative decrees of interest to the committee at the end of the year, the reforms introduced by the Social Security Finance Law for 2004 and the Law of 13

August 2004 concerning sickness insurance only had limited effects on methods of fixing tariffs and prices for medical devices in 2004. Although the basic principles in this field remain unchanged, in 2004 their application saw changes or new formalisation procedures that justified changes to way in which this area was developed in previous reports (although these reports essentially remain up to date). In addition, the steps taken by the committee to ensure the savings forecast by the government were described.

2.1. GENERAL PRINCIPLES

The process of fixing prices and tariffs for medical devices is based on three rules.

Two of these relate to tariffs.

Article R.165-4 of the Social Security Code specifies that "products or services (…) that do not bring about either an improvement of the service provided or a saving in the cost of the treatment, or are likely to lead to unjustified cost to the sickness insurance, may not be included in the list provided for by Article L.165-1".

Article R.165-14 provides that "the process of fixing the tariffs shall take account principally of the service provided, any improvement in that service, prices or tariffs of comparable products and services included on the list, predicted sales volumes, and foreseeable and actual conditions of use".

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

In practice, the committee often has to combine these regulations, most notably when a tariff and sales limit price are set at the same total. It then goes without saying that the common total must comply both with the regulations relating to tariffs and with those relating to price.

However, application of these rules to medical devices (rules that are identical in every term to those currently applicable for medicine prices) poses a number of problems in relation to the proper methods of registration of medical devices for reimbursement, the forms that innovations most often have to take, and the very diverse nature and consistency of the products and services concerned. The following developments report on the solutions adopted by the committee.

2.2. TARIFF SYSTEM BY CATEGORY

2.2.1. Inclusion in generic line or harmonised tariff

Registration of products or services that do not provide an improvement in the service offered must, under Article R. 165-4, be accompanied by a saving in treatment costs. This simple and important rule is, however, rarely applicable on practice in the field of medical devices. The code, in fact, lays down the rule (Article R.165-3) that registration for reimbursement is in principle based on the generic description of the service, the registration of a mark or brand name being the exception. As a result, the great majority of products or services eligible for reimbursement are eligible within the framework of an existing nomenclature line, and

therefore, although they do not have an ASR, at a tariff equivalent to that of equivalent products or services already reimbursed.

By extension of this concept, the committee has treated some categories of devices, registered under a brand name in application of the second case for exception from generic registration provided for by Article R. 165-3, similarly, "when the impact on sickness insurance costs, public health requirements or control of minimum technical specifications requires particular monitoring of the product". The same goes for categories of devices that before the reforms were included in the approval numbers regime and were the subject, sometimes provisionally, of a brand registration process. In these cases, the committee considered that the products concerned should be treated as if they belonged to generic lines, and the newly registered products are given a tariff and, where applicable, a sale limit price identical to that of the products already registered in that category. This practice was given a regulatory basis in Decree No. 2004-1419 dated 23 December 2004, which altered Article R.165-4 of the Social Security Code.

The first consequence of this situation was that the rule of saving on the cost of treatment only applies specifically to new devices without an ASR and not corresponding to an existing generic definition, either when the anticipated service is obtained for comparable products already registered through a different technology and method of action, or when a comparison is made with methods of treatment outside the scope of the list: surgery, treatment with medication, etc.

The second consequence is that the decrease in time of the average price of a product category, obtained naturally for medicines through the successive registration of medicines each less costly than their predecessors, can only be obtained for medical devices, when justified, through the periodic downward revision of the generic line tariffs or harmonised tariffs.

2.2.2. Development of brand name registrations

There may be great variations within generic lines with regard to the technical characteristics of products and sometimes with regard to their definition in terms of minimum technical specifications or disparity in performance between old and new products. The CEPP has therefore been compelled, when redefining a generic line on the arrival of a new product, or on its own initiative, to ask the industrial concerns and distributors marketing the products in the line in question to submit a dossier in order to allow evaluation of their products.

The CEPS wishes to speed up this differentiation between products according to their individual evaluation by announcing reductions in the generic tariff. Only products granted an ASR in relation to their line may, fully or partly, escape these reductions.

2.3. THE VALUATION OF INNOVATIONS

For products with an ASR, the criteria clearly laid down by the texts, although they provide directions and a framework for fixing prices, are not in themselves sufficient to determine the prices. In this case, the rule of Article R.165-4 authorises an additional cost, but says nothing about its magnitude. All that can be deduced is that in general, a low-level ASR does not allow the acceptance of a significant difference in tariff from the comparator, if one exists; this is not always the case in the field of medical devices. In addition, the recognition of an

ASR is a necessary condition, but is insufficient for justifying an additional cost; and regulations do not therefore forbid the registration of a new product with an ASR at a lower rate than that of the comparators already registered. Beyond the price of the comparator alone, an ASR, even a large one, granted to one or another product in relation to the minimum technical specifications laid down for marketing in a generic line (see 2.2, Tariff system by category) would not constitute a determining element for a more favourable price or tariff than that granted to the generic line, not only because the equivalent ASR products may have already been marketed at the generic line prices or tariffs, but also because there would be a need to create lines with a brand name.

In practice, therefore, the committee has to distinguish schematically between three main situations when pricing innovative devices.

In the simplest cases, it can be demonstrated that the price proposed or accepted by the company, and therefore considered by the company to be a reasonable valuation of its discovery, incurs for the sickness insurance costs that are less than, or at worst equal to, the savings made by using the discovery (in such cases, only the direct costs borne by the sickness insurance are considered, regardless of nature). Registration is not, therefore, a problem, but it is of interest in such cases to have reliable and convincing medical and economic studies available.

In the second case, it is standard practice, where implantable devices are concerned, for progress in terms of service provided to be made in the form of so-called “incremental innovations”, which have the twofold characteristic of being both modest and relatively frequent. When it appears that the potential for growth in the market share of the new product is not a sufficient valuation of the innovation, and when a price benefit is needed in addition, the committee may suggest a tariffs temporarily higher than those of comparable products already registered. In cases of time-staggered registration of another equally innovative device, the committee agrees that the new device can carry the same price/tariff benefit as its predecessor for the time remaining for the benefit granted to that device. Payment for the innovation is thus guaranteed for the period, usually short, at the end of which it can be anticipated that it will be surpassed technologically. This practice, applied by the committee for the pricing of heart pacemakers, allows the ASRs to be valued while preventing tariffs from escalating. In this situation, the minimum technical specifications for the generic line must be reviewed periodically in order to integrate the “incremental” innovations built up since the previous definition.

Finally, there are the most difficult cases, those of innovations that are both decisive and costly. The occasionally heavy increase in expense that these innovations bring to the community only has effects that cannot be measured financially in terms of improvement in patient care. Cost and efficiency studies can help in the decision-making process, but are usually complicated. In these situations, price level discussions are usually cramped by the existence of international markets and usually superseded by the issue of limiting quantities for a patient population for which the anticipated benefit of the innovation is well established. This suggests resolution, at the same time, of the question of identification and size of target populations and of the question of the various means to be applied to ensure that only these populations benefit from the innovation. In such cases, registration is invariably accompanied by agreements relating to the volumes and contributions due from the companies if the volumes are exceeded and to the setting up of surveillance studies.

For these major innovations, the importance of the price/tariff advantage conferred on the first arrival also poses problems for later arrivals that are also innovative but have a lower fixed price level. If these products are included on the T2A list, this price differential will make the competition between these devices artificial, in that the choice will no longer depend purely on the anticipated efficacy of the devices or even on their cost/efficacy ratio, but on the more significant rebates that the manufacturer of the product given the highest price/tariff will bestow on the purchaser. The problem is therefore the rapid re-establishment of normal competition conditions between equivalent products included on the T2A lists.

2.4. DISPARITIES BETWEEN PRICE AND TARIFFS

The system for defrayal of medical devices, in contrast to the system applicable for medicines prior to the introduction of reference prices, generally allows disparities to be established between the tariff, the basis for compulsory sickness insurance reimbursement, and the price.

When it is deemed necessary, against a background of equal access to care or compensation for handicap, not to allow such a disparity to come about, the only mechanism allowed by the new texts is the fixing of a sales limit price (see 2001 committee report). The committee has frequently proposed using this mechanism. However, fixing a sales limit price suggests, where applicable, that the question of additional prices invoiced in return for services or accessories in excess of the definition given for the reimbursable product or service in the list has been resolved. In particular, this is often the case in the external prosthesis and orthesis sector, where patients can request and professionals offer aesthetic or technical additions, but not only in this sector. In the field of hearing aids for young children, the professionals have stated that the disparity between price and tariffs allowed the salaries of hearing aid specialists to be paid for their involvement in adapting the device to suit their patients, a process that could, for patients of very young age or with multiple handicaps, cover many sessions. In this case, the resulting charge was most frequently borne either within the CMU framework or by the additional insurance, and in other cases through aid given by the regional or municipal assistance organisations called upon by the hearing aid specialists themselves. The difficulty, and sometimes the impossibility, of determining rational sales limit prices in that situation, and the existing opportunities for financing the outstanding balance, led the committee to postpone the fixing of a sales limit price higher than the tariff for these hearing aids.

When technical or aesthetic supplements can obviously be detached from the reimbursable product or service, there is nothing to prevent professionals issuing a separate invoice for the addition requested by the patient, provided the sale limit price for the principal is respected. When these supplements, especially those of an aesthetic nature, cannot be detached from the reimbursable device, it is advisable to avoid any deviation that could, over time, pose a significant risk of losing any offer eligible for the reimbursement tariff and thus cause difficulty of access for less well-off patients. However, the Council of State judged in 2003, with regard to made-to-measure orthopaedic footwear, that a total ban on prohibitions was illegal. In this specific case, the committee replaced the prohibition, following advice from the National Consumer Council, with a strict system for informing those covered by social security beforehand. Whether or not they are detachable, the legitimacy of these supplements presupposes that the patient has already been informed of their price and their non-reimbursable nature.

2.5. TARIFF REVIEWS BY PROFESSION

Finally, the medical devices sector contains a number of professions, mostly consisting of small or very small businesses, whose conditions of operation are more similar to those of providers of services to individuals or artisans than to those of research or industrial production companies. The tariffs and sale limit prices applicable to the reimbursable services supplied by these professions cover salary costs, often to a significant extent.

The question of tariffs is therefore raised under conditions quite different from those prevailing in other medical device fields. In particular, the criteria laid down by Article L.162-38 for fixing prices (charges, income, activity levels) naturally occupy a prominent position.

