HEALTHCARE PRODUCTS PRICING COMMITTEE

ANNUAL REPORT 2010

July 2011

CONTENTS

ILLUSTRATIONS

Under the terms of the *Code de la Sécurité Sociale* (Social Security Code), Article D. 162-2-4, the *Comité économique des produits de santé*, or CEPS (the healthcare products pricing committee), must send a report on its work each year to the Ministers for Social Security, Health, the Economy and Industry respectively. Article L. 162-17-3 of the Social Security Code provides that the report must also be sent to Parliament.

This report describes the principal aspects of the committee's work in 2010.

Part one deals with medicines, looking first at the medicines market and reimbursements in 2010 (Chapter I), followed by price setting (Chapter II), and regulation and agreements between CEPS and the pharmaceutical companies (Chapter III).

Part two deals with healthcare products other than medicines. Chapter I describes the state of the market, and changes in spending on medical devices. Chapter II describes the committee's work on tariff and price setting for the products and services defined in Article L. 165-1 of the Social Security Code. Chapter III describes the committee's work on price and tariff adjustments for medical devices.

Part three reports on the contribution made by CEPS to France’s investment attraction policy.

PART ONE - MEDICINES

CHAPTER I – REIMBURSABLE MEDICINE SALES AND EXPENDITURE IN 2010

1. General market trends

The year 2010 saw a relatively smaller increase in sales of reimbursable medicines dispensed in community pharmacies or covered through the hospital system. Over the previous five years, the average growth in wholesale turnover before tax had been 3%, whereas in 2010 it was only 1.3%.

Table 1: Growth in sales of reimbursable medicines 2000–2010

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Growth rate	7.7%	7.7%	5.7%	6.5%	6.9%	5.0%	1.8%	3.9%	2.8%	2.8%	1.3%

Source: GERS community pharmacy sales data and company tax declarations for hospital sales; CEPS data processing.

This lower growth in total sales of medicines was due to the fact that the sales to community pharmacies remained at practically the same level (+0.5% on 2009), even though sales to hospitals rose faster than in previous years (+6% on 2009).

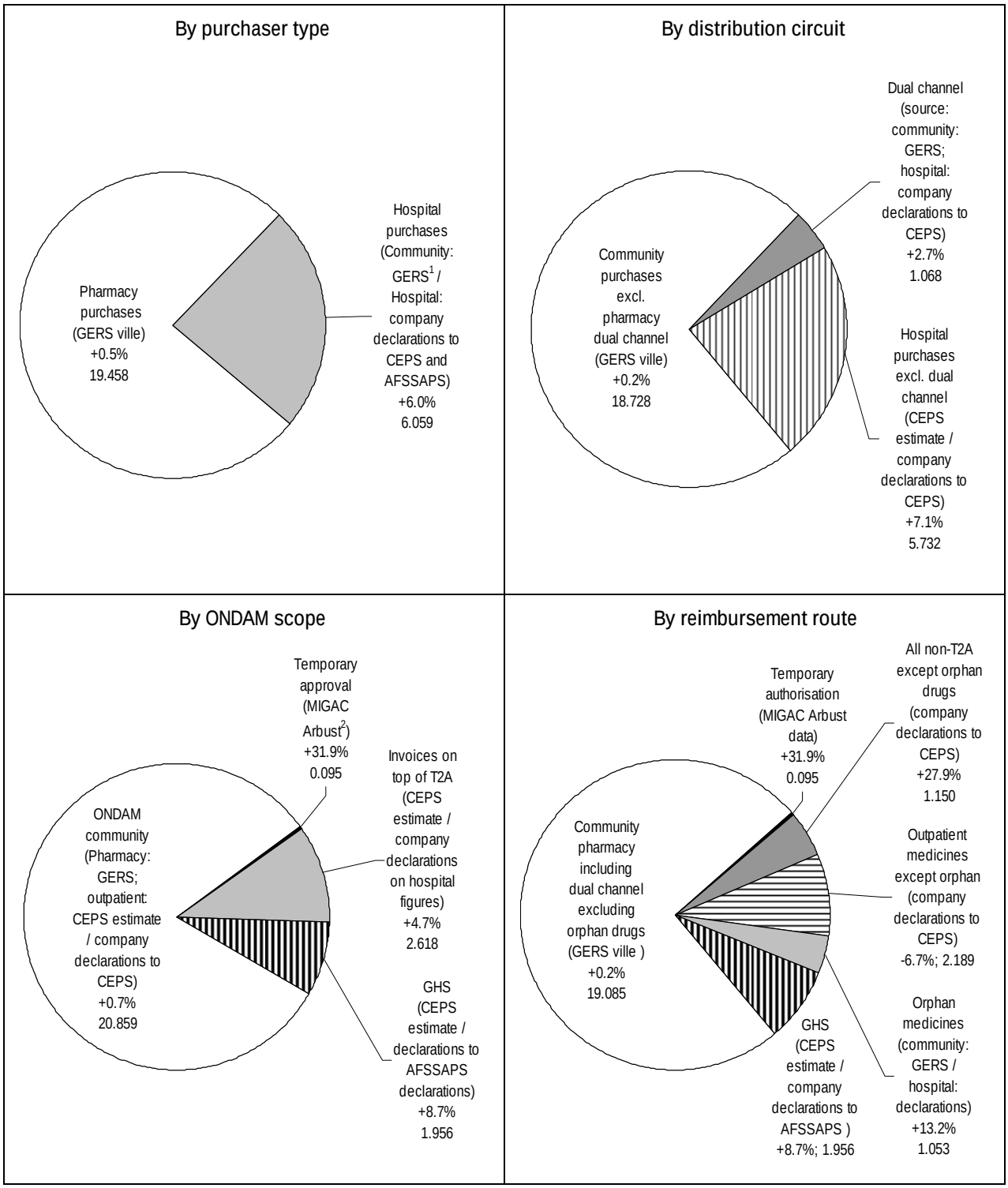
The main reasons for this slower growth are the same as those described in the committee's previous annual reports; namely: market composition effects such as lapsing of patents and the impact of generic substitution, combined with research avenues drying up and new developments slowing down, as these two factors had previously fed a strong market composition effect; the impacts of regulation, through price management and cost control by medical staff, especially in the pharmacotherapeutic groups that led growth in the early 2000s (statins, ACE inhibitors/sartans, protein pump inhibitors, anti-cancer agents, etc.). The upward market composition effect is now caused primarily by niche drugs and even orphan drugs, involving relatively limited patient numbers.

2. Sales of medicines covered by national health insurance

Sales of medicines covered by *l'Assurance maladie* (the national health insurance body) totalled EUR 25.528 billion. For the last two years, CEPS has presented the total sales of reimbursable medicines according to the different categories by which they can be broken down, in other words by type of purchaser, distribution channel, ONDAM scope or reimbursement method. CEPS arrived at this breakdown essentially by comparing the following: the companies' sales figures, as declared to AFSSAPS for the payment of the duties they owe; the data on community pharmacy sales gathered by GERS; the declarations CEPS receives from the companies for the end-of-year financial adjustments, and the data gathered by ATIH.

The committee calculates the breakdown of sales of medicines for hospital patients into those issued to outpatients and those issued to inpatients, for which *l'Assurance Maladie* is invoiced on top of the basic 'GHS' funding, by looking at the type of product and the information it has on hospital dispensing practices (for example through ATIH data).

Figure 1: Breakdown of the EUR 25.528 bn sales of medicines covered by national health insurance in 2010



1 GERS: see glossary in Appendix 7; GERS ville - statistics compiled by GERS on medicine sales to community pharmacies.
2 MIGAC – See glossary; Arbust MIGAC: software application used by ATIH.

2.1. *Sales within the scope of the ONDAM community target*

2.1.1 *Breakdown of growth in sales of medicines dispensed by community pharmacies*

In 2010, sales of medicines through community pharmacies were comparable to the 2008 figures, with a low growth rate and slower growth than the previous year. These sales, expressed as wholesale price ex VAT, were only 0.5 % higher than the 2009 figure.

The fact that there was no flu epidemic at the end of the year, and the greater price reductions compounded other factors that had already contributed to a slowing down in this market in previous years (generic substitution, the impact of cost control requirements of medical staff, the practical absence of new developments).

Table 2: Growth in sales of reimbursable medicines through community pharmacies, 2009-20010

	Sales in wholesale price ex VAT (€bn)	Sales in retail price inc VAT (€bn)
2009	19.36	27.11
2010	19.46	27.19
Growth	0.5%	0.3%

Source: GERS community pharmacy sales data, data processed by CEPS.

Price, pack and market composition effects

In 2010, the price effect reflected the price reductions brought in as a result of ministerial guidelines, which had a greater impact than those of the previous two years.

The absence of flu from the scene was reflected in an opposite effect to that observed in 2009; in other words a reduction, albeit fairly small, in sales of non-narcotic analgesics/antipyretics, antibiotics and flu-specific antiviral agents. The downward pack effect was due to lower sales volumes of medicines that had been moved to the 15% national health insurance cover band (8% lower on the 300,000,000 packs sold in 2009), and to the low level of epidemics.

This year, the growth in sales in drug groups in which the average pack price was well above the average pack price of reimbursable medicines sold in community pharmacies (see breakdown by pharmacotherapeutic category below) was not offset by sales of cheaper products or products that had recently gone off-patent. Overall, this meant that the market composition effect was higher than in 2009.

Table 3: Breakdown of growth in pre-tax sales through community pharmacies, 2010

Year	Price effect	Pack effect	Composition effect	Total growth
2004	-0.4%	-1.1%	7.8%	6.2%
2005	-1.0%	3.4%	4.4%	6.8%
2006	-3.9%	-5.6%	11.1%	0.8%
2007	-2.1%	0.0%	6.1%	3.8%
2008	-2.2%	-4.9%	8.3%	0.8%
2009	-2.2%	3.1%	1.3%	2.2%
2010	-2.5%	-0.9%	4.1%	0.5%

Source: GERS community pharmacy sales data, data processed by DSS/6B.

Average price of medicines in community pharmacies

After the drop in 2009, the average price of reimbursable medicines sold in community pharmacies, both excluding and including VAT, reached a higher level than the 2008 average.

Once again, the upward market composition effect, resulting from the bias in sales of pharmaceutical products towards the more expensive products, in spite of the increasing level of generic substitution for original drugs, offset the committee's price reductions.

The slight decrease in markup rate combined with the very low growth in turnover was reflected in a lack of movement in pharmacists' income from reimbursable medicines.

Table 4: Growth in average pack price and distribution markup on reimbursable medicine sales

	2004	2005	2006	2007	2008	2009	2010
Total sales ex VAT (€bn)	16.82	17.97	18.10	18.79	18.94	19.36	19.46
Total sales inc VAT (€bn)	24.31	25.83	25.83	26.61	26.53	27.11	27.19
Number of packs (millions)	2 724	2 817	2 658	2 656	2 529	2 607	2 582
Average wholesale pack price ex VAT (€)	6.18	6.38	6.81	7.08	7.49	7.43	7.54
Growth / year n-1	*7.40%*	*3.20%*	*6.70%*	*3.89%*	*5.90%*	*-0.85%*	*1.44%*
Average retail pack price inc VAT (€)	8.93	9.17	9.72	10.02	10.49	10.40	10.53
Growth / year n-1	*6.10%*	*2.70%*	*6.00%*	*3.05%*	*4.73%*	*-0.86%*	*1.25%*
Average markup[1]	2.57	2.60	2.71	2.74	2.78	2.76	2.78
Growth / year n-1	*2.80%*	*1.20%*	*4.10%*	*1.10%*	*1.72%*	*-0.88%*	*0.76%*
Markup rate[2]	44.50%	43.80%	42.70%	38.70%	37.13%	37.12%	36.87%

Source: GERS community pharmacy sales data, data processed by CEPS.
1. Distribution markup = wholesaler's markup + pharmacy's markup (wholesale price ex VAT + markup + VAT = retail price inc VAT).
2. 2 Markup rate = average markup on average wholesale price ex VAT.

Table 5: Prices and distribution markups of medicines on the substitution list and those not on the list in 2010

Market	Average wholesale price (AWP) ex VAT	Average retail price inc VAT	Average markup[1]	Markup rate[2]
Generics[3]	4.06 €	6.73 €	2.54 €	62.5%
Original drugs	7.16 €	10.24 €	2.87 €	40.0%
Whole substitution list	5.06 €	7.87 €	2.64 €	52.3%
Non-substitution list	8.68 €	11.77 €	2.86 €	32.9%

Source: GERS community pharmacy sales data, data processed by CEPS and DSS/6B.
1. Distribution markup = wholesaler's markup + pharmacy's markup (wholesale price ex VAT + markup + VAT = retail price inc VAT).
2. 2 Markup rate = average markup on AWP ex VAT.
3. AFSSAPS substitution list of 1 February 2011.

The markup percentages on generic and original drugs in 2010, as well as those on medicines not on the generics substitution list, were similar to the 2009 rates. The increased market share of generics with a high market, in other words generic versions of an expensive original drug, was reflected in the increased average markup rate of medicines on the substitution list.

Market share of generics

Generic groups accounted for over a third of the medicine packs sold in community pharmacies in 2010, and for a quarter of the total pre-tax wholesale turnover from community pharmacies.

The market share of generics in these groups was 67%. The pre-tax wholesale turnover from generics totalled EUR 2.6 bn in 2010, representing an 11% increase in relation to 2009.

Table 6: Market share of generic medicines 2009-2010

	2009 [1]		2010 [2]	
	Units	Value	Units	Value
Proportion of generic groups in overall market	34.72%	24.74%	36.91%	24.74%
Proportion of generics in generics group market	66.38%	49.18%	67.38%	54.20%
Proportion of generics in overall market	23.04%	12.17%	24.87%	13.41%

Source: GERS community pharmacy sales data, data processed by DSS-6B.
1– 2009 Operational substitution list; 2 – 2010 operational substitution list (these include all the generics groups listed in the Journal Officiel *in which generics were actually sold during the year in question).*

Analysis of growth by category of pharmacotherapeutic groups

In 2010, the antidiabetics category of pharmacotherapeutic groups was the main contributor to growth. In particular, the new antidiabetic treatments indicated for patients with type 2 diabetes contributed strongly to growth in this category. The pre-tax sales of sitagliptin-based drugs alone (*Januvia* and *Xelevia*), introduced onto the market in 2008, including sitagliptin plus metformin fixed dose combinations (*Janumet* and *Velmetia*), introduced onto the market in 2009, rose by EUR 63 million. However, the advent of these fixed dose combination drugs was not accompanied by a fall in sales of generic metformin, for which the pre-tax wholesale figures remained at a steady level.

As in previous years, disease-modifying antirheumatic drugs continued to rank among the main contributors to growth. They were the second largest contributors, as in 2009, and for the same reasons. Sales of TNF alpha inhibitors, used in inflammatory rheumatic diseases, chronic inflammatory intestinal conditions such as Crohn's disease and plaque psoriasis, continued to progress rapidly. The high growth in this category of pharmacotherapeutic groups was primarily due to the growth of two of these drugs, *Enbrel* and *Humira*, which on their own accounted for growth worth EUR 65 million. Similarly, ocular anti-neovascularisation agents, led by *Lucentis*, recorded growth worth EUR 53 million between 2009 and 2010.

Drugs indicated for the treatment of hepatitis and HIV/AIDS were also among the main contributors to growth. However, since these are distributed through both community and hospital channels, there is little purpose in considering the impact that growth in their sales had on the community market alone (see 2.1.3).

Pre-tax turnover on orphan medicines rose by 18% to EUR 56 million. This strong growth reflected very different trends, depending on the type of product. The main types of product concerned were:

- drugs previously covered by temporary licence and hence only issued in hospitals, which since obtaining marketing authorisation had recently been included in the community pharmacy lists also. These drugs are aimed at a small number of patients (between several tens of patients and 3 000) but the annual treatment cost is very high. These were *Afinitor*, *Nplate* (called *Romiplostim* under temporary licence); *Firdapse* (called *Zenas* under temporary licence); and accounted for growth worth EUR 35 million in the community pharmacy market in 2010.

- older drugs with a high turnover which were already on the community pharmacy lists in 2009 and continued to grow at a steady rate: *Glivec*, *Sprycel*, *Exjade*, *Tasigna*, *Xagrid* (+ EUR 23 m for these drugs alone).

Table 7: Top five groups contributing to sales growth in 2010

Group	Pre-tax sales in 2009 (in €M)	Pre-tax sales in 2010 (in €M)	Growth (in €M)	Growth rate
A10 (antidiabetic drugs) + A08A (anti-obesity products) (inc Insuplant)	712	828	116	16.3%
M01C (disease-modifying anti-rheumatic drugs) + Acadione (M05X) + Orencia, Raptiva and Roactemra (L04A) + L04B (TNF inhibitors)	434	505	71	16.3%
J05B1 (hepatitis antivirals) + J05C (HIV antiretrovirals) including Intelence + L03B1 (alpha interferons)	669	731	62	9.2%
Z (Orphan medicines)	318	374	56	17.7%
S01P (ocular antineovascularisation agents)	189	241	53	27.9%

Source: GERS community pharmacy sales data; data processed by CEPS.

At the other end of the scale, some of the pharmacotherapeutic group categories with falling sales had seen strong growth until recently. For example, pre-tax wholesale turnover from anti-platelet agents fell by EUR 197 million, due to the advent of the first generic versions of clopidogrel *(Plavix)* in October 2009. Generic versions of clopidogrel made an impact on the market immediately, but quickly reached a plateau (65% market share on average in 2010). Added to this, whereas prescriptions and sales volumes of clopidogrel had been increasing for several years, they fell sharply once the generics had come onto the market.

As regards proton pump inhibitors, cost control actions by medical staff (slowing the growth in sales volumes), combined with the committee's action on pricing, continued to exert an effect.

Table 8: Top five groups contributing to downward growth in 2010

Group	Pre-tax sales in 2009 (in €M)	Pre-tax sales in 2010 (in €M)	Growth (in €M)	Growth rate
B01C (antiplatelet agents) excluding Xagrid	576	379	-197	-34.1%
J01 (systemic antibacterials) except Alkonatrem (J01A) + J02A (systemic antimycotics) except Terbinafine + J03A (systemic sulphonamides) + J05B (antivirals excl. anti-HIV agents) except J05B1 + G04A (antiseptic agents and urinary tract anti-infective agents)	904	805	-99	-11.0%
A02B2 (proton pump inhibitors)	837	756	-81	-9.7%
C01D + E + X (treatments for coronary arterial disease) + C02 (antihypertensives) + C03 (diuretics) + C07 (beta blockers) + C08 (calcium channel blockers) + Caduet (C10A1)	1,019	955	-65	-6.3%
C09 (renin-angiotensin system drugs)	1,403	1,376	-27	-1.9%

Source: GERS community pharmacy sales data, data processed by CEPS.

2.1.2 *Medicines issued to outpatients by hospital pharmacies*

Since there is no hospital information system in a position to supply these data, CEPS calculates sales of medicines intended for hospital outpatients according to the same method it has used in previous years, in other words on the basis of the companies' declarations of sales of medicines to hospitals, and where the medicines are also on the list of medicines billed on top of 'GHS' funding, by narrowing it down to those that are actually issued and claimed for.

The committee calculates that sales of medicines actually issued and claimed for in 2010 were worth EUR 1.4 billion: a 3.5% rise compared with 2009. CNAMTS has assessed the total figure reimbursed under all the health insurance schemes as approximately EUR 1.5 billion, which represents growth in the region of 2.5% compared with 2009. This is a clear slowdown in comparison with

previous years. In 2009, the growth rates of sales and expenditure were 12.5% and 11.5% respectively, as previously reported.

Delays in invoicing make it difficult to compare sales of medicines that can be issued to outpatients and those actually claimed back from *l'Assurance Maladie*. The slower growth rate in expenditure as compared with sales is in keeping with the drop in the fixed markup per prescription line from EUR 26.00 in 2009 to EUR 22.00 in 2010, for each pharmaceutical product issued by hospital pharmacies, identified by a common dispensing unit (UCD) code.

Developments in the antiretrovirals market (see analysis of outpatient medicines below), together with the fact that in 2009 the committee put into practice its policy of reviewing the prices of medicines that had been on the approved lists for over five years, where it was found that a lower price was being charged for the same medicine in at least one of the four European reference markets, led in most cases to precipitating the slower growth of the medicines concerned, or to further slowing growth that was already moderate.

2.1.3 *The dual channel: drugs for hepatitis and HIV/AIDS*

Growth in pre-tax turnover from products distributed both through the hospitals and community pharmacies (the 'dual channel') slowed down in 2010 to 2.6%, from having been much stronger in previous years (7.4% in 2008 and 9% in 2009).

Two separate factors contributed to this slower growth. In the first instance, the antiretrovirals that had recently come onto the market progressed at a much slower rate in 2010 than during the previous two years. Secondly, the slowdown can be explained by reductions in the prices of the medicines after five years on the French market, in line with other prices in Europe.

Table 9: Growth in dual channel sales 2009-2010

	2009	2010	Growth
Sales in wholesale price ex VAT (€M)	1,040	1,068	2.6%
Proportion of sales by hospitals	36%	32%	-12.3%

Source: GERS community pharmacy sales data and tax declarations of reimbursable hospital medicine sales; CEPS data processing.

2.2. *Sales within the scope of the ONDAM hospital target*

2.2.1 *Medicines invoiced on top of 'GHS' funding*

Sales of medicines invoiced on top of basic funding rose by 4.7% in 2010, to a total of EUR 2.62 billion.

There are no shared, itemised statistics explaining this figure, therefore CEPS' calculation is based on a comparison between several different sources. The committee receives quarterly declarations of sales by UCD (common dispensing unit) from the pharmaceutical companies, covering products included on the outpatient list or on the list of products that can be invoiced on top of 'T2A' service-based funding. For drugs that are on both lists, the committee cannot find out directly what proportion of the sales is made up of sales of outpatient medicines and sales of medicines invoiced on top of 'T2A' funding respectively. However, using the data supplied by ATIH[1] it is possible to identify what proportion of the UCDs were invoiced on top of T2A funding. By comparing the companies'

[1] This is for 2009, since the data for 2010 were not available at the time of writing this report.

declarations against the ATIH data, each UCD can be allocated to one distribution channel or the other when the product is on both lists.

2.2.2 *Medicines under temporary approval*

At present, under Article L.5121-12 of the *Code de la Santé Publique* (Public Health Code) companies are not obliged to routinely declare their sales of medicines covered by temporary approval to CEPS.

Medicines with temporary approval may be issued to outpatients and claimed back from health insurance unless they are for hospital use only:

- Unlicensed medicines approved for a clinical trial (Article L.5121-12 CSP) are included on the outpatient medicines list (Articles R.5126-102 to R.5126-110 CSP).

- Unlicensed medicines approved on a named patient basis are treated as being on the outpatient medicines list. These medicines are not entered on the list by decree, therefore.

Under the rider to the CEPS-LEEM framework agreement of 7 October 2010, the pharmaceutical companies are required to make quarterly declarations for these medicines.

In the absence of more accurate information for 2010, purchases of unlicensed medicines not on the outpatient medicines list are estimated on the basis of the funds granted to the establishments under 'MIGAC' funding by the regional hospital services and healthcare agencies. In 2010, EUR 94.6 million was provided for unlicensed medicines, representing a 31.9% increase on the 2009 figure.

2.2.3 *Medicines funded under 'GHS' funding*

No detailed statistics are kept of purchases made by establishments under 'GHS' funding (general hospitalisation costs according to diagnosis-related groups). CEPS therefore estimates the total of these purchases by comparing the declarations it receives from the pharmaceutical companies against those made by the companies to AFSSAPS. The latter, however, were only partly available at the time of writing this report. The scope of the two declarations is different, however those made to AFSSAPS include medicines funded under general hospitalisation costs. According to our estimate, sales of medicines funded under the GHS heading rose by 8.7%. This rise can be explained by the inclusion of some anticancer drugs under the GHS heading.

2.3. *Orphan medicines*

Growth in sales of orphan medicines continued at a high rate in 2010 (pre-tax wholesale turnover was +13 % in relation to 2009). They accounted for sales of EUR 1.05 billion, made primarily to hospitals.

In 2010, more than sixty orphan medicines were on the market in France, of which nine accounted for 68% of the total turnover. Five others, each achieving a turnover of close to EUR 30 million, accounted for 12% of this sector, whilst turnover from the remaining fifty or so orphan medicines accounted for only 20%.

In accordance with Article 29 of the 2011 Social Security Finance ACT (*Loi de Financement de la Sécurité Sociale* – LFSS), in 2011 around ten orphan medicines will therefore no longer be exempt

from volume clawback payments due to their orphan status, under Article 18-a-3 of the framework agreement between CEPS and the pharmaceutical companies.

3. From sales of reimbursable medicines to actual reimbursements

Total sales including VAT of reimbursable medicines by community pharmacies rose to EUR 27.19 bn in 2010, representing a 0.3 % increase on the 2009 figure. Added to this is the figure for hospital outpatient medicine sales, estimated at EUR 1.37 bn, or approximately EUR 1.49 bn including markup and VAT, compared with EUR 1.45 bn in 2009. The total growth in sales of reimbursable medicines within the scope of the ONDAM community target from 2009 to 2010 can therefore be calculated as 0.4 %.

To translate the growth in sales into the growth in expenditure within the scope of the ONDAM community target, we need to know what changes there were in the average reimbursement percentage. The fact that the actual reimbursement percentage under the general health insurance scheme remained steady, and even decreased slightly over the period 2007–2009, even though the theoretical average percentage rate increased over the same period, led the committee to deduce that fewer reimbursements had been paid out to patients with chronic conditions, in other words at the 100% rate. The situation was not the same in 2010. The actual reimbursement percentage reported by CNAMTS was higher again, at 76.25 % in 2010 as opposed to 75.59 % in 2009[2], whereas the theoretical reimbursement percentage, in other words the percentage that would emerge if none of the insured were on the chronic conditions rate, remained the same (see Table 10).

Growth in reimbursements of medicines within the scope of the ONDAM community target was therefore 1.5 %, according to the data the committee received from CNAMTS.

Table 10: Growth in community pharmacy and hospital sales and in theoretical reimbursements (in € M) according to cover level, 2009-2010

	2009			2010		
Cover level (theoretical reimbursement)	Sales inc VAT	Theoretical reimbursements	Average theoretical cover level*	Sales inc VAT	Theoretical reimbursements	Average theoretical cover level
15%	-	-	66.16%	899	135	66.10%
35%	3,711	1,299		2,629	920	
65%	20,718	13,467		20,713	13,464	
100%	2,680	2,680		2,952	2,952	
100% reimbursed hospital sales	1,450	1,450		1,488	1,488	
Total under ONDAM community target	28,559	18,896		28,681	18,958	

Source: CNAMTS and GERS community pharmacy sales data and tax declarations of hospital sales; data processed by CEPS.
**average cover level for products, weighted by sales inc VAT. This can differ from the actual reimbursement level, as patients with chronic conditions receive 100% reimbursement regardless of the stated cover level.*

[2] Monthly statistics from the general health insurance scheme (*régime général*). Total expenditure as at December 2010.

CHAPTER II – PRICE SETTING WORK IN 2010

1. Price setting methods for medicines dispensed in community pharmacies

The way in which medicine prices were set did not change in 2010. It is described in Appendix 2, which repeats much of what was said in the 2009 annual report, with some additional information about the assessment of new alternatives, restricting spending on 'ASMR' rated medicines in the expensive categories and the 'risk-sharing contracts that were explained in the 2009 report.

1.1. *Smaller markdown on niche market generics*

When it is not possible to place a generic drug on the market at a price based on a 55% markdown on the original drug's wholesale price before tax, because of the restricted size of the market concerned, the complex formulation of the original drug, or the low price of the original due to the length of time it has been on the market, the committee may agree to apply a smaller markdown. The committee stipulates, sometimes in agreements with the companies, that it will increase the markdown if a wider range of generic versions comes onto the market.

The committee has also decided that the general rule whereby the original drug's price is reduced by 15% once generic versions come onto the market could prevent generic versions of some of the older drugs from being marketed. This is because where the manufacturing costs are such that the price of the generic cannot be marked down significantly in comparison with the price of the original drug, the application of the minus 15% rule results in too small a difference between the respective retail prices of the original and the generic, which compromises the legitimacy of generic substitution by pharmacists and the credibility of the policy on generics.

At the meeting of the Generics Monitoring Committee of 8 October 2009, CEPS had made known its intention to establish general guidelines, which would state that this 15% markdown could be reduced, or even removed.

The following rule was adopted and communicated to GEMME on 15 March 2010: 'Original drugs of which the first generic version obtained marketing authorisation more than five years after the original drug's patent had expired could be partly or fully exempted from the 15% markdown rule, in particular in the light of the type of product and its production cost.'

1.2. *Markdown on parallel import or parallel distribution medicines*

Parallel import or parallel distribution medicines[3] account for a small proportion of overall sales and a limited number of companies (usually known as parallel importers or parallel distributors).

In setting the prices for these medicines, the committee aims to limit the level of expense for *l'Assurance maladie*, but without contravening the principle of free movement of goods within the European Union. The companies' proposed markdowns in relation to current prices in France were very small. The committee eventually agreed to the principle of a minimum markdown of 5%, both at the time of registration on the lists and thereafter.

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[3] Parallel import: the drug has both marketing authorisation issued in its Member State of origin and in its Member State of destination.

Parallel distribution: the drug has marketing authorisation issued by the European Commission.

2. Statistics on medicines dispensed in the community

The following statistics relate to applications submitted by companies and to price change files opened at the committee's instigation.

The case files are categorised in terms of a single type of application regarding a single product: first application for registration – either on the community medicines list only or on both the community medicines and public hospital medicines lists – but only for products available in community pharmacies, re-inclusion on the lists, price change, extended indications, or changed conditions of use.

Several different products relating to the same drug may be grouped together in one file (for example different doses of the same product) and some of these may have several different formats (e.g. packed in boxes of 7 x 10mg tablets or 28 x 10mg tablets). Price change case files opened at the committee's instigation may cover several different products marketed by the same company.

2.1. *Case files opened in 2010*

The number of files opened in 2010 was just as high as in 2009, although there were fewer product formats per file and slightly fewer files relating to generics.

There was a higher proportion of generics among the re-inclusion applications compared with previous years. The number of re-inclusion applications for biosimilar drugs were added to those for generics. However, the proportion of generics among the price change files was much lower than in 2009.

In spite of the expected wave of price reductions in September 2010, price change applications only accounted for 27% of all applications in 2010 (as opposed to 43% in 2009).

Table 11: Number and type of case files for drugs opened in 2010, by application type

Type of application	Number of files	Number of products or product formats[1]	Number of files relating to generics	Percentage of files relating to generics
Extended indications	22	172	0	0%
Price change	235	1,236	490	40%
First listing	520	1,291	939	73%
Re-listing	620	1,933	913	47%
Total	1,397	4,632	2,342	51%

Source: CEPS - from Medimed software application, 12 January 2011.

1. The same product or product format could be included in more than one application over the course of the year.

2.2. *Case files closed in 2010*

In 2010, 1,256 case files, covering an average of 3.3 products or product formats, were closed (see Table 12).

Table 12: Number and type of case files for drugs opened in 2010, by application type

Type of application	Number of files	Number of products or product formats[1]	Number of files relating to generics	Percentage of files relating to generics
Extended indications	14	41	0	0%
Price change	249	1,218	464	38%
First listing	542	1,342	967	72%
Re-listing	451	1,566	916	58%
Total	1,256	4,167	2,347	56%

Source: CEPS - from Medimed software application, 12 January 2011.

1. The same product or product format could be included in more than one application over the course of the year.

As in previous years, 96% of the files processed culminated in an agreement between the committee and the respective company, leading to an announcement in the *Journal Officiel* (See Table 13). Applications abandoned by the company or rejected by the committee were rare (each accounting for 1% of the applications processed). A registration or re-inclusion application is rejected if the government departments qualified to deal with registration represented on the committee are against the registration or re-inclusion of the medicine concerned, after examining the opinion of the Transparency Commission *(Commission de la Transparence)*.

Table 13: Numbers of products or product formats by type of application and decision for files closed in 2010

Decision / Type of application	Accepted	Abandoned	Withdrawn	Rejected	Total
Extended indications	34	0	7	0	41
Price change	1,142	24	49	3	1,218
First listing	1,284	2	32	24	1,342
Re-listing	1,520	0	38	8	1,566
Total	3,980	26	126	35	4,167

Source: CEPS - from Medimed software application, 12 January 2011.

2.3. *First applications for registration on the reimbursable medicines lists*

Of the first applications for registration, 72% related to generics. This is a smaller proportion than over the last few years. In 99% of cases, first-listing applications for generics resulted in an agreement, compared with 88% for original drugs (with or without generic equivalents).

Table 14: Outcome of first listing applications handled in 2010 by numbers and type of product

decision / Type of product	Accepted	Abandoned	Withdrawn	Rejected	all
generics	955 / 99%	0 / 0%	10 / 1%	2 / 0%	967
original drugs	329 / 88%	2 / 1%	22 / 6%	22 / 6%	375
all	1,284 / 96%	2 / 0%	32 / 2%	24 / 2%	1342

Source: CEPS - from Medimed software application, 12 January 2011.

2.4. *Case files still in progress at the end of 2010*

As at 31 December 2010, 684 were still in progress. The end-of-year backlog was smaller once again, especially for first registration applications and price change applications, though not for re-listing applications.

Table 15: Number of case files still in progress on 31 December 2010

Type of application	Total number of files in progress	Percentage of files relating to generics
Extended indications	38	0%
Price change	50	41%
First listing	155	44%
Re-listing	441	32%
Total	684	33%

Source: CEPS - from Medimed software application, 12 January 2011.

3. Processing times for registration applications for the community list

3.1. *Processing of fast-track price applications*

Both applications processed via the fast-track procedure in 2010 were opposed by the committee. The reason for the committee's objection to the applications, which were both for orphan drugs, was the inadequacy of the undertakings made by the companies, considering the price level requested and the target patient group.

3.2. *Overall processing time of first applications for registration on the reimbursable medicines lists*

The average time taken to process files in 2010 was the same as in 2009 (105 days as opposed to 106). However, whilst the overall processing times were identical, compared with 2009 the processing times were slightly longer for applications resulting in an announcement in the *Journal Officiel* but were much faster for the minority of applications that were abandoned or withdrawn by the company or rejected by the committee.

Table 16: Processing times for drug listing applications in 2010 by type (in number of days)

Type of product	Accepted	Abandoned, withdrawn or rejected	All
generics	62	183	64
Non-generics	205	240	209
all	99	227	105

Source: CEPS - from Medimed software application, 12 January 2011.

3.3. *Interim processing times*

The overall time taken to process a first listing application has been broken down into the following five stages: from submission of the application up to delivery of the Transparency Commission (TC) opinion to CEPS; from delivery of this opinion up to the committee's first session (examination), from the first to the last of the committee's sessions devoted to the same case (negotiation), from the last session up to the signing of the additional clause (agreement) and from the signing of the additional

clause by both parties up to publication of the registration decree and price notice in the JO or to closure of the file in cases of withdrawn, rejected or abandoned applications.

Applications must be lodged simultaneously with both CEPS and the Transparency Commission. During this first stage, the TC examines the application and notifies CEPS of its opinion. Only non-generic medicines, with some exceptions (change of pack format from that of the original drug or non-reimbursable original drug), go through this stage of the application.

Table 17: Interim processing times for applications for registration on the community list in 2010 (in number of days)

Type of product	TC	Examination	Negotiation	Agreement	JO or closure	TOTAL
generics	1	14	1	16	33	64
Non-generics	79	19	48	25	38	209
all	ns	16	14	19	34	105

Source: CEPS - from Medimed software application, 12 January 2011.

3.3.1 *First stage: Transparency Commission*

Applications must be lodged simultaneously with both CEPS and the Transparency Commission. During this first stage, the TC examines the application and notifies CEPS of its opinion. Only non-generic medicines, with some exceptions (change of pack format from that of the original drug or non-reimbursable original drug), go through this stage of the application. In 2010, these exceptions related to 3rd generation tablets for which the original drug was non-reimbursable.

The interval between submission of the application and receipt of the Transparency Commission's opinion rose to 79 days on average for non-generic medicines.

3.3.2 *Second stage: Examination*

For non-generic medicines, this stage runs from the date on which CEPS receives the TC's opinion to the first session during which the committee examines the product or product format. This stage may include the appointment of a rapporteur after receipt of the TC's opinion, who examines the application in liaison with the pharmaceutical company and draws up a report which is given to the committee, as well as the time taken to enter the relevant application on the committee's agenda (at least one clear week after committee members have received the report).

The examination times for applications continued to decrease, from an average of 21 days in 2009 to 16 days in 2010.

3.3.3 *Third stage: Negotiation*

This third stage runs from the first to the last of the sessions during which CEPS examines the application. It corresponds to the time required by the committee to draw up its proposal, where it is not finalised in a single session, plus the time needed for negotiations between the committee and the pharmaceutical company. The committee must examine the company's counter-proposals if the latter rejects the committee's initial proposal following discussions with the rapporteur.

The average length of negotiations for generic medicines stayed the same as in 2009 (1 day). However, the overall average length of the negotiation period was longer (48 days in 2010 as opposed to 41 in 2009). One particular registration of a drug, for which the application was initially rejected in 2006 and for which the second application made in 2007 was only finalised in 2010, lengthened the average negotiation time by two days The length of the negotiation period (882 days) is partly due to

the submission of new study findings and re-assessment by the Transparency Commission after the resumption of the file.

3.3.4 *Fourth stage: Agreement*

This is the time between the last of the committee's sessions devoted to an application and the signing of the corresponding contract rider. It corresponds to the time needed to draw up the terms of the rider, which may involve several exchanges of correspondence between CEPS and the company over sometimes complex clauses, and also the time required for the logistics involved in the two parties signing the rider. The fourth stage actually includes a final negotiating period which is difficult to separate from the time required for the practical arrangements.

The length of this stage has been the same for a number of years, at an average of 19 days.

3.3.5 *Fifth stage: Signing of the decrees and publication in the Journal Officiel.*

This final stage includes the committee's drawing up of the price decrees and notices of registration on the reimbursable medicines lists, which then need to be signed by the relevant departments at the Ministry of Health. This period also includes the time taken for UNCAM's Chief Executive to decide on the reimbursement rate and for these decisions to reach the committee. Lastly, for all these texts to be published in the JO, they must first be sent to the General Cabinet Office *(secrétariat général)*.

This last stage took 34 days on average, which is shorter than in previous years.

4. Hospital prices and tariffs

4.1. *Methods for setting hospital prices and tariffs*

In the vast majority of cases, the price or tariff published is the price submitted by the company. However, for one product, after opposing the first price submission, the committee reached an agreement after the second submission. For four products, the prices submitted were definitively opposed.

However, the principles for an agreement were adopted and acknowledged by the pharmaceutical companies in riders to the framework agreement of 7 October 2010 (see Chapter III, section 1). The first agreements in the form of riders to the framework agreement were signed in 2010. These undertakings can give rise to clawback payments.

4.2. *Statistics*

The committee processed 51 registration applications in 2010 (see Table 18). These were for new products or new product formats added to existing ranges of products already on either the outpatient medicines list or the list of medicines invoiced on top of GHS funding. Each registration application comprised an average of three tariff lines (one line per common dispensing unit).

Of these 51 new applications, 30 related to outpatient medicines and 21 to medicines invoiced on top of GHS funding, 10 of which were registered on both lists.

A third of these registration applications were for original drugs. The generics that were registered were anticancer agents and one medicine indicated for the treatment of pulmonary arterial hypertension (PAH).

The following drugs were registered on both lists: a blood product (*Clairyg*), a clotting factor (*Fibrogammin*), a novel anticancer agent (*Javlor*), and an orphan drug indicated for mobilising stem cells (*Mozobil)*; the following were registered on the list of medicines invoiced on top of GHS funding only: a clotting factor (*Feiba*) and a TNFα blocker (*Cimzia*); whilst a paediatric oral vitamin E treatment (*Vedrop*) was registered on the outpatients medicines list only.

Table 18: New registrations on the hospital lists in 2010

Type of application / List	new applications	prices submitted	prices not submitted	No of generics
T2A	21	18	3	12
Outpatients	30	16	14	21
TOTAL	51	Number of these for both lists: 10 files		

Source: CEPS.

4.3. *Application processing times*

The processing times for applications for registration on the hospital medicines lists are worked out on the basis of medicines that were registered on the outpatient medicines list or the list of medicines invoiced on top of GHS funding for which a price was published in 2010.

The average interval between registration on one of the lists and publication of the price in the JO was 62 days (see Table 19). In cases where the company submitted a price, in accordance with Article 8b of the framework agreement, the interval was 58 days. Where there was no price submission by the company, the interval was 70 days. No submission was made for almost a third of the registrations, and in 2010 these concerned generics only. In these cases, the public price or tariff is the price decided unilaterally by the committee.

The average interval between registration on the outpatient medicines list and publication of the public prescription price was 81 days, whilst the interval before publication of tariffs for medicines registered on the list of medicines reimbursable on top of GHS funding was 42 days. This difference can be explained by the fact that for the 'additional medicines' list, the tariffs can be published at the committee's initiative without going through any further procedures. On average the tariffs are published 15 days after the pharmaceutical company has been notified of the committee's decision. For medicines on the outpatient list however, the price can only be published at the same time as that of the reimbursement rate after this has been registered with the public bodies and this is an average of 40 days after the pharmaceutical company has been notified of the committee's decision. Nonetheless, this interval was reduced considerably in comparison with 2009, when it was 53 days.

Table 19: Interim processing times for applications for registration on the hospital lists in 2010 (in number of days)

Price submission intervals	between registration and submission	between submission or registration and 1st meeting	between 1st meeting and decision	between decision and publication	Total
yes	6.9	11.2	9.7	30.6	58.3
no	---	40.7	5.8	22.8	69.3
Total	ns	20.2	8.5	28.2	61.7

Source: CEPS.

CHAPTER III - REGULATION

1. The rider of 7 October 2010 to the framework agreement

At LEEM's request, discussions on certain amendments to the framework agreement began at the beginning of summer 2010. They concluded on 7 October 2010. The framework agreement with the new rider signed on that date may be found in Appendix 1 to this report.

The amendments concern around a dozen clauses, most of which relate to minor points of the framework agreement, but some of which contain important provisions:

- One of these relates to the 'price consistency mechanism' (Article 13a). Reductions 'for consistency' had already applied by CEPS since it received ministerial guidelines in October 2006, but they had not been incorporated into the framework agreement. The clause provides a framework for implementing these gradual reductions, which cannot be introduced less than one year after less expensive medicines in the pharmacotherapeutic group have been placed on the market, and also makes them automatic to a certain extent. It also stipulates the type of pharmacotherapeutic groups in which 'reductions for consistency' can be applied.

- The second major provision is contained in Article 10a of the framework agreement. It sets out the conditions on which very costly orphan medicines will be included on reimbursable medicines lists, and introduces an upper limit on the annual cost of treatment with an orphan medicine, of EUR 50 000 per patient per year. It provides for specific agreements with companies selling orphan medicines where the cost exceeds this upper limit. The companies sign a rider to the company agreement, undertaking to supply the treatment to all eligible patients within the framework of the set price, in return for a price consistent with those in force in other countries. This provision guarantees all patients access to these very expensive medicines, whilst mitigating the financial risk for *l'Assurance maladie*. In 2009, the committee had already drawn attention to the fact that the rising prices of novel medicines would be unsustainable, and stated that the annual treatment costs of the latest anti-cancer treatments (approximately EUR 50 000) should act as an upper limit that must not be exceeded.

In addition, whilst the prices of medicines registered on the outpatient medicines list or the list of medicines invoiced on top of GHS funding are not set in an agreement, both the companies and the committee have confirmed their wish to enter into an agreement, in the form of a rider to the company agreement, whereby clawback payments could be made for medicines on one or other of these lists.

The rider extends the term of the framework agreement signed on 25 September 2008 to 31 December 2012.

2. Expenditure control measures

At the time the 2010 Social Security Funding Act (PLFSS) was passed, the ministers concerned asked CEPS to carry out price reductions on healthcare products (mainly community and hospital medicines, but also medical devices) in order to achieve savings of EUR 400 million. Around the time of the social security audit in June, the committee was then asked to introduce further cuts on healthcare product prices, worth a further EUR 100 million in 2010.

A total of EUR 520 million of savings were made on healthcare products within the scope of the ONDAM community spending target.

2.1. *Measures relating to the ONDAM community target*

In keeping with the ministerial guidelines, EUR 448 million of savings were achieved through price reductions on medicines within the scope of the ONDAM community spending target.

Since the actual sales volume figures for 2010 were lower than the forecasts made at the time of writing the 2009 annual report, the carry-over effect of price reductions introduced before 2010 accounted for EUR 151 million out of the EUR 448 million saved in 2010.

Of the EUR 448 million worth of savings, EUR 409 million can be identified as being the result of reductions on medicines sold through community pharmacies and EUR 39 million from savings on medicines sold through hospitals.

Of the reductions on medicines sold through community pharmacies, those concerning medicines under patent (reductions for consistency within the drug group; reductions based on specific contractual clauses for a product, or reductions for consistency with European prices) led to savings of EUR 270 million. Further savings of EUR 57 million came from price reductions applied to original drugs at the time generic versions were registered, and a further EUR 82 million from generics and from 'fixed accountability tariffs'.

The reductions decided on over the course of the year, for implementation in September 2010, concerned three pharmacotherapeutic groups. The growth in both the sales volumes of erythropoietins (EPOs) and the prices actually in use for them in hospitals led to the prices of those registered on the community pharmacy lists and the list of medicines invoiced on top of general hospitalisation costs being reduced across the board. In the case of both sartans and statins, the reductions were made for the purpose of price consistency after drugs in each of these groups went off-patent. In spite of the price reductions on sartans and statins introduced by CEPS in 2010 and 2011, the prices currently in force in France in these large drug groups are very close to those in use in the other major European markets. However, the daily treatment costs are higher in France, due to prescription patterns, since larger quantities of the more expensive drugs are prescribed in France. This difference is closely related to the way in which the state covers the costs in certain countries, which leads to the least expensive drugs being prescribed there.

In 2010, the committee continued studying the prices in use in the four reference European markets. This led to reducing the prices of 'dual channel' antiretrovirals at the end of their five-year protected marketing period in France, and to increasing reductions in line with European prices.

2.2. *Medicines under the ONDAM hospital target*

The 'responsibility tariffs' for products that had been registered on the list of medicines invoiced on top of general funding for over five years were also reduced after noting lower prices in force in Europe. The total impact of the reductions made in this respect within the scope of the ONDAM hospital spending target represented savings of EUR 7 million in 2010.

3. Post-registration studies

The committee may request studies on its own initiative in three situations:

In exceptional cases, at the initiative of the *Direction générale de la santé* of the Ministry of Health, the committee requests a study for very similar reasons to those of the Transparency Commission, where the latter has considered a study unnecessary.

In most cases, the studies requested by the committee are essentially for economic purposes and are aimed at assessing the conditions of use of a new drug in real-life practice, such as posology, co-prescription, place in the treatment strategy, type of patient population reached, etc.

Lastly, in the rare instances in which the committee has deemed it possible to enter into a 'risk-sharing contract', under the circumstances described in Chapter II, the study is an essential component of the contract.

3.1. *Post-registration studies requested by CEPS in 2010*

In 2010, the committee only requested one post-registration study on its own initiative, essentially for economic purposes, in order to assess the conditions of use of a new drug in real-life practice.

3.2. *Post-registration studies used by CEPS in 2010*

In 2010, the information from 14 post-registration studies was taken into consideration, as opposed to 6 in 2008 and 2009. However, it is too soon to be able to assess the impact of the measures introduced to reduce the time taken to produce the studies, in spite of the significant increase in the number of study reports produced in 2010, as compared with previous years.

In 2010, the price of one product was significantly reduced, after a study begun two years earlier revealed misuse, and one risk-sharing contract signed in 2005 also reached its expiration.

However, only in exceptional cases does CEPS sign a risk-sharing contract with a company based on a study aimed at proving a genuine anticipated benefit in real-life practice that could not reasonably have been proven before the product was placed on the market.

4. Sanctions involving advertising bans

In 2010, the committee made decisions on 10 cases of advertising bans introduced by the AFSSAPS Chief Executive.

In eight cases of the ten processed, the committee decided on financial penalties, worth EUR 1.5 million in total. In the other two cases, the committee considered the publication of the ban sufficient punishment for the breach that had been committed.

The penalties imposed were equivalent to between 1% and 8% of the companies' pre-tax sales in France of the product in question. For three of the advertising bans, the committee ruled that the breach could cause loss of opportunity to patients and therefore imposed penalties of between 7 and 8% of the companies' respective turnovers.

The committee takes into account any aggravating circumstances, the majority being repeat offending, as well as any attenuating circumstances, before pronouncing its decision. The repeat offence criterion is taken into account when a previous advertisement ban for the same product or a product sold by the same company has been pronounced within the previous three years. The speed of the company's response in withdrawing the advertisement may be taken into consideration as an attenuating circumstance.

With the exception of one of the cases, for which the committee made its decision after a single examination since there was no financial penalty, all the cases required two examination sessions. The committee took into consideration the evidence supplied by the pharmaceutical company during the

discussions, at which both parties presented their case, and for four of the cases it lowered the amount of the penalty.

All the penalty payments imposed have been settled in full.

5. End of year adjustments

In 2010, the agreements with the companies covered all medicines reimbursed by the national health insurance system for the very first time; in other words those dispensed by community pharmacies, to which medicines dispensed by hospital pharmacies were added in 2009, and since 2010, medicines invoiced on top of basic funding also.

In 2010, no contributions were owed by the pharmaceutical companies under the 'K' turnover threshold rule. This was because the total pre-tax turnover made in France in 2010 on products covered by the 'safeguard contributions' rule rose by 0.5%, in other words by less than the 'K' rate, set at 1% for both community and hospital sales.

5.1. *Agreements between CEPS and the pharmaceutical companies*

Of the 183 companies selling reimbursable medicines dispensed by community pharmacies or in hospitals, either those issued to outpatients and reimbursed to patients or those invoiced on top of GHS funding, 182 signed an agreement with CEPS. Under this agreement, the company is exempt from the safeguard contribution.

5.2. *Clawback credits*

Some of the credits were awarded to partially offset the price reductions introduced in 2010, for the reductions that qualify for these credits.

Credits were also awarded under the CSIS system (*Conseil stratégique des industries de santé* – the health industry strategy council) to companies who have made investments within Europe that will maintain or boost research and production activities in the European pharmaceutical sector. An example of this is companies who had entered into agreements with third party manufacturers to produce generics locally before the patents lapsed on the original drugs. They were awarded special clawback credits.

Companies who could prove they had produced patient information leaflets in Braille also received clawback credits to compensate for the expenditure they had incurred for the purpose.

Any credits not used in one year, either because no clawback payments were owing or due to cash flow constraints, may be carried over to the following year.

In 2010, the total amount of clawback credits owing to the companies was EUR 226 M, of which EUR 57 M were carried over from previous years, EUR 68 M were CSIS credits awarded in 2010 and EUR 101 M were new credits other than CSIS credits. Just over a third of these clawback credits were actually used, the remainder (EUR 144 M) being carried over to 2011.

5.3. *Actual clawback payments*

The net clawback payments owed by the companies and actually paid to ACOSS, after deduction of used clawback credits, came to a total of EUR 272 M. This total includes EUR 5.5 M of payments

on account for clawbacks for 2011 and 2012 and EUR 30 M of clawback payments that companies wished to pay in 2010 without using any of their clawback credits. A total of EUR 245 M worth of clawback payments were made under the ONDAM scope for 2010, plus EUR 24 M of clawback payments for the 2011 financial year and EUR 3.5 M for the 2012 financial year.

As at the beginning of July 2011, only EUR 29 120 was still owing, and the total of EUR 3 656 that was owing at the same time in 2010 for the 2009 financial has now been paid.

PART TWO – MEDICAL DEVICES

CHAPTER I – SALES AND EXPENDITURE ON MEDICAL DEVICES COVERED UNDER THE MEDICAL DEVICES AND SERVICES LIST (LPPR)

CEPS does not receive any systematic declaration of sales of medical devices, and at present there are no complete statistics available on sales figures.