The committee considers that it should ensure that two objectives are met within the propositions put forward by it for fixing these tariffs and for periodically revising them:

- The level of the tariffs and prices must be sufficient to guarantee maintenance of a sufficiently high level of offer and distribution across the territory, with a level of quality compatible with the anticipated service and justifying the reimbursement.
- This level must not however be such as to favour the maintenance of unproductive operating structures unfairly, thus creating a "golden opportunity" for the most competitive companies.

The committee has estimated that the objectives were more easily achieved through regular revisions of tariffs, and has therefore, in several cases, proposed fixed annual revision mechanisms according to medium-term cost trends. This procedure is accompanied by a periodic observation of actual cost and mark-up levels in order to adjust the fixed tariffs adopted, on the initiative of the committee or the professional organisations concerned.

3. Reductions in tariffs

In the context of the sickness insurance reforms, in the summer of 2004 the committee prepared to take steps in order to make the anticipated savings in the field of medical devices alongside these reforms.

Initially, five sectors were accepted as subjects for the planned reductions: oxygen therapy, medical beds and bed equipment, materials for the self-control and self-treatment of diabetes, dressings, and tissue wall repair implants. The plan also includes the reductions brought about by the creation of generic lines for heart pacemakers and the inclusion of old pacemakers previously included under a brand name in these lines at reduced tariffs.

Generally speaking, the committee decided to accompany these reductions with a sale limit price fixed at the reimbursement tariff level, in order to prevent these savings from finding expression in exclusion from compulsory sickness insurance and increase in balances payable by patients.

In accordance with the Social Security Code, the committee's plans were published in the Journal Officiel, marking the start of a period of negotiation with the professions concerned (both individual companies and representative syndicates).

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ANNEX 1: MINISTERIAL LETTER CONCERNING GENERIC MEDICINES

The French Republic

The Minister for Health and Social Protection

The State Secretariat for Health Insurance

Paris, 3 August 2004

Dear President,

Because of the involvement of health professionals, and in particular pharmacists, as well as the willingness and agreement of patients, the portion of generic medicine in the total of reimbursable products is constantly increasing. Our combined objective is for it to progress from 12% today to a total of 23% in 2007, thus allowing the situation in France to be brought into line with that in the principal neighbouring countries.

We would like to thank and encourage the pharmacists for their commitment in favouring the circulation of generic medicines. We will be pursuing this dynamic and encouraging policy in favour of better circulation of generic medicines, thanks in particular to the substitution that you are implementing between original versions and generics.

In this framework we do not wish for the reference price system (TFR) to be systematically applied. This step should not in fact be allowed to slow down the development of generic medicines, or perceived as a penalty by pharmacists who are practising substitution more and more, a process that we wish to encourage.

In the same spirit, it is our wish that in 2004 TFR should not enter into force before December. This would allow the health professionals to commit themselves fully to the substitution targets between September and November.

In this context, we have asked the President of the Economic Committee for Health Products for this tariff only to be applied when the speed of penetration by generics is insufficient to obtain the anticipated benefit of the drop in the number of patents. For the new groups, this means that the TFR would only be applied if, after about one year, the portion of the market occupied by generics does not reach 50%, or 60% for high-turnover molecules for which the increase in generics is naturally faster. The TFR could also be applied to the groups in which the level of penetration by generics after two or three years is not seeing any more long-term progression.

This step would of course be taken in consultation with the professionals concerned, pharmacists' representatives and generic and original version companies, both on the principles of application and on the implementation process. We have given instructions to the CEPS President in this regard. Our wish is that a generic medicines surveillance committee should be set up with all the health professionals concerned, in order to manage the TFR application perimeter group by group where necessary.

From January 2005 onwards, we wish for the Economic Committee for Health Products to be able to examine the application of these tariffs every month, using the same methods, in order to avoid the problems of labelling and medicine storage.

The development of generic products depends on the introduction of new molecules to the substitution list, but also on encouraging pharmacists to substitute generics for original-version medicines. This encouragement can be given through an incentive substitution payment, based both on a generic mark-up aligned to the original-version mark-up and on rebates fixed at 10.74% for generics instead of 2.5% for original versions. This mark-up system would carry an even greater incentive in view of the arrival of more costly molecules on the market. We would therefore wish to satisfy ourselves that the totals and contents of the business co-operation contracts relating to generic medicines are set up in strict compliance with legal requirements. We will therefore be asking the competent departments for a report on this matter, so that we can take the required steps where needed.

The President of the Economic Committee for Health Products will be responsible for taking account of these elements in order to modulate use of the TFR as effectively as possible and fix a fair price for generic medicines. According to the level of penetration of generics and the size of the market, justified price reductions must be implemented in order not to undermine the generics policy.

Once again, we are delighted with the quality of our exchanges and the willingness of pharmacists to continue to commit themselves to promoting generic medicines and mastering health-related expenses. It is by everybody changing a little that we will be able to change everything and be able to provide better care through better dispensing. We are convinced that you, as health professionals, will be able to respond favourably to this undertaking to the benefit of the community.

In the meantime, we send you the best expression of our respect and esteem.

Philippe Douste-Blazy Xavier Bertrand

Copy to: Mr Noël Renaudin, President of CEPS

ANNEX 2: HOSPITAL MEDICINE FRAMEWORK AGREEMENT

FRAMEWORK AGREEMENT CONCERNING MEDICINES IN HOSPITALS
Between
The Economic Committee for Health Products
And
The Drug Companies (LEEM)

In view of Community Law and the Social Security Code, and the directions taken by the Ministers as arising in particular from the presentation of the Social Security Finance Law for 2004.

Considering that, without prejudice to the application of the Procurement Contracts Code, Article L.162-16-5 of the Social Security Code provides that with regard to pharmaceutical products carrying a marketing authorisation and included in the list shown in Article L.5126-4 of the Public Health Code, an agreement specifies the conditions under which the operating companies make declarations, the criteria for opposition by the committee, the conditions under which declared sales prices can be revised, and the commitment that the company in question must make.

Considering that Article L.162-16-6 of the Social Security Code provides that with regard to the pharmaceutical products mentioned in Article L.162-22-7 of that code, an agreement specifies the procedure and conditions under which the operating companies make declarations, the criteria for opposition by the committee, the conditions under which the declared sales prices can be revised, and the commitments that the company in question must make.

Considering that the application of the conventional provisions to be laid down must, in the same way as do the compilation and updating of the hospital service tariffs and the lists provided in Articles L.162-22-7 of the Social Security Code and L.5126-4 of the Public Health Code, preserve the speed of access by patients to the most innovative medicines.

Considering that the joint application of the conventional provisions to be laid down, and of the decree in Article L.165-7 of the Social Security Code, should allow non-artificial competition between companies.

The Economic Committee for Health Products and the Drug Companies agree to implement the new provisions of the law under the conditions laid down in the present agreement.

Article 1: Uniqueness of the procedure

For Articles L.162-16-5 and L.162-16-6 of the Social Security Code to be applied, the transfer price for the products mentioned in the list shown in Article L.5126-4 of the Public Health Code and the product reference prices mentioned in the list shown in Article L.162-22-7 of the Social Security Code shall be determined according to the common procedure described in Articles 2-6, subject to the specifications made in relation to the said articles where applicable.

Article 2: Development of procedure

The price declarations formulated in accordance with Article 3 shall be handed to the committee in return for receipt or sent by registered post within eight days of the publication in the Journal Officiel of inclusion in one of the lists mentioned in Article 1, or, for the products included in the list shown in Article L. 5126-4 of the Public Health Code prior to their marketing authorisation, within ten days of receipt of the authorisation decision.

The committee may declare the declaration inadmissible or oppose the price declared under the conditions specified in Article 4, within fifteen days of receipt of the declaration. In cases of inadmissibility or opposition, the company shall have fifteen days from receipt of the committee's decision to formulate a new declaration or amplify its initial declaration. The committee shall then have ten days in which to declare the declaration inadmissible once again or oppose the price declared. The statement of inadmissibility or opposition shall constitute definitive opposition by the committee as understood by the above-mentioned Social Security Code articles. If, after the committee's initial opposition, the company has not formulated a new declaration or amplified its initial declaration within the above-mentioned fifteen-day delay, the opposition shall be definitive.

If no declaration of inadmissibility or opposition is made within the periods specified in b), the committee shall immediately publish the declared price or reference price corresponding to the declared price.

If the company fails to respect the declaration deadline specified in a), the committee may oppose the declared price without time limit other than that allowing the procedure to be completed within the 75-day legal period. In cases of opposition, the period available to the company to make a new declaration or complete its initial declaration shall be reduced by the initial excess period. If this period exceeds ten days, the opposition by the committee shall be definitive.

If the opposition is definitive or the company has not made an admissible declaration thirty days after the beginning of the period specified in a), the committee shall propose before the ministers that the transfer price or reference price should be fixed by decree.

Transitional provisions

For products registered before 15 September 2004 on the list shown in Article L.162-22-7 of the Social Security Code, price declarations may be lodged up until 1 October 2004. The corresponding liability tariffs shall be published with effect from 1 January 2005.

For products intended to be included in the list shown in Article L.5126-4 of the Public Health Code and shown in this respect in the draft list compiled by the Minister for Health, declarations may be made as soon as the draft is published. The declared sale prices, or the corresponding transfer prices where applicable, shall be published with immediate effect at the same time as the definitive list.

Article 3: Content of declarations by companies

The companies' declarations shall contain the following details for each product included in the declaration, otherwise they shall be void:

- The proposed sale price to health establishments, for each package.
- The prices applied in the main European Union Member States, plus the status of the product in relation to reimbursement and, for products marketed for more than one year, the annual sales recorded in these States.
- Where applicable, the history of prices applied in French health establishments, within a limit of three years.
- The advice(s) of the Transparency Commission, if already issued.
- Sales forecasts for three years, for information.
- The undertaking to inform the committee yearly of the prices applied and quantities sold in the main European Union Member States, plus any reimbursement alterations.
- They may also, according to the specific characteristics of the products in question, contain the undertakings made by the company, especially for the application of Article L.162-18 of the Social Security Code or for the carrying out of surveillance studies on these products.

Article 4: Criteria for opposition by the committee

Opposition by the committee must have a clearly expressed and specific basis.

Bases for opposition may be an unusually high price proposed in relation to the prices applied in the main European Union Member States, or, when there is already a market in France for directly comparable products, in relation to the prices observed on this market.

Another basis may be insufficient commitment by the company where applicable, especially when the proposed price is only justified for some of the indications of the AMM, the quantities sold incur unusually high charges for compulsory sickness insurance, or if, in view of the state of the market, inclusion in one of the lists leads to sales volumes that in terms of the price proposed by the company lead to quantity rebates.

Article 5: Revision of prices and tariffs

Prices and tariffs may be revised if the company or the committee requests, especially when there is a change to the elements on which the current price or tariff is based or to the commitments made, when new data appear in France or in the European Union. This is especially applicable with regard to the valuation of the product or the prices applied, or when the price of the product depends closely on development costs, especially those linked to health and safety requirements.

Article 6: Exchanges of information

The drug companies shall ensure that the committee has the information collected within the framework of the GERS on sales to health establishments.

The committee and the compulsory sickness insurance shall provide the drug companies with the studies produced by them on the prescription and consumption of medicines, under the same conditions as with regard to professional health organisations. In particular, they shall

provide the statistics produced from the coding of medicines invoiced by the health establishments to the sickness insurance as soon as they become available.

Article 7: Evaluating and altering the agreement

This agreement shall take effect on the date of its signature, for a period of four years.

A surveillance group shall be created, consisting of the signatories. This group shall meet at the request of one of the parties, and at least once a year. It shall examine and evaluate the way in which the agreement is being applied. On the basis of this examination and evaluation, the agreement may be altered by an amendment.

If either party terminates the agreement before its expiry date, its provisions shall be extended for a maximum of one year until a new agreement is concluded or the decrees are published as provided for in Articles L.162-16-5 & L.162-16-6 of the Social Security Code.

If the general saving made under this agreement is breached, especially after a change in the applicable legislation or regulations, a major shift in ministerial direction or any widening of the European Union, and additional obligations arise to the drug companies as a result, the agreement shall be re-negotiated in order to achieve a new contractual balance. If these negotiations fail, either party may terminate the agreement.

Compiled in Paris in two copies on 30 March 2004

For LEEM
Pierre le Sourd

For the CEPS
Noël Renaudin

ANNEX 3: MEDICAL VISIT CHARTER

The main aim of a medical visit is to ensure that the medicines are promoted before the medical organisation and contribute to the development of drug companies. In this case, it should prioritise the quality of medical treatment with the specific aim of avoiding misuse of the product, preventing unnecessary expenses, and helping to keep doctors informed.

In accordance with the law, the Medical Visit Charter aims to strengthen the role of the medical visit in ensuring proper use of the medicine and providing good information.

As part of the sickness insurance reforms and of the changes to procedures, the Medical Visit Charter should contribute, as should all the other actions taken, to the success of these reforms.

I – TASKS OF THE MEDICAL REP

1. The medical rep shall, exclusively and separately from any other commercial activity, present the pharmaceutical products with the aim of promoting them in accordance with the company's objectives, increasing awareness of them in the medical sector, and ensuring that they are used in accordance with good professional practice.

2. Increasing products awareness involves informing doctors on all the regulatory and pharmacotherapeutic provisions relating to the medicine presented: therapeutic indications on marketing authorisations, doses (and especially paediatric doses if these exist), duration of treatment, side effects, aspects of surveillance, interactions between medicines, surveillance of treatment, restrictions on prescription and methods of defrayal (indications concerning reimbursements to persons registered with social security and rates of reimbursement).

3. Ensuring good practice involves showing doctors the role of the medicine in the condition in question and the recommended treatment strategy, validated by the Transparency Commission and in accordance with the recommendations of the senior health authority, the AFSSAPS and the National Cancer Institute, as well as the consensus conferences validated by the Senior Health Authority. This role must take account of good practice campaigns and public health programmes.

4. The setting up (recruitment and financial relations with doctors) of pharmacoeconomic analysis and clinical studies, including Phase IV studies, and of observational studies, are not within the remit of the medical rep. He should, however, ensure that these are monitored.

II – THE QUALITY OF INFORMATION PROVIDED

1. Formulation of information by the company

a. Compilation of documentation and training supports

In accordance with Article L.5122 of the CSP (including compliance with the AMM), the company shall compile promotional documents to be made available to the medical rep. These documents shall show the date on which the information was produced or updated.

Information concerning the use of the product, and in particular side effects and counter-indications, shall be clearly shown so that their relation to the indication and the benefit provided can be determined.

b. Updating promotional media

The company shall ensure that the medical visit documents are kept up to date in scientific, medical and regulatory terms.

c. Post-AMM studies not taken into account by the Transparency Commission

Useable studies are those published within a reading committee review and compiled under the conditions for using the medicine as defined in the product's AMM and other existing referentials (Transparency Commission advice, good practice recommendations etc). The use of congress advice summaries (abstracts) is permissible provided they comply with summary of product characteristics (RCP) and existing reference documents that are recent (less than 12 months old) and included in a referenced review.

When the company uses these studies, it shall present them impartially.

d. Comparative publicity

Information provided on the product and on competing products with the same therapeutic aim and included in the therapeutic strategy defined by the Transparency Commission, must satisfy the criteria defined for comparative publicity, as follows.

No publicity that compares medicines by identifying medicines marketed by a competitor, either implicitly or explicitly, may be used unless:
1) It is neither deceptive nor liable to lead to error.
2) It relates to medicines that satisfy the same needs or have the same therapeutic indication.
3) It objectively compares one or more characteristics that are essential, relevant, verifiable and representative of the medicines. One of these characteristics may be the price.

Comparative publicity may not:
1) Profit unduly from the extent to which names, trade names and other distinctive signs that indicate a competitor are known.
2) Discredit or denigrate any name, trade name or other distinctive sign, or the situation of a competitor.
3) Lead to confusion between an announcer and a competitor or between the names, trade names or other distinctive signs of the announcer or of a competitor.
4) Subject to the provisions relating to generic products, present medicines as an imitation or reproduction of another medicine benefiting from a protected name or trade name.

2. Training of medical reps in the medicine presented

a. Training of medical reps
In accordance with legal, regulatory and conventional provisions, the medical rep shall benefit from sufficient initial training attested by a diploma, paper or certificate.

He shall also benefit from ongoing training aimed at updating his knowledge and maintaining and developing his professional skills.

b. Preparing for a spoken presentation
The content of the spoken presentation must comply with current laws and regulations.
The company shall ensure that the medical rep's spoken presentation satisfies the requirements of the present charter by being delivered in the presence of a scientific and medical manager commissioned by the chief pharmacist.

c) The company shall prioritise the content of the medical visit in comparison with the visits, so that the information delivered is as comprehensive and objective as possible and that in particular, there is sufficient time to inform the prescriber on the proper use of the medicine.

d) The company shall ensure that the visit conducted, with all networks combined and relating to the same product, is not unfair.

3. Documents used

The medical rep shall carry out his promotional tasks exclusively through dated documents made available to him by the company, bearing the name and signature of the chief pharmacist, and lodged with AFSSAPS. When the company has updated a document, only the most recent version may be used.

In accordance with Article R.5122-11 of the CSP, the doctor must receive:
- The product characteristics summary mentioned in Article R.5121-21 of the CSP.
- The classification of the medicine for prescription and issue purposes, mentioned in the AMM.
- The public sale limit price, when this price is fixed in application of current laws and regulations, accompanied in this case by the cost of daily treatment.
- The situation of the medicine as regards reimbursement by sickness insurance organisations or approval by the public authorities, as provided for in Article L.5123-2.
- The advice issued about the application of Article R.163-4 of the Social Security Code by the Transparency Commission mentioned in Article R.163-15 of the same code and most recently published under the conditions set out in the last paragraph of III of Article R.163-16 of that code (when the medicine is the subject of more than one notification because of extension of therapeutic indications, the concept of advice is understood to mean all the notifications containing an assessment of the medical service provided in each therapeutic indication for the medicine concerned).

The doctor must also be given the documents deemed necessary by the Senior Health Authority, the AFSSAPS or the National Cancer Institute.

These documents must be perfectly legible and contain the date of their compilation or last revision.

The following documents must be presented and may be handed over by the medical visitor: product dossier, good practice recommendations, consensus conferences or other referentials issued or validated by the Senior Health Authority, the AFSSAPS or the National Cancer Institute.

The use of audio, video or interactive supports must be accompanied by a document given to the doctor.

III – ETHICAL OBLIGATIONS OF MEDICAL REPS

By 31 July 2005, this section will be completed by specific provisions laid down for medical visits to health establishments.

1. Concerning patients

Medical reps are subject to professional secrecy and must not reveal anything that they may see or hear on the medical practice's premises during the medical visit. They must behave discreetly in the waiting room and respect the doctor, his patients and the relationship between doctor and patients (limitation of conversation between professionals, use of mobile telephone, suitable clothing of sober hue).

2. Concerning doctors

a) Organisation and frequency of visits
The Medical Reps Executive shall ensure that the organisation, planning and frequency of visits are optimised.
Medical reps must not use incentives to obtain visiting rights, or offer any payment or compensation for that purpose.
They shall comply with the pattern and timetable of visits requested by the doctor, and enquire as to when the doctor wishes to see them again.
They shall ensure that they do not disrupt the smooth running of the medical practice.

b) Identity – accompanied visits
Medical reps shall ensure that their contact is fully aware of their identity and that of the pharmaceutical company and/or network that they represent, and of the marketing authorisation for the product presented.
Accompanied visits (for example, with the Regional Director), must be approved by the doctor. The accompanying person must disclose his identity and capacity.

c) Obtaining information
The medical rep shall collect information relating to doctors in accordance with the law concerning information and liberties (Law No. 78-17 dated 6 January 1978).
The aim of obtaining this information is to understand more clearly the doctor's expectations with regard to the medicine and its use or to the therapeutic class concerned, to give him personalised information, and to rationalise the medical visitor's work.
Information listed in this database must therefore take account only of the professional and factual elements and not of any judgement of value or subjective information.
The database in which the information is stored must be declared to the CNIL. In accordance with the law, doctors shall be informed of the existence of any data-gathering process relating to them. The medical rep must inform the doctors of the data relating to them and collected during the prescription or dispensation inquiries made available to them.

d) Professional relations, congresses, gifts and samples
The medical rep must not offer the doctor any gift in cash or in kind, or respond to any form of prompting from a health professional in this area.