In its 2009 annual report, for the first time, the committee presented an analysis of sales in three categories of medical devices, partly based on reimbursement statistics obtained from CNAMTS and declarations made by the companies as part of the exchange of information under the terms of the company agreements in question. We continued our analysis of these sales for 2010.

The committee's estimates are still based on data communicated for 2010 by the three main compulsory health insurance schemes (UNCAM)[4]. The data supplied for the 2010 report, which are based on a different data extraction method than the one used in 2009, allow us to give a more detailed presentation of the expenditure by code than in the 2009 report. In spite of the change in data extraction method, the 2009 results are consistent with those presented in the 2009 report, with a difference of only 0.3% in the reimbursable totals[5]. The difference related primarily to code I. As regards code III (implantable devices), the totals presented have been extrapolated from UNCAM data.

1. Sales: general development of the reimbursable devices market

The reimbursable totals presented in Table 20 below correspond to quantities costed at the tariffs set by CEPS. The actual sale prices can be higher than these tariffs, and even much higher for Code II items, especially adult opticianry and hearing aids.

The committee estimated total reimbursable spending on medical devices listed in the reimbursable products and services list (LPPR) at EUR 6.8 bn in 2010, representing a 6.2% increase on the 2009 figure.

[4] And this year, they are also based on the portion of the expenditure under title III relating to public and private establishments, extrapolated from ATIH data for 2009 and UNCAM data.

[5] Reimbursable total for 2009 EUR 16 M higher than the total that was given in the 2009 report (EUR 2 M higher for reimbursements).

Table 20: Growth in reimbursable spending on medical devices 2009–2010 (in € M)

Service title		2009 reimbursable totals	2010 reimbursable totals	Growth rate
Code I:	EQUIPMENT AND DRESSINGS			
	CPAP	400.7	436.3	8.9%
	Other home breathing aids and oxygen therapy equipment	552.7	599.4	8.4%
	Nutrition	308.3	368.1	19.4%
	Beds (purchase, hire & accessories), mattresses and extras, cushions	319.7	316.4	-1.0%
	Diabetic self-treatment and self-testing equipment, inc. pumps	722.7	783.9	8.5%
	Hired chairs	69.0	74.0	7.2%
	Infusion equipment	165.9	192.3	15.9%
	Other home treatment equipment	120.9	136.8	13.1%
	Casting and support equipment and devices	30.0	31.7	5.6%
	Other equipment and devices for various treatments	368.5	393.9	6.9%
	Dressing items	544.3	580.9	6.7%
	Aerosol generating equipment	56.4	59.5	5.5%
	Sub-total for CODE I:	3,659.1	3,973.1	8.6%
CODE II:				
	ORTHOTIC DEVICES: small devices (ch.1)	480.8	512.6	6.6%
	MEDICAL OPTICIANRY (ch.2)			
	Medical opticianry proper	0.9	0.9	1.4%
	Frames (including frames covered by universal health cover)	85.0	88.1	3.6%
	Glass (including glass covered by universal health cover)	183.6	191.6	4.3%
	Lenses	9.4	9.4	0.0%
	EXTERNAL PROSTHETIC DEVICES			
	Electronic hearing devices (ch. 3)	133.4	144.3	8.1%
	Non-orthopaedic external prosthetic devices (ch. 4)	11.1	12.5	13.4%
	Eye and face prosthetic devices (ch. 5)	9.1	9.4	3.7%
	Orthopaedic shoes (ch.6)	87.7	91.1	3.8%
	Orthotic prosthetic devices (ch.7)	193.8	202.9	4.7%
	Devices reimbursed on an exceptional basis	0.1	0.2	129.8%
	Sub-total for CODE II:	1,194.8	1,263.1	5.7%
CODE III	INTERNAL PROSTHETIC DEVICES			
	Orthopaedic knee implants	281.6	296.6	5.3%
	Orthopaedic hip implants	309.6	313.8	1.4%
	Implantable cardiovascular devices	430.5	414.0	-3.8%
	Implantable nerve stimulators	10.8	14.5	34.1%
	Other implants	441.9	452.2	2.3%
	Sub-total for CODE III:	1,474.4	1,491.2	1.1%
CODE IV:	Mobility equipment	117.2	118.0	0.7%
Other expenses	Equipment management costs	0.0	0.0	-62.7%
	Difference for reimbursable tariffs	0.6	0.6	6.2%
	Exempted supplies and equipment	0.0	0.0	-100.0%
	AT supplement 150% LPP	0.1	0.8	661.3%
	Equipment covered under exemptions (Article 56 LFSS 2008)	0.0	0.0	
	Sub-total for other expenses	0.7	1.5	112.1%
	TOTAL	6,446.2	6,846.8	6.2%

Data from all health insurance schemes for the whole of France
Sources: CNAMTS (General plan, with local mutual sections – mainland France), RSI and MSA (all of France)
Estimates for code III (Implantable devices): keeping same public/private breakdown in 2010 of CNAMTS, RSI, MSA and ATIH reimbursable totals obtained from 2009 data.
**the growth in Code II, chapter I is only significant in terms of approved suppliers.*

1.1. *Home breathing aids and oxygen therapy equipment*

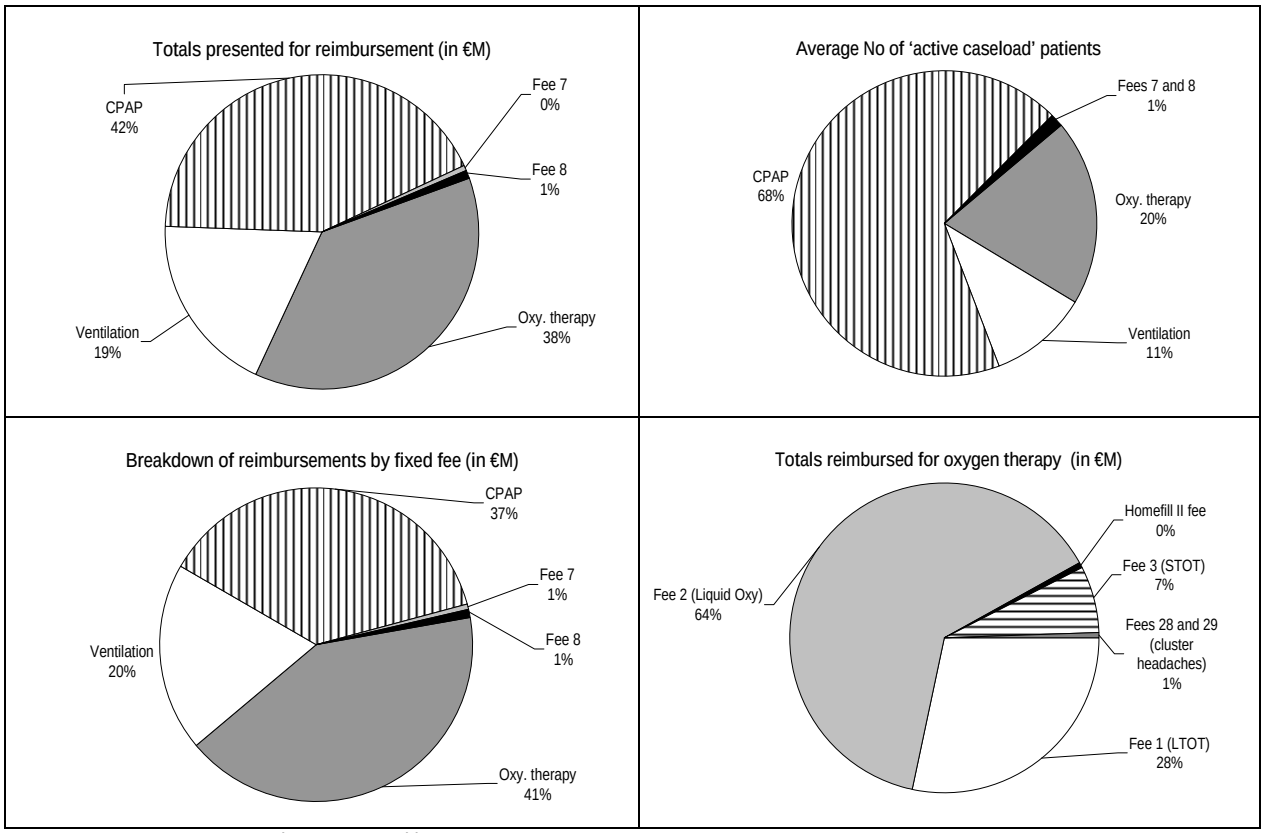
The committee has continued to analyse the home breathing equipment market, which has grown considerably over the last ten years or so and represents almost 20 % of spending by *l'Assurance maladie* on items from the reimbursable products and services list.

The different fixed fees (*forfaits*) for breathing equipment are divided into three main categories: oxygen therapy (fee categories 1 to 3 + Homefill II and categories 28 and 29 for cluster headaches), ventilation (categories 4 to 6) and continuous positive airway pressure – CPAP (fee category 9). Added to these are two individual fixed fees, category 7 (chest mobilisation and assisted coughing) and category 8 (tracheotomy without ventilation). Fee categories 4 to 9 can be combined with some oxygen therapy categories (10 to 27 and 30 to 35). For the analysis below, combined fees were added to the basic fees, with their corresponding allowance margin. The data shown were extrapolated from data gathered by CNAMTS.

In 2010, the total fixed fees presented for reimbursement reached over one million euros for the first time (EUR 1 036 M), representing a 8.6% increase on the 2009 figure, even though some tariffs were reduced on 1 April 2010 (oxygen therapy: 3 % and CPAP: 10.1 %). The reimbursement rate is almost 100%, except for category 9 (75%) and categories 28 and 29 (just under 70%). The cost for *l'Assurance maladie* was therefore nearly EUR 912 M, representing an increase of 8.8% on the 2009 figure.

The number of patients who received breathing equipment, averaged out over the year, was almost 514,000: an 11.4% increase on 2009 (this is the number obtained by dividing the number of weekly fees recorded during the year by 52) and 25,500 of these benefited from the two-fee combination. Approximately 368,000 patients were on CPAP: this is around 42,000 more than in 2009. Approximately 53,000 patients (+ 6,000) were on fee category 6 (fewer than 12 hours' ventilation per day), 46,600 on category 1 (long-term fixed oxygen) and 45,400 on category 2 (liquid oxygen) . On average in 2010, a total of around 107,000 patients were on oxygen therapy and 57,000 on ventilation.

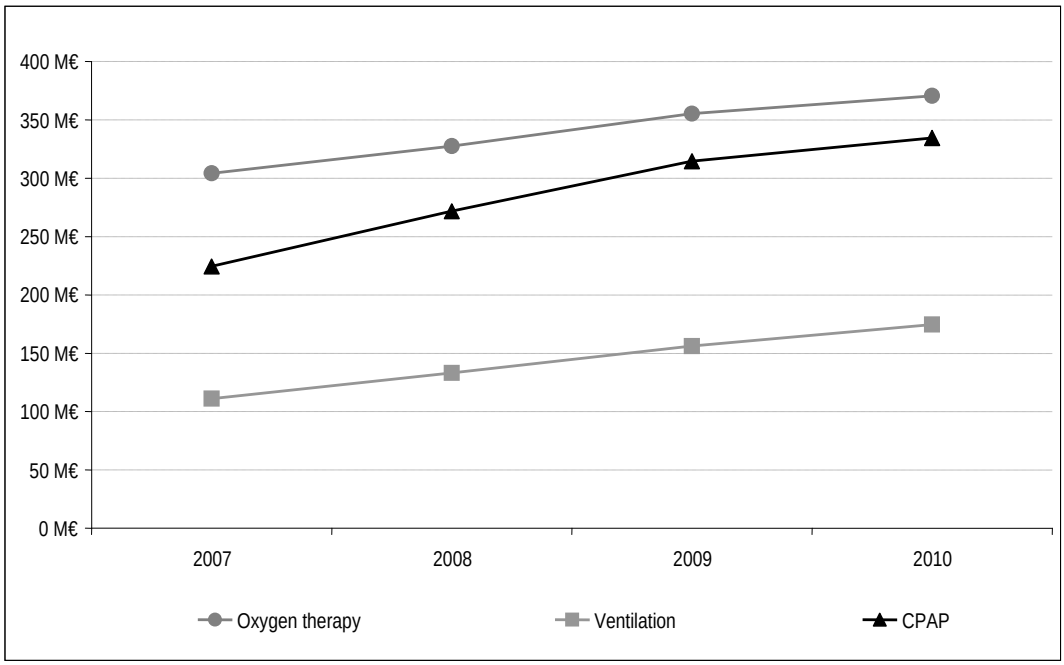
Figure 2: Home breathing aids and oxygen therapy in 2010



Sources: CNAMTS, data processed by CEPS.

Reimbursements paid out by *l'Assurance maladie* for breathing aid provision rose 37 % overall between 2007 and 2010. Among the largest expenditure categories, those that grew most over this period were fee category 6 (68%) and the CPAP categories (49%). Category 2 grew by 2%, whilst all the oxygen therapy categories put together grew by 22%.

Figure 3: Home breathing aids and oxygen therapy equipment: growth in sums reimbursed 2007–2010



Sources: CNAMTS, data processed by CEPS.

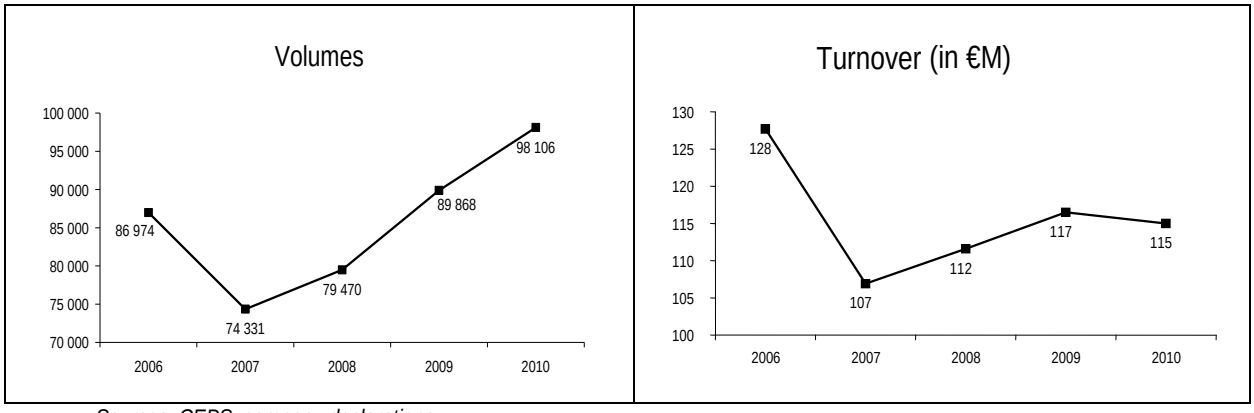
1.2. *Drug-eluting stents*

The drug-eluting stents market has been strongly affected by developments in the medical evaluation of these products. Following the claims regarding the risk of thrombosis that emerged in 2006, the market dropped significantly (-14.5%) from 2006 to 2007. Sales began to pick up again when these claims were disproved. This shows that practitioners take note of the evaluations that are carried out.

In 2006, the market was shared by three product ranges from three different manufacturers. In 2010, there were seven product ranges supplied by six manufacturers (two new ranges from two new manufacturers in 2010).

Growth in terms of turnover followed a downward trend alongside the upward trend in growth in volumes, due in the first instance to the introduction of new products at lower prices and in the second instance to the price reductions introduced, mainly in August 2009 and September 2010 (as part of a planned reduction to take account of the medico-economic assessments by HAS in September 2009). The 2009 turnover was therefore lower than the 2006 turnover, whereas the sales volumes were higher: the tariff reductions amply offset the growth in volumes in 2010.

Figure 4: Growth in sales of drug-eluting stents 2006-2010



Sources: CEPS: company declarations.

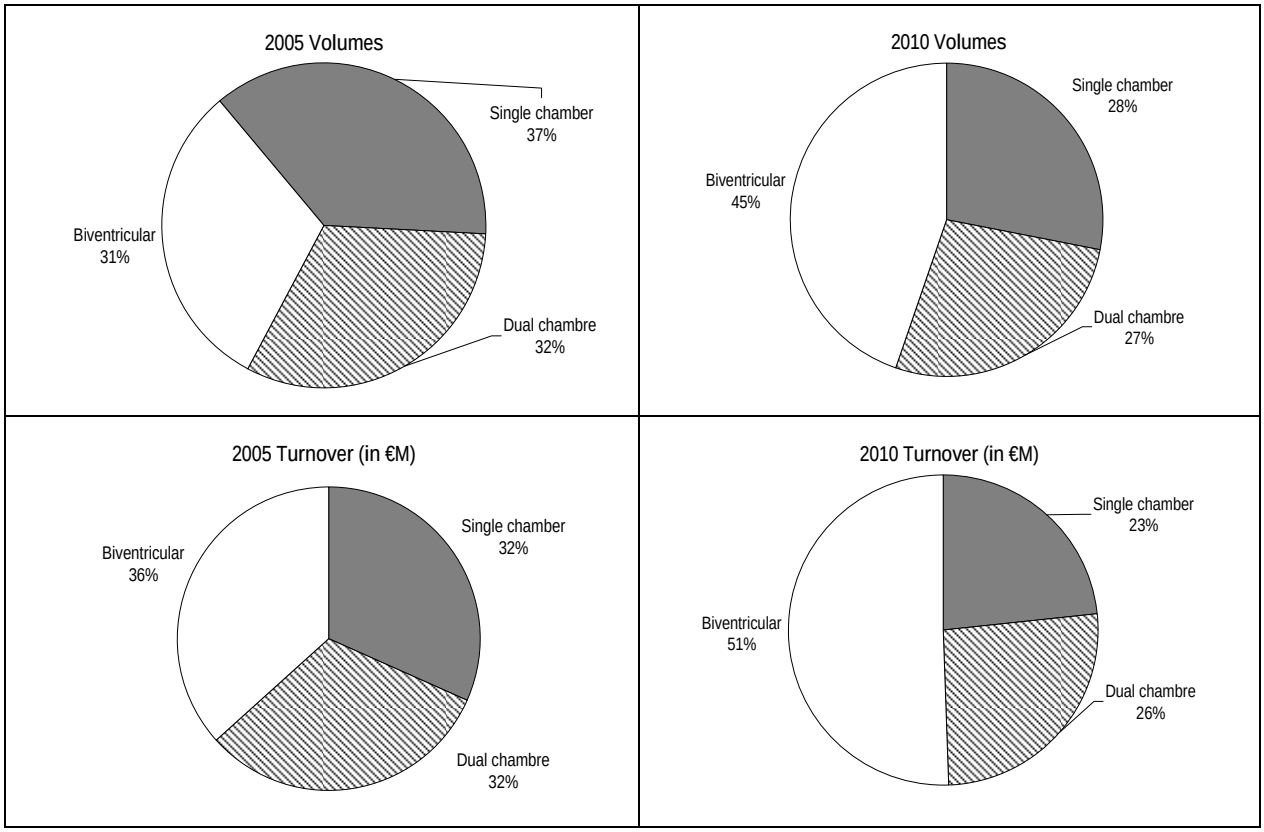
1.3. *Implantable cardioverter defibrillators*

CEPS has information regarding the quantities of reimbursable implantable cardioverter defibrillators (ICDs) sold, from the annual declarations of the five companies who share the market, submitted under the terms of its agreements with the device manufacturers and distributors.

An analysis of the data shows that sales have grown significantly over the last five years. Sales of ICDs have more than doubled, rising from 4 990 in 2005 to 10 768 in 2010 (the growth from 2009 to 2010 was 13.1%, as opposed to + 16.9% from 2008 to 2009). All three types of defibrillator grew at a similar rate over the period, although that of biventricular defibrillators was especially high.

- from 1 841 to 3 035 for single chamber devices (+ 64.9 %, 7.0% of which was from 2009–2010);
- from 1 597 to 2 926 for dual chamber devices (83.2 %, 13% of which was from 2009–2010);
- from 1 552 to 4 807 for biventricular (biventricular) devices (209.7 %, 17.4% of which was from 2009–2010);

Figure 5: Comparison of defibrillator sales 2005–2010

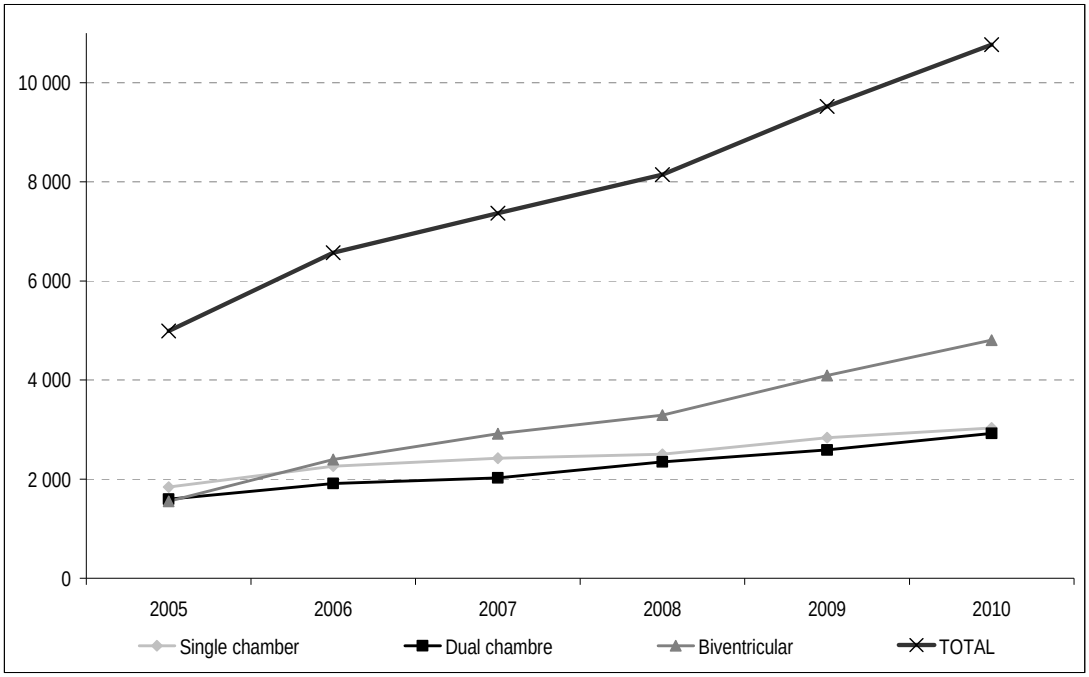


Sources: CEPS: company declarations.

In terms of turnover, the increase between 2005 and 2010 is just as high, due to increased sales of biventricular ICDs and their increasing role, in spite of the 10% price reduction introduced on 13 January 2009. The market also more than doubled between 2005 and 2010, from EUR 70 M to EUR 141 M. The reduction meant that the bias in the market towards the more expensive biventricular devices was offset.

Figure 4 traces the growth in sales of implantable cardioverter defibrillators over the last six years. A steady increase can be observed.

Figure 6: Growth in sales volumes of defibrillators 2005–2010



Sources: CEPS: company declarations.

2. Detailed analysis of reimbursement of medical devices

2.1. *Overview*

The total reimbursements for medical devices rose 5.9%, reaching EUR 6.1 bn in 2010. The average cover rate was 89%, which was close to the 2009 figure.

Table 21: Growth in reimbursable spending on medical devices 2009–2010 (in € M)

Service title		2010 reimbursements	Growth rate 2010/2009	2010 cover level	Percentage of total in 2010
Code I:	EQUIPMENT AND DRESSINGS				
	CPAP	327.7	8.7%	75.1%	5.4%
	Other home breathing aids and oxygen therapy equipment	564.5	8.1%	94.2%	9.3%
	Nutrition	322.1	19.4%	87.5%	5.3%
	Beds (purchase, hire & accessories), mattresses and extras, cushions	291.9	-1.4%	92.2%	4.8%
	Diabetic self-treatment and self-testing equipment, inc. pumps	759.0	8.4%	96.8%	12.5%
	Hired chairs	65.6	7.0%	88.7%	1.1%
	Infusion equipment	185.3	15.7%	96.4%	3.0%
	Other home treatment equipment	114.6	13.4%	83.8%	1.9%
	Casting and support equipment and devices	24.2	5.8%	76.4%	0.4%
	Other equipment and devices for various treatments	358.2	6.7%	90.9%	5.9%
	Dressing items	465.6	6.6%	80.2%	7.6%
	Aerosol generating equipment	49.1	5.9%	82.4%	0.8%
	Sub-total for CODE I:	3,527.8	8.4%	88.8%	57.9%
CODE II:					
	ORTHOTIC DEVICES: small devices (ch.1)	360.9	6.7%	70.4%	5.9%
	MEDICAL OPTICIANRY (ch.2)				
	Medical opticianry proper	0.6	2.5%	63.2%	0.0%
	Frames (including frames covered by universal health cover)	57.3	3.6%	65.0%	0.9%
	Glass (including glass covered by universal health cover)	125.9	4.4%	65.7%	2.1%
	Lenses	6.2	-0.1%	65.6%	0.1%
	EXTERNAL PROSTHETIC DEVICES				
	Electronic hearing devices (ch. 3)	100.6	7.9%	69.7%	1.7%
	Non-orthopaedic external prosthetic devices (ch. 4)	11.7	12.1%	93.6%	0.2%
	Eye and face prosthetic devices (ch. 5)	9.2	3.3%	98.4%	0.2%
	Orthopaedic shoes (ch.6)	82.3	3.8%	90.4%	1.4%
	Orthotic prosthetic devices (ch.7)	201.3	4.7%	99.2%	3.3%
	Devices reimbursed on an exceptional basis	0.2	129.9%	99.5%	0.0%
	Sub-total for CODE II:	956.2	5.6%	75.7%	15.7%
CODE III	INTERNAL PROSTHETIC DEVICES				
	Orthopaedic knee implants	295.7	5.2%	99.7%	4.9%
	Orthopaedic hip implants	313.2	1.3%	99.8%	5.1%
	Implantable cardiovascular devices	412.4	-3.9%	99.6%	6.8%
	Implantable nerve stimulators	14.3	34.2%	98.9%	0.2%
	Other implants	450.5	2.2%	99.6%	7.4%
	Sub-total for CODE III:	1,486.1	1.0%	99.7%	24.4%
CODE IV:	Mobility equipment	117.7	0.6%	99.8%	1.9%
Other expenses	Equipment management costs	0.0	-62.4%	100.0%	0.0%
	Difference for reimbursable tariffs	0.6	7.8%	99.6%	0.0%
	Exempted supplies and equipment	0.0	-100.0%		0.0%
	AT supplement 150% LPP	0.8	667.7%	100.0%	0.0%
	Equipment covered under exemptions (Article 56 LFSS 2008)	0.0	---	100.0%	0.0%
	Sub-total for other expenses	1.5	115.3%	99.9%	0.0%
	TOTAL	6,089.3	5.9%	88.9%	100.0%

Data from all health insurance schemes for the whole of France
Sources: CNAMTS (General plan, with local mutual sections – mainland France), RSI and MSA (all of France)
Estimates for code III (Implantable devices): keeping same public/private breakdown in 2010 of CNAMTS, RSI, MSA and ATIH reimbursable totals obtained from 2009 data.

2.2. *Analysis by code*

2.2.1 *Code I: Medical devices for home care and daily living aids, dietary foods and dressing supplies*

Code I includes homecare equipment and products and services for patients who are elderly, disabled, require post-operative care or have chronic conditions. At EUR 3.5 bn, Code I accounted for 58% of expenditure on medical devices in 2010. The slight drop in expenditure recorded under this code in 2009 was partly due to the fact that residential homes for the elderly (EHPADs) now have to pay for them out of their fixed funding. The expenditure under this code continued to grow once again (+8.4% between 2009 and 2010).

In 2010, the detailed data for code I provide a clearer picture of the changes that have occurred in the market for devices concerned by this funding transfer. Within this code, the only expenditure that saw negative growth (1.4%) was that on hospital-type beds, cushions, mattresses and pressure relief mattress toppers, which are still funded by *l'Assurance maladie* under the community budget. Expenditure on other devices, even though they now come under EHPAD funding, grew in 2010: spending on chair hire rose by 7%, that on nutrition by 19% and that on dressing supplies by 7%...

The main items contributing to increased expenditure under Code I were diabetic self-testing and self-treatment devices, with an increase of EUR 59 M on 2009, and nutrition, with an increase of EUR 52 M.

In spite of the tariff reductions introduced in April 2010 (see chapter III), home breathing assistance and oxygen therapy still constituted a large spending item under Code I and saw high growth (+8.3%). Continuous positive airway pressure (CPAP) alone accounted for 5.4% of total expenditure on medical devices, with a EUR 26 M increase on 2009, whilst the other breathing and oxygen therapy equipment accounted for 9.3% of expenditure (+EUR 42 M compared with 2009).

The proportion of patients receiving 100% cover for home care equipment because of a long-term condition was high (68%). The theoretical reimbursement percentage for Code I is in fact 65%, however the actual reimbursement percentage was 88.8%.

2.2.2 *Code II: External orthotic and prosthetic devices*

External orthotic and prosthetic devices accounted for 16% of total expenditure on medical devices reimbursed by compulsory national health insurance plans, representing a 5.6 % increase on 2009.

The average reimbursement rate for reimbursable expenditure under Code II, in other words for sales costed at the official tariff, was 75.7%.

The main items contributing to growth under this code were small orthotic devices (EUR 23 M) and orthotic prosthetic devices (EUR 9 M).

2.2.3 *Code III: Implantable Medical Devices (IMDs), human-derived implants and human-derived tissue grafts*

For implantable medical devices listed under Code III of the LPPR, CEPS sets maximum purchase prices identical to the reimbursement tariffs. The reimbursement percentage for these devices is 100%.

CEPS was not able to obtain ATIH data on the percentage of expenditure under Code III accounted for by public healthcare establishments. It therefore based its estimate of the total expenditure on reimbursements under this code on the data supplied by UNCAM alone, and assumed the respective public/private expenditure percentages to have remained the same. The public/private harmonisation of the scope of medical devices invoiced on top of GHS funding, introduced in March 2009, was reflected in higher growth in expenditure in the private establishments and may have led to a change in the public and private shares of the market; however the committee is not in a position to calculate these. The figures presented here are therefore both more detailed and less reliable than those in previous annual reports.

Expenditure on implantable medical devices rose by 1% in 2010, to a total of EUR 1 486 bn.

The largest expenditure item, cardiovascular medical devices, was also the only item under this code that saw downward growth. It accounted for expenditure of EUR 412, which was EUR 17 M lower than in 2009. this downward growth may be explained by the reduction in the price of stents and the change of scope, with the re-inclusion of heart valves in GHS funding.

Reimbursements for orthopaedic knee implants, which rose 5% to EUR 296 M, were the main contributors to growth in Code III.

2.2.4 *Code IV: Purchases of mobility equipment*

Between 1999 and 2009, spending under Code IV on purchases of mobility equipment (manual and electric wheelchairs, customised pushchairs and hand cycles, etc.) grew at an average yearly rate of 10%. Between 1999 and 2008, the yearly growth was always positive. Between 2008 and 2009, growth in expenditure on purchases of mobility equipment was negative (due to the re-inclusion of this equipment in EHPAD budgets), and between 2009 and 2010, was only 0.6%.

From an overall total of EUR 44 M in 1999, expenditure in this category rose to EUR 118 M in 2010.

In addition to spending associated with purchases of mobility equipment under Code IV, spending on the hire of this equipment under Code I, Chapter II: “medical devices for home care and daily living aids for people with medical conditions and disabilities” was almost EUR 66 M in 2010 (EUR 62 M in 2009) and accounted for over a third of the overall expenditure on mobility equipment.

CHAPTER II – PRICE SETTING WORK FOR MEDICAL DEVICES AND SERVICES

1. Tariff and price setting methods

Appendix 3 of the report gives a rundown of the methods for setting prices and tariffs. They were not changed in 2010. The updates given in the 2009 report on price setting according to the evaluation and on aligning the tariff and the maximum purchase price have been included in the appendix.

As explained in Appendix 3, in cases where the price set at the time the product is listed is covered by contractual conditions aimed at restricting sale volumes, the companies are obliged to pay a contribution if they exceed the stated threshold. Equal treatment of all market operators can only be maintained in practice on one of two conditions: either all the operators agree to these contractual conditions, or the consequence for any operator who refuses them is that a lower price will be set for the device they are marketing.

2. Work done by CEPS

2.1. *Work on different case types*

In 2010, the committee processed 160 application files from companies. The number of applications still in progress at the end of 2009 was 193, whilst the committee received 150 new applications in 2010. The end-of-year backlog has continued to get smaller.

Of the applications submitted in 2010, 60% were first applications for registration; 19% were applications for re-inclusion; 19% were requests for changes to the registration conditions and 2% applications for tariff increases.

In addition to the work involved in processing the applications, the committee also devotes a considerable amount of time to work on revising the categories for the lists, as described in point 3 below. This work requires repeated communication and meetings with the relevant departments at the Ministry of Health, representatives of the trade associations and other parties involved.

On top of this, changes of distributor resulting in new agreements needing to be signed and the publication of decrees are not included in the statistics for applications processed. This requires as much work from the committee's permanent members as the registration of a new product, even without the time devoted to preparation and including the items in committee sessions.

Table 22: Medical device applications examined by CEPS in 2010

Type of application	Applications in progress end 2009	Applications submitted in 2010	Applications closed in 2010	Applications in progress end 2010
First listing	100	91	83	108
Re-listing	71	28	52	47
Change	20	28	22	26
Tariff change	2	3	3	2
TOTAL	193	150	160	183

Source: CEPS.

Of the 83 registration applications that were closed in 2010, 40 were rejected for registration by the committee, were abandoned or withdrawn by the company, or were closed by HAS. In three quarters of these cases, the level of service was insufficient and was the reason for rejecting the application. Applications usually fail as a result of rejection of the registration by the committee, although it also happens that the company withdraws its application.

Table 23: Medical device applications processed by the committee in 2010

Type of application	Number of applications processed	*Rejected, withdrawn or abandoned*	*Published in the JO*	Average processing time for applications after submission (days)	Average No of examinations by CEPS
First listing	83	*40*	*43*	346	1.5
Re-listing	52	*21*	*31*	511	1.3
Change	22	*4*	*18*	361	1.7
Tariff change	3	*2*	*1*	69	1.0
TOTAL	160	*67*	93	395	1.4

Source: CEPS.
**including automatic cover renewal and rejected applications for devices included in GHS funding at the time of application.*

2.2. *Application processing times*

On average, applications processed in 2010 were completed within 395 days after submission. This was 45 days less than in 2009. The outcome for 60% of these applications was publication in the *Journal Officiel*, whilst the others did not end with registration of the product.

For first listing applications, the average time between submission of the application and completion of the process was 346 days, for all outcomes. CNEDiMTS delivered its opinion for these applications within an average of 157 days and it was sent to CEPS 12 days later. The first examination by CEPS took place on average 58 days after receipt of the CNEDiMTS opinion. In most cases, these files only needed to be examined once by CEPS. The applications were examined an average of 1.5 times, and in one case, 8 times. The decision was sent to the company or published within 96 days on average after the decision made during a committee session.

Just as in 2009, applications for re-inclusion on the lists are accompanied by price negotiations, meaning that these applications take longer to process than first listing applications. On average, these applications were examined 1.3 times by the committee and took 511 days to process.

Applications for changes to registration conditions were processed within an average of 361 days, which included 97 days between submission of the application and delivery of CNEDiMTS' opinion.

Tariff change applications were processed within 69 days.

Table 24: Average processing times for medical device applications in 2010 (number of days)

Type of application	Interval between submission and CNEDiMTS opinion	Interval before opinion sent to committee	Interval before first examination by committee	Interval between 1st and last examination	Interval between final examination and decision	Total time
First listing	157	12	58	26	96	346
Re-listing	316	20	77	27	71	511
Change	97	9	51	80	124	361
Tariff change	37			0	32	69

Source: CEPS.

3. Review of generic list entries

Article 27 of Decree No 2004-1419 of 23 December 2004, as amended, stipulates that each year the health and social security ministers must determine by decree which categories of generic list entries must be reviewed, after CNEDiMTS, which replaced the *Commission d'évaluation des produits et prestations* (CEPP) has issued an opinion. The intention is that all generic medical device categories should have an initial review, and then be reviewed again every five years thereafter. The purpose of the review is to refine the details of the indications and the prescription and usage procedures.

The opinions delivered by CNEDiMTS cannot always be directly translated into tariff categories (in the reimbursable medical device and services list - LPPR) on which reimbursement by *l'Assurance maladie* can be based. This means that the committee is obliged to carry out what is often a complex reorganisation of the categories. Following this, the negotiations with the manufacturers can be lengthy, as the new definitions proposed by CNEDiMTS can involve reformulating or reconfiguring the products, with the technical adaptations that go along with these. Finally, large numbers of tariff entries may involve price negotiations, which can entail new obligations (such as the introduction of a maximum purchase price), and this can take a considerable length of time.

In 2010, the committee dealt with the categories 'oral nutrition' (see 3.1. below) and 'energy storing prosthetic feet' (see 3.2 below).

3.1. *Oral nutrition*

Following the committee's review of the of the 'clinical oral nutrition' category in 2009, following which it set new tariffs and maximum purchase prices for clinical oral nutrition (decree published in JO, 2 March 2010), the pharmacists' associations drew the committee's attention to the fact that they were being forced to sell certain products at a very small, or in some cases negative markup, especially the cheaper, category A products.

A consultation with all the associations concerned was held in 2010, which resulted in the committee setting a target minimum profit for pharmacists, calculated according to the maximum purchase price.

3.2. *Energy storing prosthetic feet*

Following on from the CNEDiMTS opinion issued on 21 July 2009 in the context of the re-evaluation of the registration procedure and review of indications, technical specifications and usage and prescription practices, CEPS undertook a review of the prosthetic foot categories registered on the products and services list (LPPR).

Energy storing prosthetic feet (ESPFs) were previously registered by brand and split into four categories. Registration on the LPPR is subject to a technical evaluation of the device, for which the list sets out the technical specifications. A score is awarded based on the evaluation, and determines which category the product will be placed in.

In its draft amendment of the registration conditions for ESPFs, the committee followed the CNEDiMTS recommendation to create four generic list entries for these items. Three of the categories are defined according to the circumstances surrounding the type of movement and distance covered by the patient, whilst the fourth is specific to lower leg amputations.

The technical specifications are different for adult and child ESPFs.

CHAPTER III - REGULATION PRICE AND TARIFF CHANGES IN 2010

The effects of the price/tariff reductions decided by the committee in 2008–2009 led to overall savings of EUR 74.9 M in 2010, of which EUR 13.8 M was carried over from reductions introduced in 2008 and 2009 and EUR 61.1 M were the result of new decisions (see Table 25).

Table 25: Savings made in 2010 from 2008-2010 medical device price/tariff reductions

Medical device ([1])	2010 Savings (in €M)
Portable parenteral infusion systems (2008) [2]	0.3
Insulin therapy pumps (2008)	5.4
Anal sphincter implant (2008)[2]	0.0
Drug-eluting stents (2008-2009)	5.6
Defibrillators (2009)	2.5
Self-testing and self-medication (2010)[2]	12.7
Bone healing systems (2010) [2]	0.3
Breathing equipment (2010)	37.2
Pacemakers (2010) [2]	1.9
Drug-eluting stents + Titan 2 (2010)	4.4
Dressings and compresses (2010) [2]	4.6
Total	74.9

Source: CEPS.
1. year in which reduction became effective.
2. provisional data.

1. Fixed fees for breathing equipment

The breathing equipment market has grown considerably over the last ten years or so and accounts for almost 15% of spending on medical devices by *l'Assurance maladie*.

The fixed tariffs for breathing equipment were reduced on 1 April 2010 and related to the tariffs for oxygen therapy (reduced by 3%) and CPAP (reduced by 10%). These reductions should lead to savings of EUR 59 M over a full year, of which approximately EUR 37.2 M will be achieved in 2010 and EUR 21.8 M in 2011.

2. Self-testing and self-medication for diabetics

Although the tariff reviews for diabetic self-testing and self-treatment equipment took place in 2010, it was already described in CEPS' annual report for 2009, as it was part of the committee's work that year.

The savings achieved as a result of the tariff reduction are estimated at EUR 12.7 M for 2010 and EUR 3.2 M in 2011.

3. Drug-eluting stents

The opinions of CNEDiMTS of 1 September 2009 re-evaluating the drug-eluting coronary artery stents registered on the LPPR reduced their 'ASR' (added service) rating in comparison with uncoated stents, and taking into consideration both these opinions and the medico-economic evaluation by HAS, decided to undertake a reduction in the tariff/maximum purchase price of these products.

The tariffs/maximum purchase prices of the products in question were between EUR 1 100 and EUR 1 200. The committee decided to reduce the tariffs/maximum purchase prices in several stages over a two-year period, and in the event of a CNEDiMTS opinion awarding a higher ASA rating than that given at the time of CEPS' decision, the final reduction could be reversed. The first reductions, representing a 10% reduction on the initial prices, were implemented on 1 September 2010.

The effect of these reductions on the 2010 figures were a saving of EUR 4.4 M, on top of the carry-over effect from reductions introduced in 2008–2009, which contributed further savings of EUR 5.6 M in 2010.

4. Dressings and compresses

Following the review of the 'dressings and compresses' category in 2009, the committee decided on a blanket 4.5% reduction in all the tariffs. Maximum purchase prices and prescription prices were set for all dressings classed as 'technical'.

The new tariffs are based on a price reduction per cm2 for technical dressings, vaseline-coated dressings and compresses, together with a unit price set per category of dressing or compress and a price per gramme or ml for hyaluronic acid based and hydrogel dressings. The tariffs also include a small contribution per pack and an assessment for small packs and small dressings.

The committee estimates that this new tariff reduction represents savings of EUR 4.6 M in 2010 and EUR 12.7 M in 2011 for *l'Assurance maladie*.

PART THREE – CONTRIBUTION TO THE COUNTRY'S INVESTMENT ATTRACTION

In its 2009 annual report, CEPS described the part it had played in implementing policies to promote and increase the number of industrial and research activities based in Europe.

Since there were no new developments in 2010, only those aspects relating to specific tasks around developing Europe's attractiveness to research and pharmaceutical production, for which the committee has been responsible since 2005 in the context of CSIS, are presented in this report.

CSIS clawback credits are allocated for 'concrete' investments, in the form of production plants, research centres, distribution platforms or company offices. It does not award credits for clinical research expenses or financial investment. In the current global climate in which the expiry of patents and mergers are leading to marked reductions in production capacity, the committee also pays attention to the location of the plants the companies choose to keep on. It is also careful not to reward new sites with credits if they have been built in the wake of demolition of other, larger sites.

Companies that wish to receive CSIS clawback credits must submit a short but detailed file describing the nature of the investments they have made and the sums involved, and specifying in which financial years the expenditure was actually incurred.

In 2010, around 40 companies received CSIS clawback credits, either on the basis of previous allocation decisions affecting more than one financial year, or on the basis of decisions made in 2010.

In keeping with the rider to the framework agreement between the pharmaceutical companies and CEPS signed on 26 October 2009, the committee awarded CSIS clawback credits for the first time to companies that waived their intellectual property rights to a proprietary drug in an agreement signed in 2010 with a third party manufacturer. Three such agreements were entered into, allowing third party manufacturers to produce and stock generic versions of an original drug before its patent expired, thus allowing the production of generics, as well as keeping up employment in the industry within the European Union. They resulted in CEPS awarding CSIS clawback credits in 2010, and in one instance they were awarded in 2010 but for the 2011 financial year.

One of these agreements meant that some of the production of olanzapine, the generic version of Zyprexa, could be maintained in France, at a site based in Reims. Zypexra made an annual turnover of EUR 140 M and its patent is due to lapse in the second half of 2011. The second agreement related to atorvastatin (Tahor, worth EUR 425 M in pre-tax turnover), for which part of the production will be located at a site in Evreux. The third agreement will allow a sub-contracting pharmaceutical manufacturer based in Angers to manufacture generic montelukast (Singulair, worth EUR 125 M of pre-tax turnover).

APPENDICES

APPENDIX 1: Framework agreement of 25 september 2008 between the comite economique des produits de sante and the pharmaceutical companies (as amended by the riders of 26 october 2009 and 7 october 2010)

Having regard to European Union Law, the Social Security Code (*Code de la sécurité sociale*) and national ministerial policy;

Whereas Article L. 162-17-4 of the Social Security Code provides that an agreement may be drawn up setting forth the contractual framework for relations between the Comité économique des produits de santé **(**CEPS – the Healthcare products pricing committee) and each of the companies producing the medicines described in Article L. 162-16-4 of the code;

Whereas, subject to the provisions of the Public Procurement Code, Article L. 162-16-5 of the Social Security Code provides that, with regard to pharmaceutical products which have been granted marketing authorisation and are registered on the list provided in Article L. 5126-4 of the Public Health Code, an agreement should be made setting forth the procedure and conditions governing manufacturers' price submissions, the criteria for opposition by the committee, the conditions under which the declared selling prices may be reviewed and the undertakings to be made by the company;

Whereas 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 the same code, an agreement should be made setting forth the procedure and conditions governing manufacturers' price submissions, the criteria for opposition by the committee, the conditions under which the declared selling prices may be revised and the undertakings to be made by the company;

Whereas it is fitting that medicines should be given their rightful place in prevention and healthcare and that this requires both rapid access to innovative medicines, improved efficiency and rationalisation of expenditure on medicines and sustained efforts to avoid excessive consumption and promote responsible usage;

Whereas medicines can be both a source of improvement in quality of care and a source of economies for the public purse when used solely for proven medical purposes, within a competitive market in which generic medicines and self-medication are free to play their part;

Whereas advances in treatments, the demographic situation, epidemiological data and the government's public health plans must be taken into account when appraising growth in the consumption of medicines;

Having regard to the benefits of maintaining and developing a strong, competitive pharmaceutical industry and of protecting intellectual property, trademarks and registration data within European Union territory, as reaffirmed in the work done by the G10;

Whereas the majority of spending on medicines is financed out of the public purse, whose resources are finite by nature, and whereas it is therefore fitting that there should be regulation in place which is proportionate to the contribution made by medicines, in accordance with the law and ministerial policy and under fair, transparent conditions;

Whereas the most desirable means of achieving the goals set forth hereabove is through strengthened cooperation between the public bodies and the pharmaceutical companies;

The Healthcare products pricing committee (CEPS) and the pharmaceutical companies now agree to amend their framework agreement as follows.

CHAPTER I: EXCHANGING INFORMATION AND MONITORING SPENDING COVERED BY NATIONAL HEALTH INSURANCE

Article 1: Exchanging information

For the sake of transparency, the parties agree on the necessity to improve and share the information they each hold regarding consumption and prescription of reimbursable medicines and the actual reimbursements paid out for medicines.

The representatives of LEEM[6] will facilitate access by members of CEPS, via electronic means in particular, to the commercial information which the companies have available.

They will continue to send the committee, both in hard copy and electronic format, commercial data, of which the companies shall retain ownership, including but not restricted to the statistics produced by the industry's statistics gathering association GERS[7] regarding sales to both community pharmacies and healthcare establishments. Furthermore, to enable CEPS to make the necessary forecasts, at the end of each quarter the committee shall be sent information on the quarterly declarations of sales by quantity (number of common dispensing units) and by value (turnover ex VAT per common dispensing unit) to healthcare establishments which the companies governed by this agreement undertake to make to GERS, in accordance with the agreement signed between GERS and CEPS. The quarterly sales declarations shall be made with regard to both medicines covered by pre-market approvals and medicines that already have marketing authorisation, including orphan medicines, and shall cover all companies whether or not they are members of GERS.

The companies undertake to send to CEPS upon request the information available to them regarding real-life use of the products for the various indications stated in their marketing authorisations. For medicines that have been granted pre-market approval (whether in the context of a cohort programme or a named patient programme, before the file is examined the companies shall send a summary and analysis of the data from the study and information gathering protocol to both the Transparency Commission and CEPS, to provide them with a body of information, in particular on how the product should be used and the nature of the population receiving the treatment.

The companies also undertake to allow the committee access to information regarding current prices in force in other EU countries and the reimbursement situation and sales volumes in these countries.

CEPS and national health insurance (*l'assurance maladie*) shall make available to LEEM detailed information regarding the reimbursements paid out by national health insurance and reports of studies conducted into the prescription and consumption of medicines, under the same conditions in which they are made available to the professional healthcare associations, in particular studies regarding

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6 LEEM = Les Entreprises du Médicament: the pharmaceutical companies' trade association in France.

7 GERS = Groupement pour l'Élaboration et la Réalisation de Statistiques - an economic interest group of pharmaceutical companies which produces market statistics.

statistics derived from the coding of medicines claimed back from national health insurance by the healthcare establishments, as soon as these statistics are available.

CEPS shall inform LEEM every year of its forecasts regarding growth in sales of reimbursable medicines and its forecasts regarding implementation of the end-of-year adjustments under the terms of Articles 17 and 18 herebelow.

CEPS and LEEM agree to set up a joint monitoring group which will be responsible for overseeing the implementation of this framework agreement.

A Generics Monitoring Group shall also be formed, which shall be made up of members of CEPS and representatives of companies operating in the generics market: pharmaceutical companies, wholesaler-distributors and community pharmacists. LEEM shall ensure that companies selling generic drugs are specifically represented among the pharmaceutical industry representatives. The group shall meet to discuss the matters set out in Article 13 herebelow among others.

Article 2: Monitoring spending covered by national health insurance

The parties agree to monitor spending on medicines every three months in consultation with each other, in particular regarding the information mentioned in Article L.162-17-3, paragraph II of the Social Security Code (*Code de la sécurité sociale*). This consultation shall be organised within the framework of the above-mentioned joint monitoring group set up under Article 1 hereabove. The parties shall consult on all medicines covered by compulsory national health insurance, both those distributed to community pharmacies and those included on the lists set out under Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code .

Article 3: Intellectual property

Companies selling pharmaceutical products to which they hold one or more patent or supplementary protection certificate (SCP) may declare these to the committee along with the respective expiry dates. The committee shall make such declarations accessible to any pharmaceutical company that requests access to them.

Details of the registration of any generic pharmaceutical product on the national health insurance reimbursable medicines lists and where applicable the public hospital approved medicines list shall not be published more than six months before the declared expiry date of the intellectual property rights concerned, where the committee has been notified of such date.

However, any pharmaceutical company which believes that it is able to sell the generic products in question without infringing the declared rights may apply for their product to be registered on the appropriate lists. In this event, the pharmaceutical company must inform the committee, which in turn shall promptly inform the company selling the original medicine as mentioned in the first paragraph hereabove and shall then begin the registration procedure.

Article 3a: Early transfer of rights

The owner of the intellectual property rights to a reference proprietary product may, subject to the provisions of the Intellectual Property Code (*Code de la propriété intellectuelle*), assign the following rights before they have expired to a duly authorised pharmaceutical establishment acting in the capacity of sub-contractor under the terms of Chapter 7 of the Good Manufacturing Practices stipulated in Article L.5121-5 of the Public Health Code (*Code de la santé publique*):

- the right to purchase sufficient quantities of raw materials and generally speaking to carry out any activities that are necessary and essential for the manufacturing process described in the following paragraph:
- the right to manufacture a generic version, as defined in Article L.5121-1, paragraph 5 of the Public Health Code, of the proprietary product in question, on behalf of a pharmaceutical establishment authorised to use the marketing authorisation for the corresponding generic drug;
- the right to release batches of the generic product thus manufactured 48 hours before the expiry of the intellectual property rights, for the sole purpose of preparing stocks of the product and to the exclusion of any other act, carried out alone or jointly with the pharmaceutical establishment marketing the generic product, which might lead to the sale or delivery of the generic drug. These batches released at this time may not be delivered until after the expiry of the intellectual property rights pertaining to the original proprietary product. The sub-contractor shall guarantee to the owner of the intellectual property rights to the original proprietary product that the pharmaceutical establishment marketing the generic product will refrain from any actions pertaining to sale or delivery as stipulated above.