This prohibition also applies to gifts not covered by an agreement: small equipment, office furniture, vouchers of various kinds (travel voucher, gift voucher etc).
The following benefits, in accordance with Article L.4113-6 of the Public Health Code, must be the subject of an approval sent to the Order: invitation to scientific congresses or promotional show and/or training activities, and participation in research or scientific evaluations.
Medical visitors may not hand over samples. As a temporary measure, this prohibition does not apply in the DOMs.

3. Concerning competitor companies

Information provided by medical reps on the product promoted by them and on competing products with the same therapeutic aim and included in the therapeutic strategy defined by the Transparency Commission must be free from all forms of denigration and based principally on the advice of the transparency commission. The level of ASMR obtained shall be disclosed faithfully to the doctor.

In particular, medical reps shall not denigrate any products belonging to the same generic group as the product presented and thus incite the prescriber to oppose substitution by the pharmacist.

4. Concerning their company

Medical reps shall immediately advise the pharmacist responsible of any information obtained from the doctor in relation to pharmacovigilance concerning products marketed by the company.

5. Concerning sickness insurance

Medical reps shall specify the reimbursable and non-reimbursable indications for the products presented by them.

They shall present the various forms of packaging in relation to their cost to the sickness insurance, and in particular, for chronic forms of treatment, the forms of packaging best suited to the patient and most economical.

They shall specify whether the product presented has a TFR.

IV – CONTROLLING MEDICAL REPS' ACTIVITIES

1. Responsibilities of the chief pharmacist

a) Concerning content
The chief pharmacist shall be responsible for the scientific and economic quality of the papers and audio-visual aids used during the medical visit, and generally for ensuring that II-1 of the present charter is respected. He shall date and sign these documents in his own name and on the company's behalf.
He shall update the lists of documents that can and must be sent by the medical reps.
He shall be responsible for the content of messages passed by the medical reps.

b) Concerning training
The chief pharmacist shall ensure that medical reps have the knowledge necessary for carrying out their jobs and are given ongoing and regular training aimed at updating their knowledge and preparing for promotion campaigns.

c) Concerning procedures
The chief pharmacist shall ensure that proper procedures for medical visits are compiled and applied in his company.

2. Procedures

a) Traceability of documents
The chief pharmacist shall ensure that the documents used for the medical visit are always those, and only those, guaranteed by him through his dated signature to be of suitable scientific, medical and economic quality.

b) Feedback of information
Doctors visited shall be regularly invited to send the company, free of charge, their assessment of the scientific quality and objectivity of the medical visit, as well as compliance with laws and regulations and with the present charter.
The chief pharmacist shall record and analyse the assessments sent by the doctors.

c) Monitoring of contacts
The company shall obtain the means for monitoring its medical visit activity regularly. The pharmacist responsible shall hold this information.

3. Certification and audit

In accordance with Article L.162-17-4 of the Social Security Code, a certification referential shall be compiled, under conditions to be specified by the Senior Health Authority, guaranteeing compliance by the certified companies with the provisions of the present charter.

This referential shall, among other things, specify the procedures according to which personal compliance with the charter by company directors, medical visit executives and medical reps themselves is guaranteed.

When, for the purpose of promoting its medicines, a company calls on a service provider or other pharmaceutical company, it shall be responsible for compliance with the charter of the work carried out by the service provider or other pharmaceutical company in question.

V – JOINT MONITORING

The parties agree to create a joint committee for monitoring the application of the present charter and realising its objectives. This monitoring committee shall work together with doctors' representatives. It shall meet on the initiative of one or the other party and in particular in June of every year, and examine the points proposed by both parties.

Specifically, for issues requiring more time for reflection and negotiation, the parties agree to carry on discussions within this committee with the aim of preparing the appropriate provisions before 30 June 2005, including alterations or additions to the present charter:

- On Point I-4, the monitoring committee shall assess the effects of the prohibition announced in the field mentioned, in order to determine its precise scope.
- On Point II-2-c, it shall define any misuse and specify the indicators allowing it to be identified and the means of remedying it.
- On Point III-2-d, it shall analyse the consequences of the total prohibition of samples with the aim of bringing in a few necessary exceptions.
- On Point IV-3, it shall, according to the decisions or advices of the Senior Health Authority, examine any alterations to be made to the charter in order to implement the certification.

Compiled in Paris in two copies on 22 December 2004

For LEEM
Pierre Le Sourd

For the CEPS
Noël Renaudin

ANNEX 4: METHODS OF FIXING PRICES FOR MEDICINES SOLD IN PHARMACIES

Article L.162-16-4 of the Social Security Code determines the rules for fixing the prices of medicines reimbursable by social security.

"The public sale price of each medicine mentioned in the first paragraph of Article L.162-17 is fixed by agreement between the company that uses the medicine and the Economic Committee for Health Products in accordance with Article L.162-17-4, or failing that, by decree of the ministers for social security, health and the economy following the committee's advice. The fixing of the price principally takes account of the improvements in medical service provided by the medicine, the prices of medicines with the same therapeutic aim, the predicted or actual sales volumes, and the foreseeable and actual conditions under which the medicine is used".

Article R.163-5-I-2° specifies that "medicines that do not provide an improvement in the medical service assessed by the commission mentioned in Article R.163-15 or a saving in the cost of medical treatment" may not be included in the list provided for by Article L.162-17 of the Social Security Code.

In accordance with these texts, the committee's task is to obtain the most advantageous prices and economic conditions for the sickness insurance, taking account of the global medicines market, ONDAM requirements, public health needs and the need for equal treatment of companies.

Taking account of the global medicines market means that all specific discussions on the price of a medicine must be informed, beyond the bilateral framework of the negotiations, by an analysis of the economic effects of the price on market developments and costs to sickness insurance: direct and immediate consequences of effects on price structures within classes, indirect consequences on relative changes in classes, medium-term consequences when the financial burden of the reimbursement on the ONDAM has to be assessed, and further consequences when the subsequent arrival of other medicines with the same indications can be anticipated.

The aim of satisfying health needs means that the committee, through its actions, must allow patients access to the medicines they need. The fixing of prices is only one means of procuring this.

Respect for equality of treatment between medicines is applicable regardless of the companies marketing them. One particular consequence of this principle, among others, is that the committee does not consider itself justified, regardless of its interest in research and innovation, in pre-financing research through prices of medicines that do not provide the required positive result of the research. Nor does it believe, with regard to innovative medicines, in treating them differently according to country of origin.

1. Medicines without ASMR

When fixing prices of medicines without ASMR, application of the rule of Article R.163-5-I-2° assumes that the committee has answered two questions: saving in relation to what, and by how much?

1.1. Saving in relation to what?

The comparison process, by which the saving should be obtained, is sometimes clear and indisputable in the eyes of the Transparency Commission. This, however, is sometimes far from being the case.

It thus frequently occurs, when widened ranges are registered, that the committee has to ask itself whether the good comparator, for assessing the effect of the medicine's registration on social security costs, is the range in which the new product is included and will replace other products, or the equivalent products marketed at a price that may be lower by other companies. Most often, the committee applies a comparison with less costly competing medicines so that unjustified price disparities between products providing the same service are not perpetuated. Sometimes, when the agreement cannot be concluded at that price, and in particular when the new presentation is called upon to replace an existing presentation *en masse*, it agrees an intermediate price between that of the presentation replaced and that of the less costly comparison medicine.

Another common difficulty concerns the choice of measuring instrument: cost of daily treatment, cost of overall treatment, or cost of packaging. Although the cost of daily treatment (CTJ) is most frequently applied, especially in the treatment of chronic diseases through solid or injectable forms, the solution is sometimes less clear for short-term treatment or when the quantity of medicine to be taken is itself uncertain (locally applied forms, liquid forms etc). The committee only exceptionally uses reasoning based on the cost of overall treatment, having been advised that prescription practices rarely comply with the clinical study protocols or the RCP descriptions. Therefore, when the CTJ is clearly unsuitable and the cost of treatment is also uncertain, the committee decides to compare packs or bottles on the basis of similar average prescriptions.

Finally, only exceptionally does the committee agree to take account of the declared potential for reducing combined prescriptions with other medicines in the cost comparisons, even when they appear properly certified through clinical studies. Experience has in fact taught the committee that these provisions are almost always refuted in practice.

1.2. By how much?

Generally speaking, the price benefit in relation to the last price registered must be greater than the total by which the comparator price is higher, and more time must have passed between the two registrations.

The anticipated saving is not however measured by the unit price disparity between the new medicine and the already prescribed medicines compared by the Transparency Commission, but by the saving in expenditure, which is the product of price disparities by volume. This general observation has two main consequences.

The first arises from the distinction to be made between classes in which prescription volumes are rigid (sure diagnoses, precise and limited indications) and those in which there is a risk of unjustified increase in volumes. In the first group of classes, the only effect of the arrival of a new competitor will be to alter shares in the market, and this competitor is therefore welcome, even if the price benefit is relatively low. The second group of classes is however quite different, as the relative price benefit linked to the arrival of a new entrant is likely to be compensated or even exceeded by the overall increase in volume triggered by the increase in promotional pressure on prescribers. Here, the committee is more demanding.

A second consequence is that the saving will only be truly obtained if the new medicine obtains a share in the market and the saving is proportional to that market share. Because prescriptions, apart from a few exceptions, still depend more on promotional input from companies than on price disparities, it should be noted that when service provided is equal, costlier medicines sell better than less costly medicines. The committee can therefore accept prices no lower than that of the last comparative medicine inscribed, when it appears that a lower price would, for the operator of the medicine to be registered, be such an obstacle within the competition that very few packs would be sold.

Finally, the committee pays particular attention, for new galenical products without ASMR, to verifying that the registration of these new medicines does not have the effect or objective, when products whose patents are about to expire are involved, of closing the route to the development of generic products economically or legally. In this situation, in accordance with ministerial policy, the committee will not accept the registration at a price higher than that of the corresponding generics.

2. Medicines with ASMR

Registration of these medicines may incur additional expenses for social security, but determining the acceptable additional cost is a difficult question for which there is no model solution.

There is in fact no scale of acceptable price disparities associated with the ASMR scale. Discussing the price of a medicine with an ASMR is therefore an open negotiation in which the company's needs are confronted with the greater or lesser need or urgency to have the medicine registered for reimbursement in terms of satisfying health needs.