The authorisations granted by the intellectual property right owners pursuant to this article shall give rise to clawback credits, the sum of which shall be set, depending on the scope of the authorisations, by mutual agreement between the company and CEPS.

CHAPTER II: MEDICINES SOLD TO COMMUNITY PHARMACIES - AGREEMENTS BETWEEN CEPS AND PHARMACEUTICAL COMPANIES

Article 4: The contractual framework

Any company which sells medicines covered by mandatory national health insurance, provided the company is certified pursuant to Article L.162-17-4 of the Social Security Code, shall be offered the opportunity to enter into a multiannual agreement with the Healthcare products pricing committee (CEPS).

The agreements shall be drawn up with a view to ensuring that this framework agreement is implemented, whilst taking into account each company's individual situation and future development prospects and working within the rules set forth in the Social Security Code and the policy guidelines passed on to the committee each year by the relevant ministers.

Within this framework and save for any exceptions warranted by any specific aspect of the French market, for medicines given an ASMR rating of I to III, these agreements shall guarantee that the price set will be no lower than the lowest price in force in the 4 main comparable EU markets mentioned in Article 7 herebelow, for a period of five years starting from the date the medicines become available to patients by virtue of their registration on the community or hospital reimbursable medicines list. This guarantee also applies to medicines which have been given an ASMR price rating of IV in relation to medicines recently rated at ASMR levels I to III, where the Transparency Commission's opinion indicates that this rating is more beneficial to them than a rating which would have placed them at the same ASMR level as these reference products. An extra year shall be added to this guarantee for the paediatric medicines listed in Article 10 herebelow for which studies have been conducted in implementation of the paediatric investigation plan arranged with the AFSSAPS council. In the event that the Pound should fall strongly against the Euro within a short space of time, this shall not be allowed to have any short- or medium-term impact on the French equivalent of the new sale price in Euros of medicines sold in the United Kingdom, in respect of medicines whose prices were set prior to this depreciation

The companies shall inform CEPS should any significant price changes occur in these EU markets.

For medicines which have been under provisional authorisation (ATU), the companies undertake to take the necessary steps to adhere to the deadlines set by AFSSAPS for bringing the medicines into line with the terms of their marketing authorisations and to submit their applications for registration under their new marketing authorisations on the public hospital approved medicines list and/or the national health insurance reimbursable medicines list, no later than 30 days after receiving notification of the MA decision or specific national conditions. Failure to do so shall lead to the period of their European level price guarantee being reduced by a period equivalent to the length of the delay.

When a product covered by a European level price guarantee is approved for extended indications which are rated at ASMR IV or V and concern a significantly larger patient group than the group covered by the ASMR rating which initially warranted the guarantee, the initial period of the European level price guarantee may be shortened.

When a product covered by a European price level guarantee is approved for extended indications rated at ASMR I to III, the initial period of the guarantee may be extended for up to one year, provided that the new indication(s) concern a sufficiently large patient group in relation to the group covered by the existing indications.

When a "quantity clause" is inserted at the time the sale price, official rate or outpatient prescription fee is set, relating to the medicine's target population or to the indication for which the medicine was given an ASMR rating, including medicines mentioned in Article 10 a), the clause may be revised in the light of new information emerging from the post-marketing studies required by the health regulatory bodies, including relevant epidemiological data and other data that could lead to revising the target population, after the Transparency Commission has been consulted on the matter and a dossier including a summary of the updated pharmacovigilance data has been studied.

Article 5: Format and content of the multiannual agreements.

The agreements must adhere to the pro-forma agreement attached in Appendix 2. They are made up of three parts:

Part one summarises the prices of medicines which the company sells and which are registered on the national health insurance reimbursable medicines list and the special conditions attached to them where applicable, in the form of a price table and a schedule of conditions. It also includes for information purposes a list of the company's proprietary products that are registered on one or other of the lists provided in Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code (*Code de la sécurité sociale*), together with their published outpatient prescription prices or official rates and decisions made by CEPS under Article L. 162-22-7-1of the Social Security Code where applicable or any undertakings made, especially those made under Article 8 c) herebelow.

Part two contains, pursuant to Article L. 162-17-4 of the Social Security Code, the company's undertakings with regard to controlling its marketing policy and ensuring responsible use of the medicine, and any conditions setting forth the company's contribution to achieving the objectives described in Chapter IV herebelow and implementing government policy.

Part three establishes the company's acceptance of the provisions of this framework agreement, in particular those stipulated in Articles 17 and 18 herebelow where applicable, under the conditions provided in said Articles.

Companies which decide not to take advantage of the financial regulation mechanism described in Articles 17 and 18 herebelow, or for whom the mechanism is cancelled either the company itself or by the committee, may nonetheless enter into or maintain an agreement with the committee under the terms of Article L. 162-17-4, however the agreement will not exempt the company from the contributions provided in Article L. 138-10.

The agreements may be supplemented by contract riders. Parts one and two shall be renewed each year during the first six months of the calendar year. Part three shall be renewed before 31 December each year.

Article 6: General measures to promote new medicines

a) Pre-application procedure for medicines with centralised marketing authorisations

Subject to any subsequent decision by the European Commission, any pharmaceutical company whose product marketing authorisation dossier has received a favourable opinion from the human medicines committee of the European Medicines Agency may immediately submit a pre-application dossier to CEPS, the Transparency Commission and the ministers responsible for registration, to allow them to examine in advance the issues involved in registering the new product as a reimbursable medicine and to shorten the registration process. This procedure does not exempt the company from the official procedure governing the submission of applications for registration of a product on the reimbursable medicines list and price setting, in accordance with the procedures outlined in Article R. 163-8 of the Social Security Code. Once the official application has been submitted, the committee shall appoint a rapporteur to begin processing any elements of the application which do not require the Transparency Commission's opinion.

b) Special processing times for medicines which have been given an ASMR rating

The parties agree upon the benefit of shortening the usual statutory 180-day listing procedure in the case of medicines which represent an advance in treatment.

For all medicines with an ASMR rating of at least IV but which nonetheless would not fall within the scope of Article 7 herebelow, the committee undertakes to write to the company within 75 days after the date on which the Transparency Commission delivers its final opinion, proposing a draft agreement, or failing this to set out the reasons why it has not yet been able to formulate a proposal.

This same procedure shall be implemented for paediatric medicines which address the list of paediatric needs sent to LEEM by the committee.

c) Statutory processing times

For all proprietary products, CEPS shall ensure that the statutory processing time of 180 days is adhered to, among other ways by keeping track of the intervals before publication of the undertakings which the committee signs.

d) Evaluation

The procedure and the undertaking stated in the above paragraphs shall be subject to a joint annual evaluation by LEEM and CEPS.

Article 7: Fast-track registration for innovative medicines: price submission

The fast-track registration procedure provided in Article L.162-17-6 of the Social Security Code for certain medicines which have been recognised as making an innovative contribution shall be applied under the following terms and conditions:

a) Description of the procedure

No earlier than the day after and no later than one month after it has received the Transparency Commission's final opinion, a company which meets the conditions mentioned in paragraph b) herebelow may apply for a fast-track price-listing procedure for proprietary products which meet the

conditions mentioned in paragraph c) herebelow. This application must adhere to the pro-forma sample attached in Appendix 1 and must contain the undertakings stipulated in paragraph d) herebelow. If after two clear weeks following the week in which the committee received the company's application the committee has not informed the company of its opposition to the application under the terms set forth in paragraph e) herebelow, the application shall be deemed to have been accepted. The agreement shall then be signed within 48 hours and the price decree and notice shall be published in the *Journal Officiel* (the official gazette of the French government) at the earliest possible opportunity. No negotiation shall be entered into with the company regarding the application. In the event of opposition by the committee, the price shall be set according to due process.

The first two working weeks of August and the last week of the year shall not be taken into account when calculating processing times. Furthermore, no price submissions may be made during these periods.

b) Companies concerned

This procedure is open to any company which has a multiannual agreement with CEPS, pursuant to the terms of Article L.162-17-4 of the Social Security Code.

c) Medicines concerned

Proprietary products which the Transparency Commission has rated at ASMR level I to III, provided that these ASMR levels are applicable to the main indications specified in the products' marketing authorisations.
Proprietary products which the Transparency Commission has rated at ASMR level IV, subject to the following additional conditions:

1) There must be a reference medicine and the daily treatment cost of the new medicine, based on the submitted price, must be equal to or lower than that of the reference medicine. CEPS reserves the right however to accept price submissions for products where the daily treatment cost would be higher than that of the reference medicine if the applications can demonstrate that the additional cost is outweighed or exceeded by savings on other items of national health insurance expenditure.

2) The medicine must not be not intended to replace a medicine which has been genericised or is soon to be open to genericisation.

d) Undertakings to be made by the companies

- Regarding prices: the company undertakes to submit a price which is consistent with the approved prices in the following countries: Germany, Spain, Italy, and United Kingdom. In the event that the prices in force in one or more of these countries should alter this price consistency at a later date, the company also undertakes to re-establish consistency by accepting a contractual change to the original price.

- Regarding sales volumes: in the event that its sales volumes exceed the volumes in the mandatory forecast for the first four years as stated in the price submission application, the company undertakes to compensate by means of clawback payments for any additional costs to national health insurance which are not justified by public health decisions made later by public bodies.

- Regarding studies which the company may be requested to carry out in application of Article 11 herebelow.

- The company undertakes, subject to general or specific obligations of information governing pharmaceutical companies, to inform both CEPS and the Transparency Commission of any new scientific information which comes to light and which may affect the cost-benefit ratio as assessed

during the Transparency Commission's evaluation. Where the company is aware of any such information prior to the deadline for receipt of the committee's opposition, it shall waive the right to the fast-track procedure.

In addition to the above-stated mandatory undertakings, the company may make other undertakings (regarding posology, daily treatment cost, consultations, etc.) which in the light of the characteristics of the product in question it feels will make its application more favourable to the committee.

The company shall have the opportunity to present its case to the committee prior to entering into the contractual obligations.

e) Conditions governing the committee's right to opposition

The committee must present its opposition in writing, providing valid grounds for the opposition. It may oppose an application on the following grounds:

- Due to explicit public health considerations

- If the level of the proposed price is excessive in relation to the prices in force in the four above-mentioned EU Member States.

- If the sales forecasts are inconsistent with the size of the patient group identified by the Transparency Commission.

- Due to obvious inadequacy of the undertakings made by the company.

- If the company has breached any of its undertakings made during a previous application.

- With regard to ASMR IV-rated medicines, where the special conditions regarding these medicines are not met or simply where the product represents additional costs in relation to the reference product.

CHAPTER III: MEDICINES PURCHASED BY HOSPITALS

Article 8: Implementation of Articles L 162-16-5 and L 162-16-6 of the Social Security Code

a) Common procedure

For the purposes of Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code, outpatient prescription fees for the products included on the list provided in Article L.5126-4 of the Public Health Code and "accountability tariffs" (*tarifs de responsabilité*) for products included on the list provided in Article L. 162-22-7 of the Social Security Code shall be determined on the basis of the common procedure outlined in Articles b) to e) herebelow, subject to any specific conditions detailed in these Articles where applicable.

b) Conducting the procedure

Price submissions formulated according to the terms of paragraph c) herebelow should be handed to the committee in return for proof of receipt or sent by registered post within one week after details of the product's inclusion on one of the lists mentioned in paragraph a) hereabove have been published in the *Journal Officiel*, or in the case of products registered on the list provided in Article L. 5126-4 of the Public Health Code before receiving marketing authorisation, within ten days following receipt of the marketing authorisation decision.

The committee may find the submission inadmissible or may oppose the submitted price under the terms stipulated in Article d) herebelow, within two weeks following receipt of the submission. In the event of inadmissibility or opposition, the company shall be given two weeks starting from the date of receipt of the committee's decision within which to draw up a new submission or to amend its initial submission. The committee shall then have ten days within which to find the submission still inadmissible or to oppose the price submitted. In this instance, the committee's decision regarding inadmissibility or opposition shall be final, pursuant to the above-mentioned Articles of the Social Security Code. If after the committee presents its initial opposition the company does not draw up a new declaration or amend its initial declaration within the above-mentioned two-week time limit, the committee's opposition shall be final.

If the committee does not find the submission inadmissible or oppose the submission within the time limits mentioned in the previous paragraph, the committee shall publish the prescription fee or "accountability tariff" in accordance with the price submitted at the earliest possible opportunity.

In the event that the company does not adhere to the time limit for submission stipulated in the first paragraph hereabove, the committee may announce its opposition to the price at its own convenience, provided that it adheres to the overall seventy-five day statutory time limit for the procedure. If the committee does oppose the price, the time which the company shall have to draw up a new submission or amend its initial submission shall be reduced by a length of time equivalent to the initial delay. If this delay is more than ten days, any opposition by the committee shall be final.

In the event of final opposition, or if the company has not drawn up an admissible submission within thirty days after the start of the time limits stipulated in the first paragraph hereabove, the committee shall set the prescription fee or accountability tariff unilaterally.

c) Content of company price submissions

For each product included in the price submission, the company's submission must contain the following, failing which the submission shall be inadmissible:

- The proposed selling price to healthcare establishments per pack type.

- The current prices in force in the main EU Member States and the product's reimbursement status in these states, plus for products which have been on sale for more than one year, the annual sales volumes recorded in these states.

- Where applicable, up to three years' worth of data on the prices at which the products have been sold to French healthcare establishments.

- The Transparency Commission's opinion or opinions, where such opinions have already been delivered.

- An estimated sales forecast for the next three years.

- An undertaking to inform CEPS each year of the prices in force and volumes sold in the main EU Member States, as well as any alterations to the product's official reimbursement status.

Depending on the particular nature of the products in question, price submissions may also contain undertakings by the company, in particular regarding implementation of Article L. 162-18 of the Social Security Code or the conduct of follow-up studies on the products.

d) Criteria for opposition by the committee

The committee must provide explicit, clear grounds for its opposition.

It may oppose the proposed price on the grounds that it is exceptionally high in relation to the prices in force in the main EU Member States, or in relation to prices in force in the French market where directly comparable products are already being sold on the French market.

It may also oppose the price due to the inadequacy of any undertakings made by the company, in particular, in cases where the proposed price is only justified for some of the indications included in the marketing authorisation, if there is a clear risk that the quantities sold will incur exceptionally high national health insurance spending or if, given the current market, the product's inclusion on one of the lists could lead to sales volumes giving rise to volume discounts on the company's proposed price.

e) Reviewing tariffs and prices

Prices and tariffs may be reviewed either at the company's or the committee's request, in particular when a change occurs to any of the factors on which the existing price or tariff and the parties' undertakings were based; or when new information emerges in France or the European Union, especially regarding the product's evaluation or current prices, or when the product's price is closely linked with variable costs, especially those connected with product safety requirements.

Article 9: Quantity Clauses

When the committee intends to apply the terms of Article L. 162-22-7-1 of the Social Security Code to a drug included on the list provided under Article L 162-16-6 or it is considering inserting a "quantity clause" for a medicine included on the list provided under Article L. 162-16-5, which would include provisions on clawback payments or price reductions, the committee shall inform the company selling the medicine of its intention; however the publication of the official rate or the outpatient prescription price shall not be delayed until this process has been completed.

The committee shall make every effort to reach an understanding with the company and to formally set out this understanding in a rider to its agreement with the company.

If no agreement is reached, once the company has been given the opportunity to present its comments, the committee shall notify the company of its decision under Article L. 162-22-7-1 or if applicable of the conditions under which it will announce that it is requesting a price reduction in the light of the quantities that have been sold.

Article 9a: Implementation of Article L. 162-16-5-1 of the Social Security Code

The declarations regarding the maximum prices chargeable to healthcare establishments, which the companies are obliged to make under the terms of Article L. 162-16-5-1 of the Social Security Code, must be sent to CEPS within month after the drug has been given provisional authorisation (ATU) by the AFSSAPS Chief Executive.

These prices shall be published on the CEPS website.

If any clawback payment is owing by virtue of the price or tariff published after the drug has obtained marketing authorisation, this payment shall be determined at the time the price or tariff is set. The payment shall take into account the sums actually charged to the healthcare establishments and any quantities which were supplied free of charge.

CHAPTER IV: IMPROVING THE COST-EFFECTIVENESS OF SPENDING ON MEDICINES

Section I: Novel drugs, orphan drugs and paediatric drugs

Article 10: Special advantages for novel drugs, orphan drugs and paediatric drugs

In the context of agreements with CEPS, novel drugs, orphan drugs and paediatric drugs shall benefit from the provisions of Article 18 herebelow, in particular concerning provisional, full or partial exemption from clawback payments per pharmacotherapeutic class grouping.

The parties wish to promote the orphan drugs market in connection with the EU's incentive policy as expressed in regulation (EC) no 141/2000 of the European Parliament and of the Council of 16 December 1999.

The parties also wish to promote steps to bring paediatric drugs onto the market, in line with the EU regulation.

CEPS shall forward to LEEM the list of paediatric needs drawn up by AFSSAPS: new paediatric products or approval of paediatric indications for existing products.

If a drug is included on the list produced by the European Medicines Agency's paediatric committee or appears on the list of paediatric needs drawn up by AFSSAPS, its pre-tax manufacturer price shall be set so as to guarantee a daily treatment cost which is equal to the drug's daily treatment cost for adults. These provisions shall only apply to drugs which are defined as orphan drugs pursuant to regulation (EC) no 141/2000 of the European Parliament and of the Council of 16 December 1999.

Article 10 a): Access to orphan medicines

To ensure that the patients concerned continue to have access generally to orphan medicines under conditions that are acceptable to the pharmaceutical companies and *l'assurance maladie* alike, and subject to the provisions of Article 4 hereabove, the committee may request a company selling an orphan medicine costing more than €50k per patient per year, under the terms of its agreement with the company, to undertake to supply the medicine to all patients eligible for the treatment without restriction in return for setting a price in keeping with standard international prices, up to a set turnover threshold.

Article 11: Real-life monitoring of new drugs in clinical practice

The parties are agreed on the benefits of gathering data on use of new drugs in real-life situations.

This Article relates to studies which are governed by contractual agreements between CEPS and the company concerned. The studies may be initiated at the instigation of either the Transparency Commission or CEPS.

The recommendations of ADELF (Association des épidémiologistes de langue française, the French speaking epidemiologists' association) and good epidemiological practice shall apply to the manner in which the data is gathered and the studies are audited. The relevant public bodies may exercise their right to monitor compliance with these rules.

The aims of these contractual studies, the obligation to set up a scientific committee where applicable and the timescale within which the studies must be conducted and their findings obtained shall be set forth in a rider to the agreement, which may also make provision regarding the consequences of non-compliance with the timescales.

If the company can demonstrate that the findings of the study it has been requested to carry out would fully or partly duplicate the findings which the studies required as part of the marketing authorisation

application process and included in the approved risk management plan would produce within the same length of time, the contractual study shall be modified accordingly. In such cases, CEPS and where applicable the Transparency Commission must be given copies of the findings of the studies included in the risk management plan.

Where a scientific committee is formed, information on the committee's composition and its members' declarations of interest must be sent to the Transparency Commission if the Commission instigated the study or to DGS (Direction Générale de la Santé - Health Department of the Ministry of Health) for other contractual studies. The scientific committee shall be responsible for deciding which type of study is best suited to address the issues raised and/or for approving the study protocol; the committee shall also give an independent expert opinion on the team appointed to carry out the study. This opinion must be sent to either the Transparency Commission or the DGS as applicable. The contract rider stipulates that the studies must be published, notwithstanding any intellectual property rights associated with them.

For studies which the Transparency Commission has instigated and for other contractual studies where this is stipulated in the agreement, the study protocol must be submitted to the Transparency Commission, which will give an opinion as to whether the study design is fit to address the issues raised. This procedure involving the Transparency Commission shall not entitle the company to any extension of the agreed schedule for starting the study and producing the findings.

The findings of the contractual studies shall be submitted to CEPS and to the Transparency Commission, where the latter instigated the study. The parties to the agreement shall discuss what action to take on the basis of the findings.

The committee shall oversee regulation of the costs involved in the studies, which must be reasonable in relation to standard industry practice (regarding number of cases, complexity, etc.) and shall ensure that the overall, proven costs to the company of carrying out the study are proportionate to the anticipated pre-tax turnover from sales of the drug. In the event that the costs are disproportionate in this respect or that the scope of the study is extended for public health purposes to include elements other than the use of the product in question, the company may be compensated for the additional costs incurred via a reduction of its clawback payments.

CEPS may request the companies to draw up protocols which could allow the findings to be extended to other drug products with related therapeutic targets.

These provisions do not rule out the possibility that other studies presented at the company's own initiative may be taken into account.

Penalty payments payable in the event of failure to carry out the studies within the agreed timescale, under the terms of Article L. 162-17-4-5, of the Social Security Code, shall be set according to the procedure provided in Article 15 b) herebelow.

Article 12: Essential medicines

If a company plans to halt production or sale of one of its proprietary products which satisfies a particular medical need that would no longer be fulfilled if the product were removed from the market, the company undertakes to enter into discussions with CEPS regarding the financial situation involved in keeping the product on the market, failing which the company's status as an approved supplier may be removed.

If a company requests a price increase for one of its proprietary products that satisfies a medical need not catered for by any other less expensive medicine and the price increase is justified in view of the financial circumstances surrounding the production of the medicine, when evaluating the request account shall be taken of obligations arising from tests on traces of the medicine in water and of the

specific cost of the collection and disposal of sharps waste from patients self medicating with the product.

Section II: Sources of savings

Article 13: Development of generics and fixed accountability tariffs (*tarifs forfaitaires de responsabilité* – TFRs)

The parties to this agreement agree that the development of the generics drugs market represents a valuable contribution to the funding of medical advances.

The generics monitoring group shall study the development of the generics market and carry out a critical analysis of how the market is functioning and the prevailing economic conditions for companies affected by the development of this market.

The group shall be consulted about all plans to set or to change a "fixed accountability tariff", as shall the manufacturers of the proprietary products concerned.

The group shall also be consulted about all public plans to lower generics prices and about changes that the committee is considering introducing to its overall price setting procedure for the substitution list: allowance entitlements, price increase rules for original drugs and generics, etc.

The committee shall take into consideration the logistical pressures which the pharmaceutical companies will be put under by any changes to the fixed tariff levels.

Article 13 a): Price consistency

In the event that a significant number of less expensive medicines, in particular generics, emerge within a pharmacotherapeutic group in which this is justified in view of the degree to which the medicines that constitute the group are sufficiently interchangeable from an economic point of view in terms of the nature and degree of the medical benefit they provide, the prices of the more expensive medicines, in particular of those still protected by patens, may be gradually brought into line so that in the long term there will be no significant gap between the prices of these medicines and those of the less costly ones. The desired price reductions may not be introduced until at least one year after these less expensive medicines have come onto the market and shall only apply to medicines that represent little or no medical progress in the majority of their indications.

Article 14: Development of self-medication not covered by national health insurance

The parties agree that responsible self-medication should be allowed to develop in France, as it will contribute to the responsible use of medicines without affecting the levels of payments made by national health insurance.

Section III: Responsible use of medicines

Article 15: Information for prescribers, promotion and advertising

a) Information for prescribers and promotion of medicines

The parties are agreed upon the view that promotion of medicines, whilst playing an essential informative and educational role for prescribers, can to differing degrees depending on the type of medicine, exert a disproportionate influence on prescribing practices.

The parties also agree on the view that in cases where the primary aim of the promotional activities is to obtain a market share by fair competition, with no proven risk that it will lead to excessive prescription volumes or irresponsible use of the medicine, limiting the companies' corresponding marketing budgets shall not constitute a high-priority issue in the agreements between the committee and the companies.

Conversely, the parties agree that in any circumstances where there is a risk that the drugs could be prescribed in unjustifiable quantities or under unjustifiable conditions, promotional materials must be produced which pro-actively and explicitly promote the responsible use of the drugs.

To this end, for drugs which are specifically identified as being among those described in the paragraph above, the committee may require the individual agreements to contain undertakings by the companies concerned to adapt their publicity materials and the training and materials given to their medical sales personnel so that they promote responsible use of the drugs and are directed only at the appropriate patient groups. The companies must be prepared to prove at the committee's request that they are abiding by these undertakings.

The pharmaceutical companies undertake to produce and promote a sales visit quality charter setting out the training requirements for and role of their sales personnel and emphasising the quality required of the promotional materials used by sales personnel.

b) Advertising bans

For the purposes of Article L. 162-17-4 of the Social Security Code, in particular in relation to advertising bans issued by AFSSAPS and the financial penalties which may arise therefrom, the parties agree that CEPS shall follow the procedure below when making its decisions.

For advertising bans which the committee considers may give rise to financial penalties:
the committee shall designate a rapporteur who will examine the case and present it at a committee session;
the committee shall draw up a draft decision giving its grounds for the decision;
the committee shall send the company the draft decision, asking the company to present any comments in writing;
the company may request a hearing by the committee; it may also enlist the help of experts or legal advisers;
the committee shall then hold fresh discussions and shall notify the company of its decision.

Article 16: Cooperative action to promote responsible use of medicines

The pharmaceutical companies undertake to actively pursue action undertaken with regard to the responsible use of medicines, in liaison with the appropriate social security bodies.

When HAS, UNCAM, INCA or AFSSAPS[8] are planning actions of a public or general nature which may affect the economic balance of the drugs sector, LEEM may request CEPS to arrange suitable consultations, after having applied to the ministers concerned if necessary.

CHAPTER V: ANNUAL FINANCIAL ADJUSTMENTS

[8] HAS = Haute Autorité de Santé: France's independent health advisory body; UNCAM: Union Nationale des Caisses d'Assurance Maladie; INCa: Institut National du Cancer; AFSSAPS = Agence Française pour la Sécurité Sanitaire des Produits de Santé: government medicines and healthcare products regulatory agency.