On two important points, however, ministerial policies specify the framework for these negotiations. First, there are the medicines for which the ASMR equals or exceeds III, for which, in accordance with the ministerial policies and under conditions specified in the framework agreement, the committee accepts prices consistent with those in the main European Union Member States for registration. This principle does not mean that every medicine benefiting from this type of ASMR has the right to reimbursement at a European price level; rather, it means that if reimbursement is approved, it will be at this price. Indeed, if the expense incurred through this price level appears disproportionate to the anticipated benefit to patients or to public health, the product may not be reimbursed.

In particular, for these medicines, discussions on registration prices are usually accompanied by discussions on conventional clauses. These are as important as the price itself, as their aim is usually to ensure that the medicine is used in accordance with identified needs as far as possible, or to make provision, according to the total sums in question, for bulk rebates (see

2.3). Registration of these medicines also depends frequently on the completion of studies under the conditions laid down in Article 6 of the framework agreement.

In contrast, when an ASMR IV medicine is aimed at replacing a medicine that can become or is becoming generic within prescriptions, registration can only be at a price, or according to a pricing table, so that this registration does not, in the short or medium term, incur any additional cost to the sickness insurance.

Finally, for the other ASMR IVs, price discussions must take account of the characteristics of the target population. For example, when the medicine has the same target population as its comparator, the committee readily estimates that sufficient benefit to the company from the innovation shall be in the increase in market share, without the need to add a price benefit. Things may be different when the ASMR arises from a specific benefit enjoyed by a restricted section of population.

3. Price revision clauses

The fixing of prices carries revision clauses in three main circumstances.

When the initial price is established on the basis of hypotheses that only time and use can prove or disprove, and when it must be guaranteed that the real cost per patient of using a medicine remains consistent with the cost agreed with the company at the time of registration over a long period of time. This is the objective of daily treatment cost (CTJ) clauses.

When it must be ensured that the quantity of a medicine sold is consistent with the medically justified "target" for this medicine. This is the objective of volume clauses.

When, especially for medicines that benefit from a European price registration because of their ASMR, the price level and probable sale volumes justify not maintaining the price beyond the period guaranteed in the framework agreement. Unconditional price reduction clauses may then be concluded, with a due date fixed by agreement.

3.1. CTJ clauses

CTJ clauses are themselves divided into two categories: measurement range CTJ clauses and dosage clauses. Many medicines for which a "dose effect" is established for their use are offered in several different doses, either when marketed or later when additional doses are registered. In this case, the committee considers that the best way of guaranteeing good use of the various doses of the medicine and equality of treatment between competing business in the category in question is for all doses of the same medicine to be sold at the same price per galenical unit. The uniform prices prevent companies from having an interest in specifically promoting the sale of higher and more costly doses. In addition, they allow the equilibrium of relevant prices to be maintained between competing companies over time, as the actual cost of treatment is then independent from division of sales into various doses.

When a uniform price cannot be fixed, especially in cases of international price homogeneity, a measurement range CTJ clause will be substituted in order to obtain more or less the same effect. In this case, the cost agreed with the company at the time of registration is in fact a daily treatment cost (CTJ), expressed in prices for different doses according to a prescription

allocation hypothesis. If the actual allocation varies in terms of use from the assumed division of use, the prices will be revised to re-establish the cost of the conventional treatment.

The aim and mechanism of the dosage clauses are exactly the same as for the measurement range CTJ clauses. It is agreed when a treatment cost is registered on the basis of an average dose hypothesis (AMM dosage or dosage certified by studies conducted prior to registration, including in countries where the medicine is already marketed). If the dosage observed differs from that on the basis of which the sale price was established, this price will be revised in order to re-establish the agreed cost of treatment.

3.2. Volume clauses

The committee estimates that volume clauses are unjustified when their main effect is to divide markets between competing companies. In addition, they make little sense when registering products without ASMR; sales of these products will lead to a saving for social security, the saving increasing as the sales, made in place of costlier products, increase. The committee considers the quantitative end-of-year rebate mechanism for each therapeutic class appears to be more suitable.

On the other hand, these clauses are essential in the quite common cases where the ASMR for an innovative medicine is valid only for some of its indications or for a limited patient population, or when, independently of any financial consideration, there are public health grounds for requiring that a medicine should only used in restricted indications where it is essential, as is often the case for antibiotics in particular.

The committee has endeavoured to stop concluding agreements that contain CTJ or volume clauses implementation of which would only be sanctioned through payment of rebates. However, in order to prevent the thresholds specified in the clauses being slightly exceeded on a reversible basis and leading to successive marginal price alterations that are costly in administrative terms, it agrees to make the effective application of price reductions dependent upon the crossing of a variation threshold, with unrealised price reductions then being compensated by equivalent rebates. In particular, in accordance with the framework agreement, the price variation clauses concluded for ASMR-III-or-over medicines generally provide for conversion into a rebate during the first five years of marketing.

4. Price alterations

In addition to price reductions based on application of clauses, which do not need further comment, prices may be reduced on the committee's initiative in three other circumstances.

When a registration is renewed, this is the opportunity to examine the effective position of a medicine on the market. This position may be markedly different from the position predicted at the time of registration. This is particularly the case when volumes of the medicine prescribed have increased significantly since the moment of registration following an extension of indications, even when the medicine is not misused. A price reduction can also be justified, in accordance with the Social Security Code, through the marketing of equally effective and less costly competing medicines subsequent to the medicine's first registration.

In accordance with Article L.162-17-4 of the Social Security Code, when changes in expenditure on medicines are clearly not ONDAM-compliant, they may of course be in compliance with the ministerial policies and the commitments of the framework agreement.

Reductions may also be justified on the basis of studies relative to use of medicines in real situations, conducted in accordance with Article 6 of the framework agreement, and more generally, when there are significant changes to scientific and epidemiological data taken into account for concluding the agreements.

Companies may of course propose reductions. These reductions will by nature be competitive, mainly observed up until now for original versions of generic groups placed under reference pricing (TFR). The committee does not dismiss the possibility of these applied reductions being extended to medicines under patent, insofar as the prescribers' and patients' sensitivity to the price increases, and the companies, when the medical service provided is identical, have to highlight the reduced cost of their medicines in their promotional literature.

The committee will accept price increases for medicines essential for satisfying health needs and registered at a price that no longer covers their manufacturing and marketing costs. Usually, these medicines are old products for which the market is steadily shrinking, "orphan" medicines or medicines that may be likened to them without however corresponding strictly to the definition of an "orphan" medicine.

In contrast, the committee will refuse proposals from companies for price alterations with zero result, even though the immediate effect may be neutral or beneficial to the social security, if these results prove more costly in the long term and are likely to upset the relative prices within pharmaceutical and therapeutic classes.

ANNEX 5: TABLE OF THRESHOLDS TRIGGERING REBATES BY AGGREGATE

1. Establishing the table

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

- Segmentation of aggregates;
- Identifying those aggregates in which the likely sales trend is expected to lead to the payment of rebates ;
- The general balancing of the table.

A) SEGMENTATION

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

This involves making sure, especially for aggregates by virtue of which quantitative rebates will be due, that the *de facto* solidarity thus achieved between companies is fully justified by the competitive circumstances in which they are placed for the sale of their products belonging to these aggregates, and therefore that, conversely, no company is subject to rebates on account of the growth in sales of medicines not competing with its own products.

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

B) DETERMINING AGGREGATES HAVING TO GIVE RISE TO QUANTITATIVE REBATES

This is achieved by an analysis involving two successive stages. At first, the Committee assessed the prospects of a normal sales trend in each of the aggregates. It then identified those of these aggregates in which it deemed rebates to be justified as well as the relative extents to which these rebates are justified.

1) Assessment of the prospects of a normal sales trend

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

This assessment is based on four criteria:

- ***The trend in the prevalence of the condition requiring treatment***, whatever the causes of this trend: progress in screening (e.g. diabetes), ageing population (e.g. osteoporosis), environmental changes (e.g. asthma) or eating habits. The shift to

general practice healthcare of conditions previously treated only in hospitals is treated as a positive trend in the prevalence (e.g. hepatitis C);
- ***The current or potential introduction of innovations*** onto the reimbursable drugs market;
- ***The penetration of generics*** which is likely, conversely, to reduce the amount of sales in the aggregates where these drugs are introduced;
- ***Recognised public health priorities***, whether their objective is to increase the use of certain drugs (e.g. vaccines, pain relief drugs) or reduce it (e.g. antibiotics).

2) Identification of aggregates having to give rise to a more or less large proportion of rebates

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

This appraisal too is based on four criteria:
- ***medical value (SMR), as assessed by the Transparency Commission***. It seemed quite natural to the Committee that the rebate mechanism should lead, for the health insurance system, to a reduction in costs due to medicinal products whose medical value was judged insufficient to justify their inclusion in the list of reimbursable medicines;
- ***time on the market***. The Committee also considers it normal that, for older classes of drugs, even if these drugs are still protected by patents, and even if their medical value is still important, the health insurance cost should be reduced to allow, in observance of the across-the-board constraint, the financing of innovations;
- ***the excessiveness of sales of certain drug aggregates from the viewpoint of medically justified needs***. This is most notably the case of medicines whose medical value is indisputable but whose first line use has largely grown to the detriment of equally effective and cheaper products, while the price of the medicines concerned is justified only by the specific advantage which they afford to smaller patient populations or for second line use (e.g. ACE inhibitors and angiotensin II converting enzyme inhibitors in hypertension, inhaled corticosteroids specially indicated in severe asthma but used in all forms of asthma, new generations of antibiotics, etc.);
- ***the intrinsic importance of volumes sold.*** These are aggregates whose SMR is undisputed, and for which there is nothing to suggest that the volumes are not justified, but whose burden on health insurance expenditure and growth is considerable (e.g. statins, proton pump inhibitors). The rebates anticipated are in such cases purely quantity rebates, justified solely by virtue of the major client status of the French health insurance system. The appraisal of this criterion, as with the previous criterion, may take into account the variances recorded in previous years between the rates used by the Committee and actual attainments, which may account for certain rates being reduced by comparison with what had been initially anticipated for the current and subsequent years.