Article 17: Annual financial adjustments: principles

Any company wishing to be exempted from the contributions required under the terms of Article L. 138-10 of the Social Security Code must undertake in the form of a contractual clause, to pay clawback payments, known as end-of-year quantity clawbacks, to the relevant URSSAFs[9]

However, regardless of whether or not the company has signed an agreement,, no end-of-year quantity clawbacks shall be payable if the cumulative growth of sales of reimbursable medicines to community pharmacies and sales to healthcare establishments of medicines included on the list provided in Article L. 5126-4 of the Public Health Code (and as of 1 January 2010 "or on the list provided in Article L. 162-22-7 of the Social Security Code") for all the companies put together does not exceed the sales-weighted mean value of the 'K' growth rates set each year by the Social security finance law (LFSS) pursuant to Article L. 138-10 of the Social Security Code. Furthermore, the committee undertakes to ensure that the total amount of all the end-of-year quantity clawbacks paid by all the companies put together is less than the sum of the contributions which those companies would have had to pay if none of them had entered into the agreement.

At the end of each year, and by 31 January of the following year at the latest, companies which sell products included on the list provided in Article L. 5126-4 of the Public Health Code (and as of 1 January 2010 "or on the list provided in Article L. 162-22-7 of the Social Security Code") must send a declaration to CEPS, in the format of the pro-forma declaration provided in the attached appendix, giving details, for each product and product format, of the volume and actual turnover of its sales to healthcare establishments over the year and identifying among these figures all sales of products which were on the list (as of 1 January 2010, "on either list") on 31 December in the year for which the payments are owing and had been on the list since at least 1 January of the previous year.

The contractual clawback payments shall be paid to the appropriate URSSAF by 30 April the following year, on the basis of an assessment drawn up by CEPS following discussions during which the company may present arguments for a review of the amount of clawback payments calculated.

The end-of-year quantitative clawbacks are made up of payments per pharmacotherapeutic class grouping and payments based on turnover.

a) Clawback payments per pharmacotherapeutic class grouping

Each year, the committee shall draw up a table dividing the medicines concerned into groups for the whole of the sector concerned. These groups are made up of sets of pharmacotherapeutic classes defined using the EPHMRA codes. The committee shall set a growth rate for each group, in such a way that the weighted mean value of the rates is equal to the weighted mean of the 'K' growth rates established for the year in question by the social security finance law.

LEEM shall be consulted before the table is finalised.

The gross clawback payments owed by the companies, before deducting any exemptions as provided in Article 18 herebelow, shall be calculated as follows:

For each of the drug groups in which the annual growth rate is higher than the rate set by the committee, the total amount owing by all the companies who have agreements with CEPS and sell drugs belonging to that group shall be equal to the difference between the two rates multiplied by a given coefficient, which shall be the same for all groups and shall be set the committee in the light of

[9] URSSAF = Union de recouvrement des cotisations de sécurité sociale et d'allocations familiales: main social security body which collects social security insurance contributions and distributes them to ACOSS (agence central des organismes de sécurité sociale), which in turn distributes the money to the various *Caisses*.

the forecast sales growth for all the drugs concerned. For drugs sold to healthcare establishments, the sales taken into account shall be those corresponding to products included on the list (as of 1 January 2010, " on one of the lists") as at 31 December in the year for which the payments are owing which had been on the list since at least 1 January of the previous year.

The total clawback payment owing for each group shall be split into two portions, and the relative sizes of these portions, which shall be identical for all groups, shall be determined after consultation with LEEM. The first portion shall be split proportionally between all the companies with agreements who are selling drugs belonging to that group, on the basis of their respective sales figures. The second portion shall be split proportionally between those companies whose annual growth rate is higher than the rate set by the committee, on the basis of their respective excess turnover amounts.

Sales to healthcare establishments shall be calculated by multiplying the number of units sold by their prescription price (as of 1 January 2010, "or their *tarif de responsabilité*").

b) Clawbacks based on capped turnover rates

The companies shall also be liable where applicable for a clawback payment based on the difference between their turnover and a fixed threshold stipulated each year in a contract rider. The rate for this clawback is set, unless otherwise stipulated in the contract, at 10%.

For sales to healthcare establishments, the turnover figure used shall be the actual turnover.

When the sum of the safeguard contributions which the company would have had to pay if it had not signed the agreement is used as a basis for working out the threshold mentioned in the paragraph above, this sum is adjusted to cancel out, where applicable, sales of generics and products on fixed accountability tariffs and sales of drugs which were not claimed back from national health insurance.

Article 18: Annual financial adjustments: special implementation conditions

a) Exemptions from clawback payments per pharmacotherapeutic class grouping

1) Medicines which were given an ASMR rating when they were registered on the reimbursable medicines lists.

- ASMR I and II: full exemption for 36 months and 24 months respectively.
- ASMR III: 50% exemption for 24 months.
- ASMR IV: 25% exemption for 24 months.

For medicines sold to community pharmacies, these exemptions shall be effective as of the date they are sold, and for medicines on the list provided in Article L. 5126-4 of the Public Health Code (as of 1 January 2010, "or on the list described in Article L. 162-22-7 of the Social Security Code"), from the date on which the relevant sales are included in calculations for the clawback payments per pharmacotherapeutic class grouping.

Companies may opt for a fixed, non-extendable exemption period which is longer than the periods provided above, up to a period of five years. In such cases, the exemption rate shall be reduced to ensure that the length of the exemption multiplied by the rate remains constant.

Where the ASMR rating only relates to some of the drug's indications or where different indications have different ASMR ratings, the exemptions shall be worked out in proportion to the sizes of the patient groups concerned.

Where a drug has been covered by a provisional authorisation (ATU) or by a temporary treatment protocol for one of its indications which is not included in the marketing authorisation, the agreement

may stipulate clawback exemptions on a case-by-case basis, based on a similar method to the one described above. These exemptions shall be deducted from those arising from any ASMR rating given to the indication in question once marketing authorisation has been obtained.

2) Extension of indications with an ASMR rating

The sum of the clawback payments shall be reduced according to the same rates and for the same periods as stipulated in paragraph 1) above, in proportion to the amount of turnover made by virtue of the new indication, starting from the date of the Transparency Commission's final opinion. Likewise, if a drug which has been exempted on the basis of its ASMR rating has one of its non-ASMR rated indications extended, the exemption shall be proportionally reduced, starting from the date of the Transparency Commission's opinion on the extended indication, according to the size of the patient group concerned. The pro-rata rates shall be established in the individual agreements.

3) Orphan drugs and paediatric drugs

Orphan drugs as defined in the legislation shall be exempted from clawback payments, unless otherwise stipulated in the agreements. For the purposes of the agreements, orphan drugs may be taken to include both legally defined orphan drugs and de facto orphan drugs which were marketed before the relevant legislation came into force.

Paediatric drugs included on the list announced by CEPS shall be exempt from clawback payments, under the same conditions as those stated in paragraph 1) above except that their ASMR ratings shall be set one level higher for these purposes than the level set by the Transparency Commission.

4) Low cost drugs

Generic medicines, medicines on generic prices and medicines on fixed accountability tariffs (TFR) whose price is equal to or lower than that of the tariff, shall be exempt from clawback payments.

5) Medicines for which a significant percentage of sales are not presented for reimbursement

The clawback payments owing shall be reduced proportionally in relation to the value of sales which were not presented for reimbursement, calculated from national health insurance reimbursements data.

6) (until 31 December 2009) Where a drug which is listed on the outpatient medicines list but is primarily issued to inpatients represents a significant proportion of the gross clawback figure payable by a company due to the size of its sales or sales growth, the agreement may contain conditions regarding partial exemption from clawback payments due to this drug.

b) Rules governing double clawbacks per pharmacotherapeutic class grouping and for products under special contractual conditions

Where clawback payments are owing under the terms of an individual agreement relating to a specific drug (e.g. daily treatment cost refunds, volume discounts etc.), any clawback payment per pharmacotherapeutic class grouping which the company owes for this drug shall be recalculated to take the sales of this medicine and any excess turnover made on it as the net sales actually earned by the company (GERS turnover data-specific rebates).

c) Clawback credits

1) Clawback credits for price reductions or reimbursement reclassifications

Price reductions proposed by the companies, with the exception of reductions proposed following the creation of generic groups or in groups on fixed accountability tariffs, shall give rise to a clawback

credit equivalent, unless otherwise stipulated in the agreements, to the amount of the reduction of the manufacturer price ex VAT multiplied by the number of units sold during the twelve months preceding the reduction.

Price reductions proposed by CEPS under the terms of Article L. 162-17-4 of the Social Security Code and put into practice through the company's agreement with CEPS may give rise, under the terms stipulated in the agreement, to clawback credits.

The above two paragraphs shall be applicable to reductions in the outpatient prescription prices or the official rates for medicines included on one or other of the lists under Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code (*Code de la sécurité sociale*), provided that these reductions also relate to the sale prices used in practice and on condition that the reductions are not being introduced for the purpose of bringing the prices back into line with current prices in the main European Union Member States.

Refund reclassifications may give rise, under the terms stipulated in the agreements envisaged in Articles 4 and 5 hereabove, to partial compensation in the form of clawback credits.

2) Clawback credits for Braille

Contributions which companies make to funding the production of patient information leaflets in Braille shall be recognised in the form of clawback credits.

3) Carrying over credits

The companies shall be entitled to carry any clawback credits they receive over into subsequent years.

CHAPTER VI: SCOPE OF THE AGREEMENT

Article 19: Scope and term of the framework agreement

This agreement, which replaces the 'community' framework agreement of 13 June 2003 as amended and the "hospital" framework agreement of 23 March 2004 as amended, shall be effective until 31 December 2012.

The agreement constitutes a framework agreement under the terms of Article L. 162-17-4 of the Social Security Code.

Subject to statutory and regulatory provisions relating to the pharmaceutical sector and in particular to the taxes applicable to the sale and marketing of drugs, this agreement sets out the conditions regarding financial regulation of medicines as they apply to companies which enter into an agreement with CEPS pursuant to Article L. 162-17-4 of the Social Security Code.

The agreement may be supplemented by riders.

In the event that one of the parties should withdraw from the agreement before it expires, the terms of the agreement shall be extended for a maximum period of one year until such time as a new agreement is signed or, for the purposes of Article 8 hereabove, until publication of the decrees provided in Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code.

In the event that the overall balance of this agreement should be altered, in particular following amendments to the applicable statutory or regulatory provisions, a major change in government policy

or consequences of the enlargement of the European Union, in such a way as to increase the burden of the pharmaceutical companies' obligations, the agreement shall be renegotiated in order to re-establish a balance between the parties. If such negotiations are unsuccessful, the agreement may be terminated by either party.

Signed in Paris in two original copies, 25 September 2008

For the pharmaceutical companies

Christian Lajoux

For the Comité économique des produits de santé

Noël Renaudin

APPENDIX 2: Methods for setting medicine prices

1. Methods for setting the prices of medicines sold in community pharmacies

Article L.162-16-4 of the Social Security Code sets out the rules governing price setting for medicines that are reimbursable under the social security system:

'The retail price of each of the drugs mentioned in Article L. 162-17 paragraph 1, shall be set by means of a contract between the company selling the drug and the *Comité économique des produits de santé* (CEPS), pursuant to Article L. 162-17-4 of the code, otherwise they shall be set by decree of the ministers for social security, health and the economy after consultation with CEPS. The primary considerations when setting the prices are any additional medical benefit which the drug provides, the prices of other drugs providing the same treatment, the forecast or recorded sales volumes of the drug, and the foreseeable and actual circumstances surrounding use of the medicine'.

Article R.163-5-I-2 stipulates that 'drugs that provide no additional medical benefit as assessed by the commission provided for in Article R.163-15 and no savings on medical treatment costs' may not be included on the list provided for in Article L.162-17 of the Social Security Code.

The drug's additional medical benefit is assessed in an opinion of the Transparency Commission. CEPS makes its decision on the basis of this opinion in almost every case. However, in keeping with case law, as an exception the committee may base its decision on a different assessment than that of the Commission, and may attribute an ASMR rating to a medicine which previously did not have one. This happens in particular in the case of illnesses for which the drug requirements are partially unmet, due to some patients not responding or no longer responding to the existing treatments, where medicines come forward that have a different mechanism of action and are therefore likely to go at least some way towards fulfilling the unmet needs, and yet which are not – and probably cannot be – shown to be superior to the reference products. In these cases, the Transparency Commission considers that it cannot grant an ASMR rating higher than V to these products, whilst at the same time sometimes indicating that they are useful alternative treatments. When on top of this, the treatments costs of the old reference products are very low and hence incompatible with the costs required to market more recently developed drugs, the committee is sometimes obliged to make an exception, as it is allowed to do according to the case law, and to grant an ASMR rating in order to make a drug available to patients, without disregarding the fundamental rule of the *Code de la Sécurité Sociale* (Social security Code). The committee may also decide that a medicine which the Transparency Commission recognised as providing additional medical benefit should not be given an ASMR rating.

In compliance with the above provisions, the committee's task is to obtain the most advantageous price and financial conditions for the national health insurance system, whilst taking into consideration both the pharmaceutical market as a whole and the limitations of the ONDAM budget, as well as public health needs and the obligation to treat all the companies equally.

Consideration of the pharmaceutical market as a whole requires that all discussions about an individual drug price should look beyond the bilateral negotiating framework and take into consideration the economic consequences the price may have on development of the market and national health insurance spending: the direct, immediate consequences on price structures within therapeutic groups; indirect consequences on the relative growth among the different groups; medium-term consequences in terms of estimating the financial burden which the associated reimbursements will have on the ONDAM budget, and more long-term consequences if it is foreseeable that medicines with the same indications may be developed at a later date.

The goal of fulfilling health needs requires the committee to ensure through its actions that patients have access to the medicines they need, and in this respect price setting is merely a means to an end.

Upholding the principle of equal treatment between medicines must apply regardless of which companies are selling them. Among other things, this principle dictates specifically that the committee should not see it as part of its role, regardless of the benefit that this may bring to research and innovation, to finance research up-front through its pricing of medicines that are not themselves the results of this research, and even less, to treat novel medicines differently depending on the country of origin of the innovation.

1.1. Medicines with no ASMR rating

With regard to setting prices for medicines with no ASMR rating, the rule in Article R.163-5-I-2 implies that the committee should address two questions: Saving in relation to what? and what is the size of the saving?

1.1.1. Saving in relation to what?

In some cases, the choice of reference treatment against which to measure the saving is obvious and indisputable in light of the Transparency Commission's opinion. However, this is not always the case by any means.

Often, therefore, when a new product in an existing range is registered, the committee must decide whether the most appropriate way to determine the impact of the product's registration on social security expenditure is to compare it against the range to which the new product belongs and which it will, to a certain extent, replace, or to compare it against equivalent products being sold by other companies (possibly at a lower price). In most cases, the committee decides to compare the new product with cheaper rival medicines, so as not to perpetuate any unjustified price variations between different products that provide the same service. Sometimes, when an agreement cannot be reached at that price, and especially when the new product is intended to replace an existing product en masse, the committee agrees to set a price mid-way between the price of the product being replaced and that of the cheaper rival product.

Another common problem encountered relates to the choice of measurement criterion, between daily treatment cost, course of treatment cost or pack cost. While the daily treatment cost is the one used most often, especially for solid or injectable treatments for chronic conditions, the solution can be less obvious for short-term treatments or when there is no fixed dose (topical applications, liquid forms, etc.). Arguments in favour of the course of treatment cost are rarely accepted by the committee, as it is aware that prescription practices frequently fail to comply with clinical trial protocols or with the SPC (Summary of Product Characteristics). Therefore, in some cases, when it is clearly inappropriate to use the daily treatment cost but the course of treatment cost is far too unclear, the committee decides to compare boxes or bottles, on the basis of comparable average prescriptions.

Finally, the committee very rarely agrees to take into consideration, for purposes of cost comparison, assertions that the number of co-prescriptions with other medicines will fall, even if this seems to be borne out by the clinical trials. Past experience has shown that these forecasts are almost always disproved in practice.

1.1.2. Size of the saving

Generally speaking, the price advantage compared with the last product registered should be relatively greater the higher the price of the reference product and the more time that has elapsed between the two registrations.

However, the expected saving is not measured in terms of the difference in unit price between the new medicinal product and the already registered product with which the Transparency Commission is comparing it. It is measured in terms of overall saving, which is obtained by calculating price differentials by volumes. This general observation leads to two main consequences.

The first results from the distinction between drug groups in which prescription volumes are fixed (definite diagnoses; clear, restricted indications) and groups in which there is a risk of unjustified growth in sales volumes. In the first instance, the only possible effect of a new competitor is to shift market shares, and therefore it is welcome, even if the price advantage is relatively insignificant. In the second instance however, the relative price advantage gained from the arrival of a new competitor could be offset or even cancelled out by the overall increase in volumes resulting from greater promotional pressure on prescribers. Hence the committee is more exacting in this case.

A second consequence is that savings will only really be achieved if the new product wins a share of the market, and these savings will be proportional to the market share. Given the fact that all prescriptions without exception are based more on the laboratories' promotional efforts than on price differentials, it has to be said that for the same level of service, higher-priced medicines sell more than their cheaper counterparts. Therefore, the committee can accept prices that are equal to or higher than that of the last similar product registered if it believes that a lower price would be such a competitive handicap to the manufacturer of the new product that it would sell only very few.

Finally, in the case of novel pharmaceutical products with no ASMR rating, the committee is careful to make sure that registration of these new products will not inadvertently - or indeed purposely, where products coming to the end of their patents are concerned – prevent the development of generics for commercial or legal reasons. In such a case, in accordance with ministerial guidelines, the committee will only approve the registration at a price equal to or lower than that of the corresponding generics.

1.2. Medicines with an ASMR rating

Registering these medicines on the lists can lead to additional expenditure by national health insurance, however the decision as to what constitutes an acceptable extra cost is a difficult matter and it is impossible to devise a standard formula.

There is no scale of acceptable price differences that corresponds to the ASMR rating scale. Discussions on the price for an ASMR-rated drug are therefore open to negotiation and the company's demands need to be weighed up against the need or urgency for the drug to be registered on the reimbursable list, in terms of healthcare needs.

However, ministerial policy does provide a framework for these negotiations on two particular points. The first relates to medicines with an ASMR rating of III or higher, for which the committee should accept an initial listing price that is consistent with the prices in force in the main EU Member States, in accordance with ministerial guidelines and under the terms provided in the framework agreement. This principle does not imply that all medicines with these ASMR ratings should automatically be registered on the reimbursable lists at a European level price, but rather that if they are accepted onto the lists, it should be at this price. If the expenditure that this price level will entail is out of proportion with the anticipated benefit for patients or for public health, it cannot be ruled out that the product will not be accepted onto the reimbursable medicines lists.

In particular, more often than not the discussions regarding the initial listing price for these medicines go hand-in-hand with a discussion on contractual conditions, which are as important as the price itself, since they are usually drawn up to ensure that the medicine is used appropriately in relation to the identified needs, or to anticipate discounts on volumes sold, depending on the size of the sums in question (c.f. 2.3). Registration of these medicines on the respective lists is also often subject to an undertaking to conduct studies, under the terms set out in Article 6 of the framework agreement.

The committee has also sought to put a stop to the uninterrupted rise in the prices of the most expensive medicines. In most countries, for a very long time there had been the tacit acceptance that a higher price could be asked for medicines that represented a significant improvement in treatment compared with that of the reference medicine, as authorised in France by the *Code de la Sécurité*

Sociale. In some drug groups, and anti-cancer drugs in particular, in which new products have succeeded each other at a fairly constant rate, this system has sometimes resulted in prices that translate as high treatment costs: up to around EUR 50 000 per year per patient for some products. The committee considers that at these price levels, access to the French market is enough of a benefit for the innovating companies, whilst it is not necessary or justifiable for *l'Assurance maladie* to take on further costs.

For ASMR IV-rated medicines, price negotiations must take into account the nature of the target patient group. For example, where a medicine has the same target patient group as the reference medicine, the committee may quite easily decide that an increased market share will be adequate reward for the company's innovation, without the need for a price advantage on top of this. The decision may be different if the ASMR rating is based on a specific benefit for a restricted patient group.

1.3. Setting prices for 'me too' and 'follow-on' drugs

As regards price setting for 'me too' and 'follow-on' drugs, it is important to first clarify what is meant by these terms.

For a drug with no ASMR rating (ASMR V) which a company is applying to have registered on the reimbursable medicines list, it is important to distinguish whether the new drug is sold by the same company that sells the already listed drug compared with which the new drug has no additional medical benefit, or by a rival company.

In the first situation, in practice the new drug will be a substitute for the existing drug where the latter has gone off-patent or will be going off-patent in the near future. In these instances the new drug is referred to as a follow-on. It is a simple matter of fact and CEPS is not concerned with what the company's intentions may be. The new drug is usually a variation on its predecessor: an enantiomeric form, new pharmaceutical form, prodrug, etc. levocetirizine, prolonged release tamsulosin and pregabalin are some examples. In such cases, the rule set in the ministerial guidelines is straightforward: the price of the new drug must be the same as the price of generic versions of the original drug. The committee applies this rule to daily treatment cost and to retail price including VAT. When the new drug is developed a sufficient distance before its predecessor is due to go off-patent, the committee may agree to list it at the same price, under the contractual condition that once the generics of the original drug come onto the market, if the second drug has not been genericised itself, its price will be reduced to that of the generics of the original. Some examples of this are desloratadine and lansoprazole oral suspension.

When the new drug has been given an ASMR IV rating in relation to the original, it is still classed as a follow-on, but the price-setting rule is more favourable. The price is set in such a way that the prescription costs of the new drug are no higher in retail price including VAT than the prescription cost of the original, taking the degree to which it is substituting the original into account. In this case, the registration agreement stipulates that the price will be reduced at a later date, to reflect progress in the market share held by generics, where applicable. Some examples of this are esomeprazole and escitalopram.

In the latter situation, when the new drug is sold by a rival company to the company selling the reference drug, a distinction is made on the basis of the length of time since the reference drug came onto the market. If this period is sufficiently short – up to just a few years – and even if the modes of action of the two drug products in question are very similar, it indicates that the two drugs are each the product of independent research, and the companies have incurred the same level of risk. These are not 'me-too' drugs, but competing drugs that have arrived on the market at different times. CEPS considers that restricting the number and diversity of competing drugs in principle would only bring disadvantages, both in terms of cost (new drugs represent savings for national health insurance under the terms of the Social Security Code) and for medical reasons (even a product which is not given a ASMR rating can be a preferable choice for some patients). Another reason is that if all healthcare

systems only allowed the first or first few comers access to the market, this would create an unsustainable burden of ‘all or nothing’ on the companies' research work.

The term ‘me-too’ is therefore only used for drugs that have been inspired by the success of their predecessors and have entailed a relatively low level of risk for the company. By definition, the marketing of ‘me-too’ drugs takes place many years after the leaders in the group first cam onto the market. Some examples of this are olmesartan, rosuvastatin and lercanidipine. There is no simple price setting rule for these drugs. The committee's aim is to obtain the greatest possible saving; therefore it seeks to find a happy medium between the saving per pack sold, where the lower the pack price the greater the saving, and the number of packs sold instead of a more expensive rival, where the number of packs sold will be greater if the price is set at a level that will allow resources for more intense marketing.

The above principles apply to the initial listing of the drugs in question. Further down the line, market conditions may change, especially due to the growth both in market share and in price of medicines in the generics substitution list. The committee then implements ministerial policy on 'price consistency', and in drug groups in which generics are emerging and growing, this leads to a gradual reduction in the price differences between the generics and medicines providing the same treatment that are still patent-protected.

1.4. ‘Financial risk sharing’ contracts

In several European countries, ‘risk-sharing’ contracts are currently being used, though in widely differing forms. Their purpose is to seek an acceptable compromise when taking on the costs of medicines that are likely to involve considerable extra costs, but whose conditions of use or efficacy are still highly uncertain. Most of these contracts are only risk-sharing by name and are in fact simple price-volume contracts or contracts based on the posology or treatment duration used in practice, such as those often used by CEPS.

Genuine risk-sharing contracts could be considered when a medicine is put forward accompanied by clinical documentation that does not warrant a high ASMR rating, even though it may have strong potential as an improvement on existing drugs. In the majority of cases, the committee relies on what has already been proven, at the risk that the medicine may not be registered on the reimbursable medicines list if no price agreement can be reached under the terms of the Social Security Code. However, in some very rare instances, CEPS has agreed to give these medicines a chance, even though in principle the evaluation would not warrant the price requested; however this is done on very strict conditions. In the first place, the anticipated, but unproven, benefit must be such that it could not reasonably have been proven during the clinical trials carried out prior to marketing authorisation; or, for example, that it can only be proven in real-life practice. In the second place, if this benefit exists, it must represent a clear advantage and be preferable in public health terms. In the third place, a study must be devised that, by the end of the fixed-term trial period, will unequivocally prove that the benefit both exists and is considerable. Finally, the company marketing the medicine must enter into an agreement whereby it undertakes among other things to bear the financial costs in the event of failure of the medicine.

It goes without saying that the risk involved in this approach relates to profit levels, not to tolerance of the medicine.

1.5. Price review clauses

Price review clauses are introduced at the time of price setting in three main situations:

- Where certain assumptions are made when setting the initial price that only time and usage will confirm or negate, and it is necessary to guarantee that the actual cost per patient of use of the medicine remains consistent with the level that was agreed with the company at the time of registration. In essence, this is the situation that ‘daily treatment cost clauses’ are designed to cover.

- Where it is necessary to ensure that the sales volumes achieved by the drug remain consistent with its medically established target patient group. These situations are covered by ‘volume clauses’.

- Where the price level and the likely sales volumes, especially for drugs that have been listed at a protected European-level price because of their ASMR rating, warrant a price reduction at the end of the period guaranteed in the framework agreement. In these cases, unconditional price reduction clauses may be drawn up that become effective on a set date.

1.5.1. Daily treatment cost clauses

Daily treatment cost clauses are split into two categories: ‘range of dose’ clauses and ‘posology’ clauses. Where a dose-related effect has been established in their use, many medicines are sold in several different dose sizes, either from the time they are authorised, or at a later date when additional dose sizes are added. In these cases, the committee decided that the best way to ensure both that the different dose sizes of the drug were properly used and that rival companies in the drug group in question were treated fairly, was for all dose sizes of the same drug to be sold at the same price per pharmaceutical unit. With these uniform prices, it is not in the pharmaceutical companies' interest to specifically promote the sale of the highest, most expensive dose sizes. It also means that the treatment cost and the balance of relative prices between rival companies can be maintained at the same level over time, since the actual treatment costs are independent of the distribution of sales volumes between the different dose sizes.