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

C) GENERAL BALANCING OF THE TABLE

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

- The variances between the rates used and the normal trend prospects in the aggregates, as established according to the criteria set forth in point 1), must be consistent with the analysis of point 2). In other words, and by way of an example, an aggregate in which the criteria of point 2) converge, thereby leading the Committee to consider that the rebates must be proportionally large, will be allocated a much lower rate, positive or negative, than that of the normal trend in its sales. Conversely, an aggregate for which none of the criteria of point 2) justify rebates will be allocated a rate, positive or negative alike, equal at least to the normal trend in its sales.
- The system adopted must produce results acceptable to the companies. This is a practical constraint, which prohibits the use of rates, even where fully justified according to the foregoing principles and criteria, which would however result in requiring rebates from a company or group of companies with special arrangements under the health insurance scheme representing a disproportionate amount of their turnover.
- The weighted sum of the rates used must be equal to the threshold rate triggering the "safeguard" contribution. This is the core principle behind the establishment of the table, and its very raison d'être. The main outcome is that the rates used have no indisputable value as absolute figures, but that the Committee has endeavoured, on the contrary, to be able to ascertain, by applying the stated criteria and by adopting a relative approach between aggregates, the sense and scale of the variances between the rates used and the normal prospects of the trend in sales in these aggregates.

The mechanism put in place culminates for each drug aggregate in a rate of growth expressed as a disparity in relation to the ONDAM rate so that the trend on the basis of each of these rates in each of the drug groups leads to an overall result equivalent to the ONDAM forecast. The justification of the rate disparities is the adjustment, without altering the nominal price of the medicines, of the actual prices (less rebates) paid by the general taxpaying public for the various drugs groups and their marginal usefulness. This mechanism, coupled with the exemptions provided most notably for generics or highly innovative drugs, ensures consistency between the financial regulation procedures and the fundamental guidelines of Government policy on medicinal products : proper use of medicinal products and elimination of waste, development of the generics market, support for innovation. Secondarily, this type of regulation may act as a marginal but real incentive for companies to direct their promotional efforts towards the drugs groups for which the threshold triggering rebates is greater than the spontaneous trend in sales and which should not give rise therefore to rebates.

2 – Rebate calculation methods

A) MECHANISM

1) Total rebate

The total rebate due under an aggregate in which the sales trend was greater than the rate appearing in the Committee's table is spread between the companies marketing products in this aggregate as follows:

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

The aim is to not penalise the marketing of new products, including when they have no ASMR rating and they represent a saving for social security.

2) Exemption of innovations

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

3) Exemptions of low-cost products

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

B) THE REBATE RATE

The rebate rate is set at 28% of the overruns recorded in relation to the rates appearing in the Committee's table. It remains an established fact, under the framework agreement, that the net total (all companies combined having contractual arrangements under the public health insurance scheme) of rebates actually paid by way of the rebate by aggregate and by way of rebates on turnover will not be greater than the total contributions which the same companies would have had to pay in pursuance of article L. 138-10 of the Social Security Code. To ensure compliance with this limit, the 28% rate will, if necessary, be uniformly reduced for all aggregates giving rise to payment of rebates.

3. Table of thresholds triggering rebates per aggregate, period 2004-2007

Group	Turnover 2003 (K€)	2004 rate, inc. K rate	2005 rate, inc. K rate	2006 rate, inc. K rate	2007 rate, inc. K rate
A02A (antacids, anti-flatulence drugs) + **A02B, B3, B9** (H2 receptor antagonists, prostaglandins, other ulcer treatments)	151,800	-2	-4	-4	0

A02B2, proton pump inhibitors	944,891	-2	-6	-10	-5
A03 (anti-spasmodics, anti-cholinergics and propulsives) **+ A04A9** (other anti-emetics)	188,096	0	0	0	0
A04A1 anti-emetics: serotonin antagonists	21,881	3	0	0	0
A05A1 + B + C choleretics, hepatoprotectors, cholagogues + **Desintex** (V03A) **+ A06** laxatives + **A07** (except A07E) anti-diarrhoea products + **Nalcron** & **Intercron** + **A09A** digestive products, inc. Enzymes	231,617	-7	-8	-3	0
A05A2 anti-lithiasis drugs + **A07E** intestinal anti-inflammatories (excluding Nalcron & Intercron)	49,187	3	0	0	0
A10 anti-diabetics	412,420	10	6	5	5
A11 + C10B (vitamins) + **A12A** calcium (excluding calcium Sorbisterit & Phosphoneuros) + **A12B** potassium	113,972	0	-2	-2	0
A12C + A13 magnesium, other mineral supplements and tonics (exc. Phosphorus Medifa & Nonan) **+ A15** orexigens	70,757	-15	-50	-50	0
B01A non-injectable anti-coagulants + **B01B** injectable anti-coagulants	214,499	5	7	7	0
B01C platelet aggregation inhibitors	344,888	8	0	0	0
B01D fibrinolytics + **B02** anti-haemorrhagic drugs, haemostatics + **B03** anti-anaemics + **A14** anabolic agents Folinoral & Lederfoline **(V03D)**	35,651	3	0	0	0
C01(A + C) + C06 heart glycol. stimul. (sf Dopa) and others (including **Anapen**) + **C01B** anti-arrhythmic drugs	132,739	1	-2	0	0
C01D coronary treatment + **C01E** nitric derivatives + **C02** anti-hypertensives + **C03** diuretics + **C07** beta-blockers + **C08** calcium antagonists	1,146,109	2	-1	-2	-3
C04 + N06D vasodilators & nootropics + Olmifon	276,276	-15	-50	-50	-50
C05 anti-haemorrhoidals and vasoprotectors	373,399	-12	-50	-50	-50
C09 renin-angiotensin system modifiers	1,020,599	4	0	0	0
C10A anti-cholesterol/triglycerides (except C10A1)	163,825	0	0	-2	0
C10A1 HMG-CoA reductase inhibitors	946,696	5	0	0	0
D dermatology + **Lamisil oral** (J02A)	415,019	2	-1	-1	0
G01 gynaecological anti-infectious drugs + **G04A** urinary antiseptics and anti-infectious drugs	73,630	-3	-3	-3	0
G02 (other gynaecological products) + **G03A** (ovulation inhibitors) + **G03C** (oestrogens) + **G03D** (progesterones) + **G03F** (oestroprogesterones other than **G03A**) + **G03H** (other sex hormones, excluding Evista, Optruma)	321,324	-10	-5	-5	0
G03B androgens (except G03E, F) + **G04B** urology (prostate, erection, incontinence, enuresis, others) + **G04C**	265,666	3	0	1	0
G03G gonadotrophins/ovulation inducers + **H01C** GNRH analogues (including **Orgalutran** ex H04V)	108,573	6	3	3	0
H01A ACTH + **H02** corticosteroids + **H04A**	170,478	3	-3	-3	-1

calcitonins + **H04B** glucagon + **H04D** anti-diuretic hormones + **H04V** other hormones and similar products					
H03 thyroid and anti-thyroid hormones	31,284	3	0	0	0
H04C growth hormones	86,587	2	-2	-3	-3
J01 general system antibiotics + **J02A** anti-fungal exc. Lamisil + **J03** + **J05B** anti-viral exc. anti-HIV (exc. Rebetol and Copegus)	973,384	-3	-3	-3	-3
J05C HIV anti-viral + **L03B1** alpha interferons + **Rebetol** & **Copegus** (J05B)	250,991	20	5	5	0
J06 + J07 (exc. J07C) serums, vaccines + **V01A** allergens	212,706	15	0	5	5
K massive solutions **+ Nonan** (A12C2)	19,564	13	10	10	0
L01+L02 anti-cancer drugs + cytostatic hormones + **Immucyst** & **Neulasta** (L03A)	378,729	30	15	12	10
L03B2 beta interferons + **Copaxone** (L03A)	160,657	4	0	0	0
L04 immunosuppressants	78,429	70	5	5	5
M01A1 + A3 anti-inflammatories, general system anti-rheumatics (exc. Art 50 & Zondar) **+ M04** anti-gout drugs	419,819	0	-5	-5	0
M01C + **Acadione** (M05X)	27,236	200	120	30	10
M01A2 + M02 + M06 local action (AINS, balms, revulsives) + anti-inf. enzymes + **M03** muscle relaxants with peripheral and/or central action	135,647	-7	-3	-3	-3
M05B anti-osteoclasts (including osteoporosis drugs + **Evista, Optruma**)	194,260	13	10	5	0
M05X other locomotive applications (exc. Acadione) **+ Art50** & **Zondar** (M01A1)	223,013	2	-2	-5	0
N01 anaesthetics	18,881	7	0	0	0
N02A narcotic painkillers **group 1** (narcotics exc. substitute treatments) **+ N02B** non-narcotic anti-pyretic painkillers + **N02C9** anti-migraine painkillers (exc. triptans) + **N07C** anti-dizziness drugs	772,651	3	0	0	0
N02C1 anti-migraine painkillers (triptans)	102,177	5	0	0	0
N03A anti-epileptics	190,200	8	2	2	2
N04A anti-Parkinson's products	73,962	5	2	2	2
N05A1 non-typical anti-psychotics	180,749	11	2	0	0
N05A9 conventional anti-psychotics + **N06A3** mood regulators	85,235	-1	-3	-4	0
N05B hypnotics & sedatives + **N05C** tranquillisers	285,252	-2	-5	-4	-5
N06A group 1 imipramines + IMAO	32,671	0	-4	-4	-5
N06A group 2 other anti-depressants (inc. IRS) (exc. Levotonin)	541,436	-1	-8	-10	-5
N02A group 2 substitute treatments + **N06B** psycho-stimulants + **N07E** alcohol dependency products + **N07F** opiate dependency products + **Rilutek** (N07X) + **Levotonine** (N06A1)	127,928	6	3	3	0
N07D anti-Alzheimer's products + **N07X** myasthenia products (exc. Rilutek & Olmifon)	129,555	18	12	12	5

P anti-parasite preparations + J04 anti-TB preparations, anti-leprosy preparations	11,817	4	1	1	0
R01A1 + A3 + A6 corticosteroids (alone or in combination) and other local allergic rhinitis preparations + **R06** anti-histamines	315,890	1	-3	-3	0
R01A4 + A7 + A9 + R01B anti-infectious rhinological drugs without corticoids + **R02** anti-infectious pharyngeal decongestants + **A01** stomatological products	143,159	-12	-30	0	0
R03 anti-asthmatics & bronchodilators (exc. R03X)	745,628	6	3	0	0
R04+R05 +R03X revulsives, cough medicines, expectorants, bronchopulmonary products, other bronchodilators + alpha-amylase **(M06)** + **Gomenoleo (V03)** + **R07** other products for respiratory use + **J07C** other vaccines	231,948	-12	-30	-3	0
S01 ophthalmology (exc. S1E & Visudyne)	110,176	-5	-5	-3	-1
S01E myotics, anti-glaucoma products	155,070	8	5	0	0
S01X1 Visudyne alone	29,877	18	0	0	0
S02 otology	12,213	3	0	0	0
T01 diagnostic products	86,702	8	2	0	0
T02 other diagnostic tests	6,501	3	0	0	0
V03 à V07 group 1 other medicines & miscellaneous (exc. Desintex, Desintex infant & Gomenoleo) not belonging to Group 2	47,767	-5	-3	-3	-3
V03 à V07 group 2 antidotes & chelating agents + **Phosphoneuros** (A12A), **Phosphorus Medifa** (A12C), **Calcium Sorbisterit** (A12A) + **Renagel**	16,293	53	0	0	0