When it is not possible to set uniform prices, for example for the sake of international price consistency, a ‘range of dose’ daily treatment cost clause is signed instead, with a view to producing a more or less similar effect. In these cases, what is agreed with the company at the time of the drug's registration is actually a daily treatment cost reflected in the prices of the different dose sizes, on the basis of an assumed distribution pattern of prescriptions. If the statistics show that the actual distribution is different from the assumed distribution, the prices are revised to establish a new agreed treatment cost.

The purpose and the mechanism of ‘posolgy’ clauses are exactly the same as those for the ‘range of dose’ daily treatment cost clauses. At the time of the drug's registration, a daily treatment cost is agreed on, based on an assumed average posology (as stated in the MA or as demonstrated in studies conducted prior to registration, including in countries where the drug has already been marketed). If the actual posology observed in real life is different from the posology used to establish the selling price, the price is revised to re-establish the agreed daily treatment cost.

1.5.2. Volume clauses

The committee considers that volume clauses are not warranted when their main effect would be to distribute market shares between competing companies. Except in a few cases, they also do not make sense when registering non ASMR-rated drugs on the lists, as sales of these drugs represent savings for national health insurance and the larger the volumes sold instead of more costly drugs, the greater the savings. In these instances, the committee feels that the system of end-of-year quantity clawbacks per category of pharmacotherapeutic groups is more appropriate.

However, volume clauses are essential in the relatively frequent situations where a novel drug's ASMR rating is only applicable to some of its indications or to a small patient group, or where, regardless of any financial considerations, public health requirements dictate that a drug should only be used for a limited number of indications for which it is absolutely essential, as is often the case for antibiotics, for example.

The committee has insisted on not signing any more agreements containing daily treatment cost or volume clauses that would only be implemented via volume discounts. However, to prevent minor and potentially reversible excess sales above the contractual thresholds from leading to a series of marginal price alterations entailing high administrative costs, the committee frequently agrees in practice to

make the implementation of price reductions subject to exceeding a variation threshold, where price reductions that are not implemented are compensated for by an equivalent amount of volume discounts. Above all, in accordance with the framework agreement, price variation clauses entered into for drugs rated at ASMR levels III or higher usually stipulate that the reductions will be converted into clawback payments for the drug's first five years on the market.

1.6. Other price changes

In addition to price reductions introduced in implementation of specific clauses, which do not require further commentary, prices may also be reduced at the committee's initiative in three different situations:

- When the drug is due to have its registration renewed. This is an opportunity for looking at the position that the drug has actually gained in the market, which can vary widely from what may have been anticipated at the time of the drug's first listing. This is the case in particular, even where there has been no improper use of the drug, when the drug's prescription volumes have risen significantly since it was listed, in particular following an extension of its indications. A price reduction may also be justified, in accordance with the Social Security Code, when equally effective and less costly rival drugs have come onto the market since the drug in question was first listed.

- Pursuant to Article L. 162-17-4 of the Social Security Code, when the growth in spending on a drug is clearly inconsistent with the ONDAM target, even if it is consistent with ministerial policy and the provisions of the framework agreement.

- Reductions may also be warranted once the findings of the follow-up studies on real-life use of the drugs, conducted in accordance with Article 6 of the framework agreement, are known, and more generally, when the scientific and epidemiological data used as a basis for the agreements change significantly.

Companies are of course free to propose price reductions themselves. By definition, these are competitive price reductions, which to date have usually been for market leaders of generic groups that have been put on a 'fixed accountability tariff' (*tarif forfaitaire de responsabilité*). The committee is not without hope that this type of reduction could be extended to medicines still under patent, as prescribers' and patients' price awareness grows and as companies are obliged to use low price as a marketing lever for their drug where it has no added medical benefit.

CEPS accepts price increases for essential drugs that meet healthcare needs and were listed at a price that did not allow the companies to cover their manufacturing and marketing costs. These are generally: long-standing products whose market has progressively diminished; orphan drugs, or drugs that although not strictly defined as orphan drugs can be classed along with them for financial purposes.

However, the committee rejects companies' proposals for so-called 'win-win' price changes, since although their immediate effect may be neutral or beneficial for national health insurance, they tend to prove more costly in the long term and always upset the relative price balance within pharmacotherapeutic groups.

2. Setting hospital medicine prices and tariffs

Within the scope and on the bases laid down in the 2004 Social Security Finance Act (LFSS) and the National Health Insurance Act of 13 August 2004, the CEPS-LEEM hospital medicines framework agreement now provides the framework for the procedures, processes and conditions for the setting and reviewing of prescription fees for medicines on the outpatient medicines list and of 'accountability tariffs' (*tarifs de responsabilité*) for products on the T2A list.

2.1. Criteria contained in the Social Security Code

For outpatient medicines, Article L. 162-16-5 of the Social Security Code and for T2A list medicines Article L. 162-16-6 of the same code stipulate that the price setting approach for outpatient prescription fees or the accountability tariff for medicines charged on top of general hospitalisation costs should primarily take into account the current prices in use for the medicine, the current prices of medicines that provide the same treatment, the forecast or actual sales volumes, the foreseeable or actual use of the medicine in practice and the improved medical benefit it provides, as assessed by the Transparency Commission.

2.2. Criteria contained in the hospital medicines framework agreement

In accordance with the above-cited Articles of the Social Security Code, Article 8 of the hospital medicines framework agreement of 25 September 2008 sets out the criteria governing opposition by CEPS to a company's submitted price.

CEPS may oppose the proposed price on the grounds that it is exceptionally high in relation to the prices in force in the main EU Member States, or in relation to prices in force in the French market, where directly comparable products are already being sold on the French market. It may also oppose the price due to the inadequacy of the undertakings made by the company where applicable, in particular if there is a clear risk, where the proposed price is only justified for some of the indications included in the marketing authorisation, that the quantities sold will incur exceptionally high spending by the national health insurance system or if, taking market conditions into account, the product's inclusion on one of the lists leads to sales volumes that give rise to volume discounts on the company's proposed price.

2.3. The committee's approach

The committee's acceptance of or opposition to the company's submitted price has therefore been based on either the Social Security Code criteria, the criteria contained in the framework agreement, or a combination of the two.

For all the products concerned, the committee has based its examination on two main sets of information, the first being information derived from processing the companies' declarations for payment of their duties, which provides a picture of the volumes they have sold to healthcare establishments over the last few years, as well as the average prices used and growth in both prices and volumes; the second being information on prices and sometimes sales volumes of some of the medicines, obtained from other countries and primarily from bodies in the main European countries. The committee has compared both sets of information when making its decisions. The committee has also taken into consideration the fact that registration on the T2A list could act as a growth stimulus for the products concerned. It has also paid close attention to avoiding price discrepancies within the various groups of interchangeable medicines.

2.3.1. European prices as a benchmark

Paradoxically, although this benchmark was adopted in order to provide a guaranteed price for companies selling recent original drugs that would be no lower than prices in force elsewhere in Europe, it has often proved to be a basis for opposing the companies' price submissions, in the many cases where the committee noted that the prices used for French healthcare establishments up to that point or being submitted for the first time were actually higher than all the other European prices, whilst the quantities sold in France were higher than elsewhere in proportion to the size of the patient groups. In exceptional circumstances, the benchmark has led the committee to accept price submissions that were higher than those currently practised in France, where for essential medicines it emerged that the French prices were significantly lower than most other European prices.

2.3.2. The general market as a benchmark

As a whole, the committee felt that there was no reason why this new procedure should begin a general practice of setting higher prices than those in force in France up to that point within a

framework of free pricing. In view of the fact that prices had risen considerably in 2003 and 2004 for a large number of medicines, the committee frequently opposed price submissions matching these prices, in order to return to 2003 levels.

Attention should be drawn to two particular situations:

- the first concerns 'dual channel' medicines, which patients can obtain from either hospital or community pharmacies. These are medicines for hepatitis and HIV/AIDS. For these products, CEPS considered that the prices negotiated in the agreements for sales via community pharmacies, which without exception were set in relation to the European benchmark, should also be applied to hospital sales, with no added markup.

- the second concerns products on the T2A list that are largely interchangeable, for which any discrepancies in the prices accepted by CEPS would lead to companies giving discounts, where the greater the price advantage for them, the higher the discount they could give, and could induce hospital buyers to buy on the basis of the discounts, thus distorting the competitive element and acting as a type of indirect subsidy to healthcare establishments by compulsory national health insurance payments. With this possibility in mind, the committee decided to standardise the accountability tariffs within each of the interchangeable product groups.

More generally, the committee believes that the difference between the tariff that is reimbursed by national health insurance and the prices actually paid by the healthcare establishments could lead to inappropriate buying practices by the hospitals and that therefore the difference should be restricted to the usual price differences based on the quantities bought by the establishments or specific services they can provide for the sellers.

APPENDIX 3: Tariff and price setting for medical devices

The first decision to be made when setting medical device tariffs and prices is whether the products should be listed by generic category or by brand name. This choice is down to the Minister, but CEPS is required to produce proposals, which it bases on the opinions of CNEDiMTS (the Medical device and technology assessment committee) (section 1). Accountability tariffs, and where applicable maximum purchase prices, are then set according to general principles (section 2) which are implemented according to individual circumstances (sections 3 to 6).

1. Registration by generic category or by brand name

Article R. 165-3 of the *Code de la Sécurité Sociale* (Social Security Code) specifies that items should be listed by brand or commercial name if they have innovative features or if the product needs to be specially monitored because of its impact on expenditure by *l'Assurance maladie*, for public health purposes or to monitor the technical specifications. The tariff is set subject to conditions regarding clawback payments or price adjustments according to the quantities sold or to the actual usage of the product in practice.

The committee's view, which has consistently informed the proposals it has made to the Health Minister concerning the registration conditions for each individual case, is that registration by generic category should be the rule and registration by brand the exception.

This does not mean that registration by brand represents a particular distinction or, indeed that it signifies superiority in terms of service provided. On the contrary, it goes without saying that the requirements concerning the level of service provided should be the same for both types of registration, which both relate to products that will be covered by national health insurance and are for use by people with a medical condition or disability.

It also does not suggest that registration by brand should be a rare occurrence and registration under generic categories should be more frequent.

It simply means that registration by generic category should be chosen unless – and this is where registration by brand constitutes the exception – generic registration is not possible or is clearly undesirable.

In practice, all instances in which registration by generic category is not possible boil down to the same situation, in which it is not possible to produce a generic description and, where applicable, technical specifications capable of guaranteeing that any devices that comply with the description will provide the expected service. This is of course often the case for devices that have been recognised as providing an improved service level or expected service level that can be proven in clinical trials, but for which it is not possible to define the required technical features until the necessary real-life experience has been gained.

In addition, there are two types of reason why registration by generic category is not desirable. The first type of situation relates to public health concerns and essentially falls within the remit of CNEDiMTS. The other reasons are of a financial nature, and fall within CEPS' remit. They are usually linked to the need to enter into agreements with the companies on other aspects in addition to tariff or price setting, and hence the need to get to know the companies. This is the case, for example, each time the tariff set is accompanied by conditions on clawback payments or price adjustments based on quantities sold or actual usage of the product in practice.

Registration by brand can also be necessary when an innovative product has done all the work of demonstrating the service provided by a new type of device, costing the company both time and money. This is to avoid a situation, for a certain time at least, where products that are simply imitators

can come onto the market and be registered under a generic category, without having to go through any formalities other than CE marking.

2. General principles governing tariff and price setting

The approach to tariff and price setting for medical devices is based on three rules.

Two of these relate to tariffs:

Article R. 165-4 of the Social Security Code stipulates that 'products and services (...) that represent neither an improvement to the service expected or the service provided, nor savings on treatment costs, or that are likely to entail unjustifiable national health insurance spending, may not be registered on the list provided for in Article L. 165-1 of the code.

Article R. 165-14 provides that 'the primary considerations when setting tariffs should be: the service expected or provided; any improvement to this service; the tariffs and prices of comparable products or services already included on the list; the sales forecasts and the foreseeable conditions surrounding actual use in practice.

As regards prices, they should be determined on the basis of the very broad provisions of Article L. 162-38 of the same code, according to which the setting of prices or markups by decree for products or services that are to be covered by mandatory national health insurance plans 'must take into account changes in workload, income and business for the practitioners or companies concerned'.

In practice, the committee is often obliged to combine these rules, and it does so automatically when the same figure is set for a tariff and a maximum purchase price at the same time. In these instances, it goes without saying that this figure must be in keeping with the rules on both tariffs and prices.

Applying these rules on tariffs, which are identical to the rules on tariffs for medicines, to medical devices, can however pose certain problems linked to the specific procedures for registering medical devices on the reimbursable lists, the typical nature of innovation in this field and the very diverse types of products and services concerned. The following explanations describe the solutions that the committee has adopted.

3. Tariff setting by category

For products or services that do not represent any improved expected service (ASA - *amélioration du service attendu*) or improved service provided (ASR - *amélioration du service rendu*) to be included on the list, they must represent savings in treatment costs, pursuant to Article R. 165-4 of the code. However, in practice, this simple, important rule is difficult to apply to the field of medical devices. The code stipulates (Article R. 165-3) that as a rule, a reimbursable item should be registered according to the generic description of the product or service and should only be registered by brand or commercial name as an exception. The result of this is that the vast majority of products and services registered as reimbursable items are entered under an existing category and therefore at the same tariff, even though they have not been given an 'ASR' rating, as the products or services already registered as covered items.

The committee has dealt similarly, by extension, with certain device categories that have been registered under their brand names in implementation of the second exception to the generic registration rule provided in Article R. 165-3, 'if the product needs to be specially monitored because of its impact on expenditure by *l'Assurance maladie*, for public health purposes or to monitor the technical specifications'. The same was done for device categories that were listed under the 'approval numbers' system prior to the reform and were registered, sometimes temporarily, under their brand names. For these cases, the committee decided that it was appropriate to treat the products in question

as if they were under generic categories and for newly included products to be given a tariff and where applicable a maximum purchase price identical to those of products already registered in the category. This practice was given a legal basis in the form of the decree of 23 December 2004 amending Article R. 165-4 of the Social Security Code.

The first consequence of this situation is that the rule on treatment cost savings only applies in practice to new devices with no ASA or ASR rating that do not match an existing generic definition, either because the service expected or provided is obtained, for comparable devices already listed, via a different mode of action or technology, or because the comparison is being made with treatment methods that do not fall within the scope of the list, such as surgical procedures, drug treatments, etc.

The second consequence is that for medical devices, a reduction in the average price in a product category over time, which for medicines occurs naturally with the successive registration of new medicines each cheaper than the last, can only be obtained, when justified, by periodically lowering the prices of generic categories or standardised tariffs.

4. Recognising innovation

For products that do provide an improved level of expected or provided service (ASA or ASR), the criteria expressly laid down in the legislation provide a framework and guidelines for setting tariffs, however they are not enough on their own. The rule in Article R. 165-4 authorises a higher price or tariff for these products, but does not specify the size of the premium. The most that can be deduced from this is that generally speaking, a low ASA or ASR rating does not justify a major tariff difference compared with the reference product if there is one, which is not always the case in the medical device field. Added to this, the existence of an ASA or ASR rating is a necessary pre-requisite, but does not suffice on its own to warrant extra expense, and the rules do not therefore prevent a new ASA or ASR rated product from being registered at a lower tariff than that of already listed reference products. Aside from the price of the reference product, even if a certain product is given a high ASA or ASR rating in the light of the minimum technical specifications required to sell it under a generic category, this cannot be the sole criterion for setting a higher price or tariff than those given to the generic category. This is partly because products with an equal ASA or ASR rating may already have been on the market at the prices or tariffs applicable to the generic category, but also because it may be necessary to create entries under brand names.

In practice, therefore, the committee has to distinguish quite schematically between three main situations when setting tariffs for innovative products.

In the simplest cases, it can be demonstrated that the price that the company has proposed or accepted, which it therefore considers a fair recognition of its innovation work, will entail costs for national health insurance that are lower than, or at the worst equal to, the savings that the use of the product will lead to. In these cases, the registration process is straightforward, however, it does highlight the importance of having reliable, convincing medico-economic studies.

In the second instance, it often happens, especially in the case of implantable devices, that progress in terms of the service provided takes place in the form of small, frequent ‘incremental’ innovations. When it seems that the prospect of the new product's higher market share is not sufficient remuneration for the innovation work and a price advantage is also required, the committee may propose higher tariffs than those of comparable products already listed, for a limited period only. In the event that another equally innovative product is registered some time later, the committee allows the new device the same price or tariff advantage as its predecessor for whatever time remains of the temporary price advantage period. This means that innovation work is rewarded for a certain, usually short, period before being overtaken by a new, more technologically advanced product. This practice, which the committee has implemented in its tariff setting for pacemakers, means that the ASA or ASR ratings can be recognised whilst avoiding spiralling costs. In this context, the minimum technical specifications attached to the generic category must be periodically revised to incorporate the incremental innovations that have accumulated since the previous definition.

This leaves the most difficult cases: innovations that represent both significant advances and high costs, for which the payback for the sometimes significant extra costs they represent for the public purse can only be measured in terms of improved patient care that is not financially quantifiable. Medico-economic studies can be used as decision-making aids, but they are usually problematic.

In these situations, the discussions on price are linked to a discussion of the no less important issue of restricting limiting the quantities of the product to patient groups for which the expected advantage of the innovation has been well established.

This presupposes that the issue of identifying and measuring the target patient groups has been dealt with, as well as that of all the different resources that need to be put in place to ensure only those groups are given the benefit of the innovation. In these cases, contractual provisions are made at the time the product is registered, covering limitation of sales volumes, compensation payable by the companies if they exceed these quantities, and the obligation to conduct follow-up studies.

When setting prices for innovative products, even though there is no agreement or guideline to this effect between CEPS and the medical device companies, in practice the committee must often compare the price applied for with prices in force in other countries, especially European countries. Extreme care needs to be taken when making comparisons, to ensure that the prices under consideration relate to the same items at the equivalent distribution stages.

For these major innovations, the price or tariff advantage given to the market leader can pose problems as soon as equally innovative rival products emerge whose price or tariff will need to be lower. If these products are registered on the hospital 'T2A' list, this price differential could skew the competition between the devices, in that the choice will no longer depend only on the expected efficacy of the devices or even on their cost/benefit ratio, but also on the size of the discounts that the manufacturer of the product with the highest price or tariff will be able to offer buyers. The issue then is to re-establish normal competition conditions between equivalent products included on the T2A lists as quickly as possible.

It can happen in rare cases that the devices included on the reimbursement lists do not completely fulfil the needs, due to the diversity of the patient group. In such cases, the inclusion of a new device on the lists can provide a solution that goes at least some way towards fulfilling these unmet needs, regardless of its added service (ASA), if any, compared to devices already on the lists. Their value and necessity lie in the that they are different, rather than being superior. When these devices cannot be obtained at the same price as the reference products, the committee may accept a higher price.

5. Discrepancies between prices and tariffs

The reimbursement system for medical devices, unlike the system for medicines that was in force before 'fixed accountability tariffs' were introduced, is such that in general situations, there can be discrepancies between the tariff, which is the national health insurance reimbursement base, and the actual price.

When the committee considers it necessary, for reasons of equal access to care or disability support, to prevent such a discrepancy from being established, the only means available since the new rules were introduced is to set a maximum purchase price (c.f. CEPS annual report 2001). The committee's aim is to set maximum purchase prices on an almost routine basis. It considers that the contribution made by medical devices to the preservation or restoration of individuals' health or quality of life is as important as that of the other elements of care provision, including medicines. It therefore considers that the percentage left for patients to pay, especially if this is not kept under control, can constitute a threat to their equality of access to care.

In particular, when tariff reductions are introduced, the committee is keen to ensure that these go hand-in-hand with a maximum purchase price, and where applicable a prescription price, in order to

avoid a situation where savings are made at the patient's expense and act as a reduction in their reimbursement, an area over which the committee has no jurisdiction.

It is safe to say that at present, with the notable exception of adult opticianry and hearing aids, the vast majority of devices or services included on the reimbursable medical devices and services list have a maximum purchase price and for those which do not have one or are yet to have one, the prices in force are in any case identical or very close to the tariffs.

However, setting a maximum purchase price presupposes that a solution must be found to the issue of the extra costs charged for services or accessories that go beyond the definition of the reimbursable product or service as stipulated on the list. This is often the case for external prosthetic devices and orthotic devices, where patients may request, and the operators involved may offer extra aesthetic or technical features; however these are not the only cases. For example, in the area of hearing devices for young children, those working in the profession have highlighted the fact that the discrepancy between the tariff and the price left room to pay the salaries of the hearing device personnel, who might be needed for a number of session, to adapt the appliance to the patient, especially very young patients or patients with multiple disabilities. In the event, the patient's share of the costs was usually taken care of by universal health cover (CMU), top-up insurance or help provided by regional or municipal aid bodies approached by the support personnel themselves. The difficult, sometimes impossible task of determining a maximum purchase price according to logical criteria, and the possibilities available for funding the patients' share of the costs led the committee to opt for setting a maximum purchase price for these hearing devices that was higher than the reimbursement tariff.

For extras of an aesthetic nature, when they are easy to separate from the defined reimbursable product or service per se, there is no reason why the operators involved should not produce separate bills for the patient's extra share, whilst adhering to the maximum purchase price for the main element. When these extras cannot be separated from the reimbursable device, it is important to avoid exemptions, which could gradually lead to a strong risk of all satisfactory products being taken off the reimbursable list and thus to access problems for less well-off patients. However, in 2003, the *Conseil d'Etat* ruled that in the case of customised orthopaedic shoes a complete ban on exemptions was illegal. In this instance, after taking advice from the national consumer's association (*Conseil national de la consommation*), the committee replaced the ban with a strict procedure requiring patients to be given information in advance. Whether or not the extras can be separated from the main product, if they are legal, patients must be given information regarding the non-reimbursable elements in advance.

6. Price revisions by profession

The medical devices sector covers several different professions, many of which are made up of small or very small businesses whose operations are more comparable to those of private service providers or small-scale craft industries than those of companies carrying out research and industrial-scale production. A large proportion of the tariffs and maximum purchase prices applicable to the reimbursable services provided by these professions often goes towards salary costs.

In these cases, the issue surrounding tariffs is somewhat different than in the other medical device fields. In particular, the criteria on price setting provided in Article L. 162-38 of the Social Security Code (workload, income, business operations) play a key role.

As regards the tariff-setting proposals it formulates and above all periodic tariff reviews, the committee feels it is important to adhere to two objectives:

- the tariff and price levels must be high enough to guarantee a continuous, uniform supply across the whole country, and a quality level consistent with the service expected or provided that warranted inclusion on the list.

- these price levels should not however be such as to unduly favour unproductive operations, which would effectively turn the products of more competitive businesses into a bargain.

The committee has decided that the most effective way of achieving these objectives is by regular tariff revisions, and has therefore proposed annual set tariff revision mechanisms in several cases, based on medium-term cost increases. This procedure goes hand-in-hand with regular monitoring of actual costs and profits, so that the fixed rates adopted can be altered if necessary, either at the committee's initiative or at the initiative of the trade associations concerned.

APPENDIX 4: Table of clawback payment thresholds per category of pharmacotherapeutic groups for 2010-2013

For the 2010 financial year, the coefficient provided in Article 17a) of the framework agreement is set at 25%. For each group, the portions of the overall clawback figure based respectively on turnover and excess are set at 65% and 35%.

NB: Products issued to outpatients or invoiced on top of T2A funding are marked in italics, except for categories made up primarily of these products.

Category L04A no longer exists in the 2010 GERS data, but still exists in the hospital declarations for the 2nd quarter of 2010. It has been replaced by L04B (TNF blockers) and L04X (other immune suppressants).