ANNEX 6: PRICING CONVENTION AND STANDARD CLAUSES

1. Pricing convention for medicines

AMENDMENT
to the agreement dated dd/mm/yy
between
Economic Committee for Health Products
and the Company XXXX

Having regard to the Social Security Code and in particular articles L.162-16-4 & L 162-17-4.
Having regard to decree no. 99-554 of 2 July 1999 relating to the pricing and registration of medicines on the lists provided in articles L.162-17 of the Social Security Code and L.618 of the Public Health Code, and amending the Social Security Code.
Having regard to the order of 4 August 1987, as amended, relating to prices and margins set for reimbursablemedicines.
Having regard to the General Tax Code, in particular Article 281(8).
Having regard to the Public Health Code, in particular Articles L.5123-1, L.5121-8, L.5121-13 & L.5121-1.
Having regard to the long-term agreement entered into on dd/mm/yy between the Economic Committee for Health Products and Company XXXX.
The Economic Committee for Health Products and Company XXXX agree to the following provisions:

Article 1: The prices stated in the following table apply with effect from their publication in the *Journal Officiel*.

Registration or renewal of registration

Presentation	Class	PFHT	PPTTC
CIP code, brand name, dose (active principal), galenical form, packaging		€	€
……..		€	€
……..		€	€

Article 2: (see below "standard clauses").

Article 3: Annex 3 of the foregoing agreement is amended in accordance with article 1. Annex 4 of the foregoing agreement is amended in accordance with article 2.

Paris, (date)

Mr …
….
of companies XXX

Noël Renaudin
Chairman of the Economic Committee for Health Products

2. Standard clauses for medicines

2.1. Standard dose clause

Article 2
2.1. The price fixed in Article 1 (manufacturer price net of reference tax or $PFHT_R$) is fixed subject to the condition that the stated dose (P_C) is at least equal to (…) (reference dose: P_R).

2.2. The dose (P_C) is examined every year, and for the first time, on the dd/mm/yy on the basis of the latest Dorema published prior to that date.
If the stated dose (P_C) exceeds the reference dose (P_R), the PFHT fixed in Article 1 will be amended ($PFHT_M$) so that:

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

Once an initial price alteration is made in application of this clause, no new price alteration can be made in application of this clause unless the stated dose is greater than the dose on which the previous price change was based.

If $(P_C - P_R) / P_R$ is less than x%, the $PFHT_R$ is not altered and the company is owed a refund (R) calculated according to the formula shown in 2.3.

2.3. If the stated dose (P_C) is greater than the reference dose (P_R), the company may *in addition* be owed a refund (R) calculated according to the formula:

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

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

2.4. The Economic Committee for Health Products shall notify the company of the total refund due. The company shall pay the refund to ACOSS one month after notification from the CEPS. The company will inform the CEPS by mail of the date and total of the payment made.

(The total refund may, by agreement, be deducted from the basis of assessment of the corresponding year-end class rebate payable by the company).

2.2. Standard clause for daily treatment cost (CTJ) by range

Article 1
The first registration charges (or price alterations…) indicated in the following table are applicable from the date of their publication in the Journal Officiel (or… shall enter into force on dd/mm/yy).

Presentations	Class	PFHT	PPTTC
First registration – CIP Code, Presentation aaa, …		€	€
First registration – CIP Code, Presentation bbb, …		€	€
Price alteration – CIP Code, Presentation ccc, …		€	€

Article 2
2.1. The prices in Article 1 are set subject to the condition that the stated daily treatment cost ($CTJG_C$) calculated on the range consisting of aaa, bbb, ccc etc. equals at least €(…), the reference daily treatment cost by range ($CTJG_R$).

2.2. The $CTJG_C$ is examined every year and for the first time for the 12-month period preceding dd/mm/yy. It is calculated on the basis of the doses for each presentation mentioned in Point 2.1 and appearing in the latest Dorema published prior to dd/mm/yy and of sales over 12 months shown in the latest GERS published prior to that date.

The $CTJG_C$ is calculated by dividing the turnover achieved over the entire range (CAHTG), recorded in the GERS, by the number of treatment days by range (NJTG), namely:

$$CTJG_C = CAHTG/NJTG$$

NJTG is equal to the total number of treatment days for each presentation in the range, namely:

$$NJTG = \Sigma NJT_i$$

The number of treatment days, NJT_i, is equal to the number of tablets (doses, units) sold for each presentation *i* in the range, divided by the corresponding dose (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 $CTJG_R$, the PFHT for at least one of the range's presentations mentioned in 2.1 is reduced so that the CTJG is equal to the $CTJG_R$.

2.3 and following (see dose clause)

2.3. Standard unit volume clause

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

2.2. The sales volume V_C is examined each year, and for the first time on dd/mm/yy on the basis of the last GERS published prior to that date.

If the recorded annual sales volume (V_C) is greater than a reference volume (V_R), the PFHT is amended ($PFHT_M$) so that:
$PFHT_M = x\ PFHT_R + (1 - x)\ PFHT_R \times (V_R / V_C)$, with $0 < x < 1$.

Once an initial price alteration is made in application of this article, a new price alteration can only be made in application of this clause if the stated volume is greater than the volume on which the previous price change was based.

2.3 and following (see dose clause).

3. Convention and standard clause for medical devices

AGREEMENT
Between the Economic Committee for Health Products
and the Company XXXX

Having regard to the Social Security Code and in particular Articles L.165-2, L.165-3 & L.165-4.
Having regard to the opinion of the Products and Services Evaluation Committee (CEPP) dated dd/mm/yy.
The Economic Committee for Health Products (CEPS) and the Company XXXX agree to the following provisions.

Article 1: This agreement is concluded subject to the suspensive condition of signature by the ministers of the decree relating to the registration, and the setting of the limit retail sale price, of YYYY. This agreement shall be effective from the date of publication of the decree in question in the Journal Officiel.

Article 2: XXXX undertakes to provide the Committee each year, during the month of mm, as a flexible year ending in the month of mm and for the first time during the month of mm/ yyyy, the total number of devices YYYY sold by it in France during the previous year.

Article 3

3.1 If the number (N) of devices YYYY sold annually exceeds a number (n), the prices/tariffs (P) shown in the order referred to in Article 1 shall be altered (P_M) using the formula $P_M = (a \times P) + [(1-a) \times P \times (n/N)]$ (*with* $0 < a < 1$). The company shall then be owed a rebate (R), calculated according to the formula $R = (P_V - P_M) \times N$. In this formula, P_V is the current price of the device in question. If however $P_M / P_V > x\%$, no price reduction shall be made and the company shall still be owed the rebate R.

3.2 Once a price reduction is made in accordance with Paragraph 3.1, a new reduction can be made in application of Paragraph 3.1 only if the number N' of devices sold YYYY, recorded on that occasion, is greater that the number (N) giving rise to the previous reduction and if $P_M / P_V > x\%$. If $N' > n$ and $P_V > P_M$, the company shall be liable for a rebate $R = (P_V - P_M) \times N'$.

3.3. The Economic Committee for Health Products shall notify the company of the total for the refund mentioned in Article 3. The company shall pay the refund in favour of ACOSS, one month after notification from the CEPS. The company shall inform CEPS by mail of the date and sum of the payment made.

Article 4: The company XXXX undertakes to conduct and finance a study (…). This study must allow (…). The results of the study shall be communicated to the CEPP and CEPS.

Paris (date)
Signature: For the company XXXX
Signature: Chairman of the Economic Committee for Health Products

ANNEX 7: COMPOSITION OF THE COMMITTEE

1. Members of the Economic Committee for Health Products

Noël Renaudin, President

1.1. Medicines Section

Bernard Teissière, Vice-President

Representatives of Social Security Director: Ministry for Solidarity, Health & Family Affairs
Stéphane Seiller, Deputy Director, Care Systems Finance Sub-Directorate
Michèle Larreur, Pharmaceutical Adviser, Care Systems Finance Sub-Directorate, followed by :
Arlette Meyer, Pharmaceutical Adviser, Care Systems Finance Sub-Directorate
Eric Parpaillon, Head of Office of Health Products
Vincent Houdry, Deputy Head of Office of Health Products

Representatives of Director-General for Health: Ministry for Solidarity, Health & Family Affairs
Hélène Sainte-Marie, Deputy Director, Health Products Policy Sub-Directorate
Jean-François Clerc, Head of Office of Medicines
Sophie Fégueux, Deputy Head of Office of Medicines
Nathalie Manteau, Office of Medicines

Representatives of Director-General of Competition, Consumption and Fraud Prevention: Ministry of the Economy, Finance and Industry
Claudine Ségelle, Deputy Director of Health, Industry and Commerce Sub-Directorate
Anne Dux, Head of Health Bureau E1
Annick Biolley-Coornaert, Health Bureau E1
Nolwenn Delaruelle, Health Bureau E1
Sylvie FAGES, Health Bureau E1.

Representatives of Director-General of Companies: Ministry of the Economy, Finance and Industry
Gérard Mathieu, Manager of Life Industry and Technology Sub-Directorate, Chemistry and Materials
François Lhoste, Manager of Economic Tasks, Chemistry, Pharmaceuticals & Biotechnology Sub-Directorate
Catherine Trenque, Deputy Sub-Director, Chemistry, Pharmaceuticals and Biotechnology Sub-Directorate

Representatives of national sickness funds nominated by the Director-General of the National Sickness Insurance Fund for Salaried Workers
Brigitte Moreau followed by Jocelyn Courtois, Deputy Director
Christian Marty, Deputy Director, Medicines Specialist for Delegated Risks Director

Emmanuelle Fabre, Medicines Division
Martine Pigeon, Medicines Division Manager

Representative of national sickness funds, nominated together with the Director of CNAMM for non-salaried workers in non-agricultural professions and by the Director of CNMSA
Brigitte Heuls-Bernin, Deputy National Adviser

Representative of Hospital Admissions and Care Organisation Director: Ministry for Solidarity, Health and Family Affairs
Dominique Lagarde, Task Manager for Hospital Admissions and Care Organisation Director

Representative of Minister for Research
Jean Deregnaucourt, Director of Department of Bio-Engineering

Representative of additional insurance funds
….

1.2. Medical Devices Section

(…), Vice-President

Representatives of Social Security Director: Ministry for Solidarity, Health & Family Affairs
Stéphane Seiller, Deputy Directors, Care System Finance Sub-Directorate
Eric Parpaillon, Head of Office of Health Products
Isabelle Cheiney, Deputy Head of Office of Health Products
Olivier Verney, Office of Health Products

Representatives of Director-General for Health: Ministry for Solidarity, Health & Family Affairs
Hélène Sainte-Marie, Deputy Director, Health Products Policy Sub-Directorate
Bernard Kirschen, Head of Office of Medical Devices and Other Health Products, followed by :
Sandrine Le Gall, Head of Office of Medical Devices and Other Health Products
Sophie Casanova, Office of Medical Devices and Other Health Products
Laure Prestat, Public Health Doctor, Office of Medical Devices and Other Health Products

Representative of Hospital Admissions and Care Organisation Director: Ministry for Solidarity, Health and Family Affairs
Françoise Cabane, Task Manager for T2A mission, followed by :
Anne L'Hostis, Doctor and Inspector-General of Public Health, Task Manager

Representatives of Director-General of Competition, Consumption and Fraud Prevention: Ministry of the Economy, Finance and Industry
Claudine Ségelle, Deputy Director, Health, Industry and Commerce Sub-Directorate
Anne Dux, Head of Health Bureau E1
Daniel Miles, Health Bureau E1
Arlette Turier, Health Bureau E1

Representatives of Director-General of Companies: Ministry of the Economy, Finance and Industry

Gérard Mathieu, Manager of Life Industry and Technology Sub-Directorate, Chemistry and Materials
Marie-Claire Sebag, Head of Medical Devices Division

Representative of national sickness insurance funds
Jocelyn Courtois, Deputy Director
Christian Marty, Deputy-Director
Christine Vaulont, Economic Studies Manager, Medicines and Medical Devices Department

Representative of national sickness funds, nominated together with the Director of CNAMM for non-salaried workers in non-agricultural professions and by the Director of CNMSA
Brigitte Heuls-Bernin, Deputy National Adviser

Representative of additional insurance funds
(…)

2.Rapporteurs to the committee

Mrs Michèle AUDEOUD-FAURIS, Mrs Hélène BOURDEL, Mrs Élisabeth CREPON, Mr Nicolas GASPARD, Mrs Claire OGET-GENDRE, Mr Jean-Marc GROGNET, Mr Philippe LALANDE, Mrs Régine LEMÉE-PECQUEUR, Mr Jean-François MATTEI, Mrs Michèle MSIKA-BOUTIGNY, Mrs Marie-Françoise PENY, Mrs Catherine PHILIPPE, Mr Michel ROUSSEAU, Mr Franck SUDON, Mr Bruno STALLA, Mr André TANTI, Mr Jean-Pierre YVERT.

3. Declarations of interest

NATURE OF INTEREST	
Employment Contract	CT
Financial participation in capital of company	PF
Work carried out for a consideration (participation in clinical tests, studies, consultations, research etc	TR
Other declared interests	A

3.1. Committee members and persons participating in committee meetings

Full name (section)	Nature of interests
Economic Committee for Health Products	
Mr Noël RENAUDIN	CT: none. TR: none. PF: none. A: none
Mr Bernard TEISSEIRE (M)	CT: none. TR: none. PF: none. A: none
Mrs Michèle AUDEOUD-FAURIS (M)	CT: none. TR: none. PF: none. A: none.
Mrs Sylvette LAPLANCHE	CT: none. TR: none. PF: none. A: none.
Mrs Claire OGET-GENDRE (DM)	CT: none. TR: none. PF: none. A: none.
Mr Michel ROUSSEAU	CT: none. TR: none. PF: none. A: none.
Social Security Directorate	
Mr Stéphane SEILLER	CT: none. TR: none. PF: none. A: none.
Mrs Isabelle CHEINEY (DM)	CT: none. TR: none. PF: Air Liquide. A: none
Mr Vincent HOUDRY (M)	CT: none. TR: none. PF: none. A: none.
Mrs Michèle LARREUR (M)	CT: none. TR: none. PF: none. A: none.
Mrs Arlette MEYER (M)	CT: none. TR: none. PF: none. A: none.

Mr Eric PARPAILLON	CT: none. TR: none. PF: none. A: none.
Mr Olivier VERNEY (DM)	CT: none. TR: none. PF: none. A: none.
Health Directorate-General	
Mrs Hélène SAINTE-MARIE	CT: none. TR: none. PF: none. A: none.
Mr Jean-François CLERC (M)	CT: none. TR: none. PF: none. A: none.
Mr Bernard KIRSCHEN (DM)	CT: none. TR: none. PF: none. A: none.
Mrs Sophie FEGUEUX (M)	CT: none. TR: none. PF: none. A: none.
Mrs Sandrine LE GALL (DM)	CT: none. TR: none. PF: none. A: none.
Mrs Nathalie MANTEAU (M)	CT: none. TR: none. PF: none. A: spouse works with Biogen IDEC
Mrs Sophie CASANOVA (DM)	CT: none. TR: none. PF: none. A: none
Hospital Admissions and Care Organisation Directorate	
Mrs Françoise CABANE (DM)	CT: none. TR: none. PF: none. A: none.
Mrs Dominique LAGARDE (M)	CT: none. TR: none. PF: none. A: none.
Mrs Anne L'HOSTIS (DM)	CT: none TR: none. PF: none. A: none.
Directorate-General of Competition, Consumption and Fraud Prevention	
Mrs Claudine SEGELLE	CT: none TR: none. PF: none. A: none.
Mrs Anne DUX	CT: none. TR: none. PF: none. A: none.
Mrs Annick BIOLLEY-COORNAERT(M)	CT: none. TR: none. PF: none. A: none.
Mrs Nolwenn DELARUELLE (M)	CT: none. TR: none. PF: none. A: none.
Mrs Sylvie FAGES (M)	CT: none. TR: none. PF: none. A: none.
Mr Daniel MILES (DM)	CT: none. TR: none. PF: none. A: none.
Mrs Arlette TURIER (DM)	CT: none. TR: none. PF: none. A: none.
Directorate-General for Companies	
Mr Gérard MATHIEU	CT: none. TR: none. PF: none. A: none.
Mr François LHOSTE (M)	CT: none. TR: none. PF: none. A: none.
Mrs Catherine TRENQUE (M)	CT: none. TR: none. PF: none. A: none.
Mrs Marie-Claire SEBAG (DM)	CT: none. TR: none. PF: none. A: none.
Compulsory Sickness Insurance	
Mr Jocelyn COURTOIS	CT: none. TR: none. PF: none. A: none.
Mr Christian MARTY	CT: none. TR: none. PF: none. A: none.
Mrs Brigitte HEULS-BERNIN	CT: none. TR: none. PF: none. A: none.
Mrs Martine PIGEON (M)	CT: none. TR: none. PF: none. A: none.
Mrs Christine VAULONT (DM)	CT: none. TR: none. PF: none. A: none.
Ministry of Research – Technology Directorate	
Mr Jean DEREGNAUCOURT	CT: none. TR: none. PF: none. A: none.

3.2 *Rapporteurs* to the Economic Committee for Health Products

Rapporteurs	Nature of interests
Mrs Hélène BOURDEL	CT: none. TR: none. PF: none. A: none.
Mrs Elisabeth CREPON	CT: none. TR: none. PF: none. A: none.
Mr Nicolas GASPARD	CT: none. TR: none. PF: none. A: none.
Mr Jean-Marc GROGNET	CT: none. TR: none. PF: none. A: none.
Mr Philippe LALANDE	CT: none. TR: none. PF: none. A: none.
Mrs Régine LEMEE-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: none. 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 Jean-Pierre YVERT	CT: none. TR: none. PF: none. A: none.

4. Details of persons serving on the committee

Name	Duties	Telephone	Fax	E-mail
Michèle Audéoud-Fauris	Deputy Secretary-General, Medicines Section Manager	01.40.56.75.54	01.40.56.71.79	michele.audeoud-fauris@sante.gouv.fr
Anne-Marie Bouchard	Hospital Medicines: monitoring of applications, compilation of decisions and publication in JO	01.40.56.60.70	01.40.56.71.79	anne-marie.bouchard@sante.gouv.fr
Ghislaine Brouard	Assistant to President and Vice-Presidents	01.40.56.78.64	01.43.06.30.02	Ghislaine.brouard@sante.gouv.fr
Marie-José Calvo	Assistant, Medical Devices Section			
Marie-Thérèse David	Assistant, Medicines Section	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
Sylvette Laplanche	Secretary-General	01.40.56.46.95	01.40.56.71.79	sylvette.laplanche@sante.gouv.fr
Soheila Léger	Monitoring of agreements – medicines	01.40.56.71.27	01.40.56.71.79	soheila.leger@sante.gouv.fr
Marie Lucet	Compilation and JO publication of decrees, decisions and advices - medicines	01.40.56.44.27	01.40.56.71.79	marie.lucet@sante.gouv.fr
Claire Oget-Gendre	Deputy Secretary-General, Medical Devices Section Manager	01.40.56.45.60	01.40.56.40.50	claire.oget-gendre@sante.gouv.fr
Viviane Pierre	Administrative monitoring – medical devices	01.40.56.57.55	01.40.56.40.50	viviane.pierre@sante.gouv.fr
Catherine de Pretto	Registration of price and reimbursement applications	01.40.56.46.84	01.40.56.71.79	Catherine.depretto@sante.gouv.fr
Maryvonne Richer	Manager, databases and computer files	01.40.56.53.46	01.40.56.40.50	Maryvonne.richer@sante.gouv.fr
Michel Rousseau	General Rapporteur	01.40.56.49.51	01.40.56.71.79	michel.rousseau@sante.gouv.fr
Geneviève Uchida-Ernouf	International information gathering	01.40.56.72.14	01.40.56.71.79	genevieve.uchida-ernouf@sante.gouv.fr