Category	Pre-tax turnover for the category (U x P) 2009	2010 rate	2010 rate (K rate not included)	2011 rate (K rate not included)	2012 rate (K rate not included)	2013 rate (K rate not included)
A02 (antacids and anti-flatulent agents) other than A02B2	117,057,046	1.0%	0.0%	0.0%	0.0%	0.0%
A02B2 (proton pump inhibitors)	837,125,569	-7.0%	-8.0%	-5.0%	-10.0%	-10.0%
A03 (antispasmodics, anticholinergics and gastro-intestinal motility treatments) + Vogalene (A04A9) *(including Prepulsid and Debridat inj.*)	134,633,467	1.0%	0.0%	0.0%	0.0%	0.0%
A04 (antiemetics) except Vogalene (A04A9)	32,393,727	1.0%	0.0%	0.0%	0.0%	0.0%
A05A1 (bile therapy and cholecystokinin) + A05B (hepatic protectors, lipotropics) + A06 (laxatives) inc Relistor + A07 (anti diarrhoeals) except A07E + A09 (digestives including digestive enzymes)	190,369,571	1.0%	0.0%	0.0%	0.0%	0.0%
A05A2 (bile stone therapy) + A07E (intestinal anti-inflammatory agents) + budesonide (H02A2)	69,032,399	1.0%	0.0%	0.0%	0.0%	0.0%
A10 (antidiabetic agents) + A08A (anti-obesity products) (inc Insuplant)	714,393,859	10.0%	9.0%	4.0%	4.0%	4.0%
A11 (vitamins) + A12A (calcium products) except Calcium Sorbisterit, Phosphoneuros and Phosphosorb + A12B (potassium products) + A12C2 (other mineral supplements) except phosphorous + C10B (natural anti atheroma preparations) (including *un-alfa inj.*)	116,027,717	1.0%	0.0%	0.0%	0.0%	0.0%
A12C (mineral supplements) except A12C2 + A15 (appetite stimulants) + A16A (other gastrointestinal products: Proglicem)	39,174,784	1.0%	0.0%	-95.0%	0.0%	0.0%

Category	Pre-tax turnover for the category (U x P) 2009	2010 rate	2010 rate (K rate not included)	2011 rate (K rate not included)	2012 rate (K rate not included)	2013 rate (K rate not included)
B01A (non-injectable anticoagulants) + B01B (injectable anticoagulants: heparins) + B01E (direct thrombin inhibitors) + B01X (other anti-thrombotic agents) except Ceprotin and Protexel (including *Orgaran and Xigris*)	319,807,113	1.0%	0.0%	0.0%	0.0%	0.0%
B01C (antiplatelet agents) except Xagrid	576,052,141	-29.0%	-30.0%	-20.0%	0.0%	0.0%
B02A and B (haemostatic agents) + B03 (anti-anaemic preparations) except B03C and Eporatio (B03X) + A14A1 (anabolic hormones) + Lederfoline, Elvorine and Folinoral (V03D) (including *Venofer*)	59,483,806	1.0%	0.0%	0.0%	0.0%	0.0%
B02C and D (clotting factors) + Ceprotin and Protexel (B01X) + J06 (sera and gamma-globulin) except Synagis (J06H9)	744,550,603	7.0%	6.0%	6.0%	6.0%	6.0%
B03C (erythropoietin products including Retacrit) + Eporatio (B03X)	503,724,891	0.0%	-1.0%	0.0%	0.0%	0.0%
C01A + B + C (cardiac glycosides, anti-arrhythmics and cardiac stimulants)	102,506,592	6.0%	5.0%	7.0%	7.0%	7.0%
C01D + E + X (coronary arterial disease treatments) + C02 (antihypertensives) + C03 (diuretics) + C07 (beta blockers) + C08 (calcium channel blockers) + Caduet (C10A1)	1,019,386,494	1.0%	0.0%	0.0%	0.0%	0.0%
C04 (vasodilators) + N6D (nootropics) + Olmifon (N07X)	137,939,273	-1.0%	-2.0%	-5.0%	-4.0%	0.0%
C09 (renin-angiotensin system drugs)	1,403,042,404	-5.0%	-6.0%	-6.0%	-3.0%	-3.0%
C10A (cholesterol and triglyceride regulating agents) + C10C (lipid regulating drug for use in combination)	1,245,738,671	-5.0%	-6.0%	-3.0%	-5.0%	-5.0%
D (dermatologicals) + Terbinafine (J02A) + Metvixia (L01X9) + Efudix (L01B)	411,191,408	1.0%	0.0%	0.0%	0.0%	0.0%
G01 (gynaecological anti-infectives) + Florgynal (G02F)	28,778,076	1.0%	0.0%	0.0%	0.0%	0.0%
G02 (other gynaecologicals) except Florgynal (G02F) + G03 (ovulation inhibitors) except G03B, G and J	196,444,387	2.0%	1.0%	0.0%	0.0%	0.0%
G03B (androgens), G04 (urologicals) except G04A and Revatio	262,146,771	1.0%	0.0%	0.0%	0.0%	0.0%
G03G (gonadotrophins / ovulation stimulants) + H01C1 and C3 (hypothalamic hormones) *(inc Salvacyl)*	126,998,802	6.0%	5.0%	5.0%	0.0%	0.0%
H01A (ACTH) + H01C2 (anti hGH antibodies) + H02 (oral corticosteroids) except budesonide (H02A2) + H04A, B and D (calcitonins, glucagon and antidiuretic hormones) *(inc Minirin inj.)* + Akonatrem (J01A)	177,457,427	-1.0%	-2.0%	-1.0%	0.0%	0.0%
H03 (thyroid treatments) *(inc Proracyl*)	44,121,290	1.0%	0.0%	0.0%	0.0%	0.0%
H4C (growth hormones)	151,017,037	1.0%	0.0%	-1.0%	-1.0%	-1.0%

Category	Pre-tax turnover for the category (U x P) 2009	2010 rate	2010 rate (K rate not included)	2011 rate (K rate not included)	2012 rate (K rate not included)	2013 rate (K rate not included)
J01 (systemic antibacterials) + J02A (systemic antifungal agents) except Terbinafine + J03A (systemic sulphonamides) + J05B (antivirals excl. anti-HIV agents) except J05B1 + G04A (antiseptic agents and urinary tract anti-infective agents) - Alkonatrem (J01A)	1,092,886,050	-1.0%	-2.0%	-2.0%	-2.0%	-2.0%
J05B1 (hepatitis antivirals) + J05C (HIV antiretrovirals) including Intelence + L03B1 (alpha interferons)	1,022,973,471	6.0%	5.0%	3.0%	0.0%	0.0%
J07 (vaccines) + V01A (allergy treatments) + Synagis (J06H9)	473,527,348	10.0%	9.0%	5.0%	0.0%	0.0%
K (solutions for hospital use) + Nonan, Decan, Tracutil and Tracitrans (A12C2)	46,015,294	8.0%	7.0%	6.0%	3.0%	0.0%
L01 except Metvixia (L01X9) and Efudix (L01B) + L02 (anti-cancer agents and cytostatic hormone therapy) + L03A (growth factors) except Copaxone (L03A9)	2,553,479,306	7.0%	6.0%	4.0%	2.0%	1.0%
L03B2 (beta interferons) + Copaxone (L03A9) and Tysabri (L04X)	308,298,019	3.0%	2.0%	2.0%	2.0%	2.0%
L04X (other immune suppressants) except Ilaris and Tysabri	213,510,579	5.0%	4.0%	0.0%	0.0%	0.0%
M01A1 (anti-rheumatics, non-steroidal plain) except diacerein and glucosamine based products + M01A3 (Coxibs, plain) + M04 (anti-gout preparations)	220,051,378	1.0%	0.0%	0.0%	0.0%	0.0%
M01A2 (antirheumatic, non-steroidal in combination)+ M02 (topical antirheumatics and analgesics) + M03 (muscle relaxants)	112,427,033	0.0%	-1.0%	0.0%	0.0%	0.0%
M01C (disease-modifying anti-rheumatic drugs) + Acadione (M05X) + Orencia, Raptiva and Roactemra (L04A) + L04B (TNF blockers)	648,745,157	6.0%	5.0%	2.0%	0.0%	0.0%
M05B (Biphosphonates) + G03J (Oestrogen receptor modulators) + Forsteo (H04E), Protelos, Osigraft and Inductos (M05X)	405,790,424	1.0%	0.0%	-5.0%	-4.0%	0.0%
M05X (other musculoskeletal treatments) except Acadione and Protelos + diacerein and glucosamine based products in M01A1	251,090,297	-1.0%	-2.0%	-5.0%	-2.0%	0.0%
N01 (anaesthetics) (inc *Naropeine and Versatis*)	45,509,600	1.0%	0.0%	0.0%	0.0%	0.0%
N02 (analgesics) excluding Buprenorphine and Methadone + N07C (antivertigo preparations)	1,072,823,374	1.0%	0.0%	0.0%	0.0%	0.0%
N03A (antiepileptics) *(inc Taloxa*)	321,423,272	4.0%	3.0%	3.0%	2.0%	2.0%
N04A (antiparkinson drugs) + Adartrel (N07X)	115,651,302	4.0%	3.0%	3.0%	2.0%	2.0%
N05A1 (atypical antipsychotics)	354,225,545	-1.0%	-2.0%	-4.0%	-4.0%	-2.0%

Category	Pre-tax turnover for the category (U x P) 2009	2010 rate	2010 rate (K rate not included)	2011 rate (K rate not included)	2012 rate (K rate not included)	2013 rate (K rate not included)
N05A9 (conventional antipsychotics) + N06A3 (mood regulators)	87,096,904	3.0%	2.0%	0.0%	0.0%	0.0%
N05B (hypnotics and sedatives) + N05C (tranquilisers)	189,607,138	1.0%	0.0%	0.0%	0.0%	0.0%
N06A (antidepressants) except N06A3 and Levotonine (N06A9)	441,145,656	-4.0%	-5.0%	-2.0%	0.0%	0.0%
N06B (psychostimulants) + N07E (alcohol dependence treatments) + N07F (opioid dependence treatments) + Rilutek (N07X), Levotonine (N06A9), Buprenorphine and Methadone (N02A)	147,945,556	3.0%	2.0%	0.0%	0.0%	0.0%
N07D (anti-Alzheimer's products)+ Mestinon, Prostigmine and Mytelase (N07X)	248,081,072	4.0%	3.0%	0.0%	0.0%	0.0%
P (anti-parasitic products) + J04 (tuberculosis and lepra treatments) *(inc Eskazole, Lamprene and Notezine*)	23,214,503	5.0%	4.0%	0.0%	0.0%	0.0%
R01A1 + A6 (nasal corticosteroids and other topical nasal preparations) + R06A (systemic antihistamines)	345,487,873	-2.0%	-3.0%	-5.0%	-5.0%	-5.0%
R01A4 + A7 + A9 + B (nasal anti-infectives) + R02 (throat decongestant preparations) + R05 (cough preparations) + R07 (other respiratory products) + A01 (stomatologicals) + Pulmozyme (V03H)	168,359,499	-4.0%	-5.0%	-5.0%	-5.0%	-5.0%
R03 (anti-asthma and COPD products)	1,035,196,642	3.0%	2.0%	-3.0%	-3.0%	-3.0%
S01 (ophthalmologicals) except S01E and S01P + S02 (ear treatments)	134,945,489	1.0%	0.0%	0.0%	0.0%	0.0%
S01E (miotics and antiglaucoma preparations)	228,506,434	0.0%	-1.0%	-1.0%	-1.0%	-1.0%
S01P (anti-neovascularisation products)	188,730,773	11.0%	10.0%	5.0%	0.0%	0.0%
T01 (diagnostic imaging products) + T02X (other diagnostic tests) + Helikit (V03X), Lipiocis and Quadramet (V03C)	157,459,226	5.0%	4.0%	4.0%	4.0%	2.0%
V03 (miscellaneous treatments) except Lederfoline, Elvorine, Folinoral, Pulmozyme, Helikit, Lipiocis and Quadramet + Mimpara, Phosphorous, Phosphoneuros, Phosphosorb and Calcium Sorbisterit *(inc Cardioxane, Uromitexan, Ferriprox, Fasturtec and Ethyol*)	84,188,656	1.0%	0.0%	0.0%	0.0%	0.0%
V06 (dietetic agents) + V07 (other products) + C05 (haemorrhoid and varicose vein treatments)	46,054,682	-4.0%	-5.0%	-2.0%	-2.0%	-2.0%
Z (orphan medicines)	897,943,211	1.0%	0.0%	0.0%	0.0%	0.0%
Total	23,442,986,087	1.0%	0.0%	0.0%	0.0%	0.0%

APPENDIX 5: Price agreements and pro-forma clauses

1. Price agreements for medicines

RIDER TO THE AGREEMENT OF .....
between the Comité économique des produits de santé (CEPS)
and *X*

Having regard to the Social Security Code, in particular Articles L 162-16-4 and L 162-17-4,
Having regard to Decree no 99-554 of 2 July 1999 amending the Social Security Code regarding the 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 the setting of prices for such medicines,
Having regard to the ruling of 4 August 1987 regarding prices and markups on reimbursable medicines,
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 and L. 5121-1,
Having regard to the multiannual agreement made on *dd/mm/yy* between the Comité économique des produits de santé (CEPS) and *X*;
The Comité économique des produits de santé (CEPS) and *X* now agree on the following provisions:

ARTICLE 1:

The prices stated in the table below shall be applicable as of the effective date of the decision.
Price registration or price change

Product	EphMRA / ATC category	Manufacturer price ex VAT	Public price inc VAT	TFR (Fixed accountability tariff)	Effective date
CIP code, name, dose (of active ingredient), pharmaceutical form, packaging, (of company marketing the product)					Date of publication in the *Journal Officiel* or later date

ARTICLE II: (c.f. pro-forma clauses below)

ARTICLE III:

Appendix 3 to the above-mentioned agreement shall be amended in accordance with Article I.
Appendix 4 to the above-mentioned agreement shall be amended in accordance with Article II.

Done in Paris, on

First name, Surname
Position
Company *X*

First name, Surname
Chairman of the Comité économique
des produits de santé

2. Pro-forma clauses regarding medicines

2.1. Pro-forma posology clause

Article 2:

2.1. The price set in Article I (reference manufacturer price ex VAT: $PFHT_R$) is set on condition that the posology established ($Poso_n$) should be equal to or less than ……. (Reference posology: $Poso_R$).

2.2. The posology ($Poso_n$) shall be monitored every year, and on the first occasion, which shall be dd/mm/yy, it shall be monitored with reference to the most recent EPPM[10] published before this date.
If the poslogy observed ($Poso_n$) is greater than the reference posology ($Poso_R$), the manufacturer price ex VAT as set in Article I shall be modified ($PFHT_{n+1}$) on the basis of the following formula:

$$PFHT_{n+1} = \frac{Poso_R}{Poso_n} \times PFHT_n$$

If there has already been one price change on the basis of this clause, a further price change may only be introduced on the basis of this clause if the posology observed is higher than the posology observed at the time of the first price change.
If ($Poso_n$ - $Poso_R$) / $Poso_R$ is less than *x* %, the $PFHT_n$ shall not be changed and the company shall instead owe a rebate (R_n) calculated according to the formula given in 2.3 herebelow.

2.3 If the poslogy observed ($Poso_n$) is greater than the reference posology ($Poso_R$), the company may also be liable to pay a rebate (R_n), calculated according to the following formula:

$$R_n = CAHT_n - (PFHT_{n+1} \times V_n)$$

where:

- $CAHT_n$ equals the sales figure established by GERS over the 12 months preceding the date given in 2.2 hereabove;
- V_n equals the sales volume of which GERS has been informed for the same period.

2.4. The company shall be notified of the sum of the rebate owing by CEPS, who will inform the relevant local URSSAF of the payment owing (Paris-RP URSSAF for the Ile de France regions and Lyon URSSAF for all other regions). The company shall pay the sum owing upon receipt of the contribution request from the relevant URSSAF office. The company shall inform CEPS by post of the date and actual sum of the payment.

(The sum of the rebate may be deducted by agreement from the sum used to work out the corresponding end-of-year clawback by pharmacotherapeutic class grouping owed by the company).

[10] Étude permanente de la prescription médicale (Ongoing medical prescription monitoring).

2.2. Pro-forma product range daily treatment cost clause

Article 1:

The initial listing prices (or price changes) given in the table below shall be applicable as of the date they are published in the *Journal Officiel* (or shall be effective as of *dd/mm/yy*).
Product

Product	**Category**	**Manufacturer price ex VAT**	**Public price inc VAT**
First listing – CIP code, product aaa, ..……	€…,..	€…,..	
First listing – CIP code, product bbb, ……	€…,..	€…,..	
Price change – CIP code, product ccc, ……	€…,..	€…,..	

Article 2:

2.1. The prices set in Article 1 are set on condition that the established daily treatment cost for the product range ($CTJG_n$), calculated for the range comprising aaa, bbb, ccc, …., should be less than or equal to € ---.--: the reference product range daily treatment cost ($CTJG_R$).

2.2. The $CTJG_n$ value shall be monitored every year (n) and the first monitoring shall cover the 12-months preceding dd/mm/yy. The value shall be calculated on the basis of the average yearly cost of the number of treatment days (NJT_n) and of the posologies of each of the products mentioned in 2.1 hereabove which are included in the EPPM (IMS) data published before dd/mm/yy and the 12-month sales figure stated in the most recent GERS data published prior to this date.
$CTJG_n$ shall be calculated by dividing the sales figure for the whole range ($CAHTG_n$) as declared to GERS, by the number of days' treatment using products in the range ($NJTG_n$), or:

$$CTJG_C = CAHTG_n / NJTG_n$$

where $NJTG_n$ equals the sum of the number of days' treatment with each of the products in the range, or:

$$NJTG_n = \Sigma NJT_{in}$$

The number of days' treatment, NJT_{in} is equal to the number of tablets (or doses/units) sold for each product or product format (i) in the range divided by the corresponding posology (P_i) reported in the EPPM (IMS), or:

$$NJT_{in} = (number\ of\ units\ per\ pack\ x\ number\ of\ packs_i) / Poso_{in}$$

If $CTJG_C > CTJG_R$, the manufacturer price ex VAT of each of the products or product formats in the range mentioned in 2.1. hereabove shall be uniformly modified $(PFHT_{n+1})$ with the result that $PFHT_{n+1} = PFHT_n \times CTJG_R / CTJG_n$ and the company shall be liable for a clawback payment R_n, *where* $R_n = NJTG_n \times (CTJG_n - CTJG_R)$.

However, if $PFHT_{n+1} / PFHT_n > x\%$, no price reduction shall be made and the company shall still be liable to make a clawback payment.

2.3. Pro-forma unit volumes clause

Article 2

2.1. The price (manufacturer price ex VAT) mentioned in Article I (reference manufacturer price ex VAT: $PFHT_R$) is set on condition that the annual sales volume (V_n) shall be less than or equal to the reference sales volume (V_R).

2.2. The sales volume (V_n) shall be reported every year in the GERS data for month *M*, the first occasion being the GERS data published in month *M* of year *A*.

2.3 If the annual sales volume reported (V_n) is greater than the reference sales volume (V_R), the manufacturer price ex VAT shall be modified ($PFHT_{n+1}$) according to the following formula:

$$PFHT_{n+1} = [V_R \text{ x } PFHT_n + (V_n - V_R) \text{ x } a \text{ x } PFHT_n] / V_n$$

$$= [1 + a \text{ x } (V_n - V_R) / V_n] \text{ x } PFHT_n \text{ where } 0 < a < 1.$$

In addition, the company will be liable for a clawback payment:

$$R_n = (V_n - V_R) \text{ x } a \text{ x } PFHT_n$$

2.4 However, if $PFHT_{n+1} / PFHT_n > x$ %, no price reduction shall be made and the company shall still be liable to make a clawback payment.

2.5 Subsequent to any price modification introduced pursuant to 2.2 hereabove, the current price in force ($PFHT_n$) shall only be reduced if the annual sales volume reported (V_{n+i}) is both higher than both V_R and than the sales volume which led to the previous price change (V_n).
If $V_{n+i} > V_n > V_R$, the company shall also be liable to pay a new clawback payment:

$$R_n = (V_{n+i} - V_n) \text{ x } a \text{ x } PFHT_n$$

2.6 The committee reserves the right to revise the price and the above-mentioned provisions in the event of an extension of the product's indications.

2.7 The company shall be notified of the sum of the rebate owing by CEPS, who will inform the relevant local URSSAF of the payment owing (Paris-RP URSSAF for the Ile de France regions and Lyon URSSAF for all other regions). The company shall pay the sum owing upon receipt of the contribution request from the relevant URSSAF office. The company shall inform CEPS by post of the date and actual sum of the payment.

2.3. Pro-forma pooled sales turnover clause

Article 2

2.1. The price (PFHT – manufacturer price ex VAT) mentioned in Article 1, (reference manufacturer price ex VAT: $PFHT_R$) is set on condition that the annual pre-tax turnover ($CAHT_n$) shall be less than or equal to the reference annual pre-tax turnover ($CAHT_R$).

2.2. The annual pre-tax turnover of the product range mentioned in Article 1 ($CAHT_{Xn}$) and the annual pre-tax turnover of this range and new proprietary products sharing the same indications ($CAHT_n$) shall be reported every year (n) in the GERS data for month *M*, the first occasion being the GERS data published in month *M* of year *A*.

2.3 On the basis of the turnover for one year (n), beyond a reference annual turnover ($CAHT_R$) for all the products mentioned in Article 1 and the new proprietary products sharing the same indications, the company shall be liable to pay a clawback payment:

$$R_{Xn} = (CAHT_{Xn} / CAHT_n) \times [(CAHT_n - CAHT_R) / PFHT_n] \times a \times PFHT_n$$ where $0 < a < 1$

$$= (CAHT_{Xn} / CAHT_n) \times (CAHT_n - CAHT_R) \times a$$

where ($PFHT_n$) is the current manufacturer price ex VAT in force per tablet / mg / capsule, etc.
Furhtermore, the manufacturer price ex VAT per tablet / mg / capsule, etc. of the products mentioned in Article 1 shall be changed ($PFHT_{n+1}$) according to the following formula:

$$PFHT_{n+1} = ((CAHT_{Xn} - R_{Xn}) / CAHT_{Xn}) \times PFHT_n$$

2.4 However if $PFHT_{n+1} / PFHT_n > x$ %, no price reduction shall be made and the company shall still be liable to make a clawback payment.

2.5 Subsequent to any price modification introduced pursuant to 2.3 hereabove, the current price in force ($PFHT_n$) shall only be reduced if the turnvoer reported ($CAHT_{n+i}$) is higher than the turnover which led to the previous price change ($CAHT_n$).
If $CAHT_{n+i} > CAHT_n > CAHT_R$, the company shall also be liable to pay a new clawback payment:

$$R_{Xn+i} = (CAHT_{Xn+i} / CAHT_{n+i}) \times (CAHT_{n+i} - CAHT_n) \times a \text{ where } 0 < a < 1.$$

2.6 The committee reserves the right to revise the price and the above-mentioned provisions in the event of an extension of the product's indications.

2.7 The company shall be notified of the sum of the rebate owing by CEPS, who will inform the relevant local URSSAF of the payment owing (Paris-RP URSSAF for the Ile de France regions and Lyon URSSAF for all other regions). The company shall pay the sum owing upon receipt of the contribution request from the relevant URSSAF office. The company shall inform CEPS by post of the date and actual sum of the payment.

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3. Agreement regarding medical devices (including study clause)

This Agreement is made
between the Comité économique des produits de santé (CEPS)
and the company *(X)*

Having regard to the Social Security Code, in particular Articles L 165-2, L. 165-3and L. 165-4;
Having regard to the opinion of the Medical device and technology assessment committee (CEPP);
whereby the Comité économique des produits de santé (CEPS) and *(X)* agree on the following provisions:

Article 1: This agreement is made under the condition precedent that the decree relating to the registration of device(s) (*Y*) shall be signed by the relevant ministers. This agreement shall be effective as of the corresponding effective date of publication of the decree in the *Journal Officiel.*

Article 2: The tariffs and maximum public selling prices including VAT stated in the table below are set as follows:

Code	**Category** **€Max, public price inc VAT**	**€Tariff inc VAT**
aaa, ……	€…,..	€…,..
bbb, ……	€…,..	€…,..
ccc, ……	€…,..	€…,..

Article 3: (see pro-forma clauses herebelow)

Article 4: The company (*X*) undertakes to conduct and fund a study …. The aim of this study will be: …. The results of the study shall be sent to CNEDiMTS and to CEPS.

Paris, date

MM Chairman of the *Comité économique*

Company *XXXX* *des produits de santé*

4. Pro-forma clause for medical devices

4.1. *Pro-forma unit volumes clause*

Article 3:

3.1 The company (*X*) undertakes to inform the committee every year, during the course of month *mm*, for the year finishing in the *mm* month, and for the first time during the month *mm*/*aaaa*, of the total number of devices (*Y*) that is has sold in France during the previous year.

3.2 If the number (*N*) of devices (*Y*) sold in the year exceeds a certain number (*n*), the prices/tariffs (*P*) stated in the decree, which are shown in Article 1 hereabove, shall be modified (P_M) on the basis of the formula:

$P_M = (a \times P) + [(1 - a) \times P \times (n / N)]$, where $0 < a < 1$

And the company shall be liable to pay a clawback payment (*R*) which shall be calculated according to the formula:

$R = (P_V - P_M) \times N$

where (P_V) is the current price of the device in question.

However if $P_M / P_V > x$ %, the price shall not be reduced but the company shall still be liable for the clawback payment (*R*).

3.3 Where there has already been one price reduction under the terms of paragraph 3.2 hereabove, no new price reduction may be introduced on the basis of paragraph 3.2, unless the number (*N'*) of devices (*Y*) sold established on this occasion is greater that the number (*N*) on which the previous reduction was based and if $P_M / P_V > x$ %.

If $N' > n$ and $P_V > P_M$, the company shall be liable to pay a clawback payment $R = (P_V - P_M) \times N'$.

3.4 The company shall be notified of the sum of the rebate owing by CEPS, who will inform the relevant local URSSAF of the payment owing (Paris-RP URSSAF for the Ile de France regions and Lyon URSSAF for all other regions). The company shall pay the sum owing upon receipt of the contribution request from the relevant URSSAF office. The company shall inform CEPS by post of the date and actual sum of the payment.

4.2. Pro-forma pooled sales turnover clause

Article 3:

3.1 The company (*X*) undertakes to inform the committee every year, together with all companies selling the devices (*Y*) in France, during the course of month *mm*, for the year finishing in the *mm* month, and for the first time during the month *mm*/*aaaa*, of the total number of devices (Y_x) that is has sold in France during the previous year.

3.2 On the basis of these declarations, the annual sales by company *(X)* of device (*Y*) and those by each of the companies selling (*Y*) in France shall be evaluated by multiplying the number of (*Y*) sold by the current LPPR tariffs in force, giving a theoretical annual turnover including VAT for each of the companies: $CATTTCy_x$ for company (*X*) and *CATTTCy* the sum of the theoretical annual turnovers including VAT of all companies selling (*Y*) in France.

If $CATTTCy > CATTTCy_{Ref1}$, the company shall be liable to pay a clawback payment, calculated according to the formulae in the table below:

CATTTC threshold (turnover after tax)	**Clawback payment owing**
If $CATTTCy \leq CATTTCy_{Ref2}$ where $0 < a < 1$	$R_x = a \times (CATTTCy - CATTTCy_{Ref1}) \times (CATTTCy_x / CATTTCy)$
If $CATTTCy > CATTTCy_{Ref2}$	$R_x = [a \times CATTTCy_{Ref1} + b \times (CATTTCy - CATTTCy_{Ref2})] \times (CATTTCy_x / CATTTCy)$ where $0 < a < b \leq 1$

Furthermore, if $CATTTCy > CATTTCy_{Ref2}$, the prices /tariffs (P_V) stated in the decree, as mentioned in Article 1 shall be changed (P_M) on the basis of the formula: $P_M = [(CATTTC_y - R_x) / CATTTC_y] \times P_V$.

3.3 However if $P_M / P_V > x$ %, the price shall not be reduced but the company shall still be liable for the clawback payment (R_x).

3.4 In the event that a price reduction is implemented pursuant to 3.2 hereabove, the conditions of the agreement shall be revised.

3.5 The company shall be notified of the sum of the rebate owing by CEPS, who will inform the relevant local URSSAF of the payment owing (Paris-RP URSSAF for the Ile de France regions and Lyon URSSAF for all other regions). The company shall pay the sum owing upon receipt of the contribution request from the relevant URSSAF office. The company shall inform CEPS by post of the date and actual sum of the payment.

APPENDIX 6: Committee Members

1. Members of CEPS

Noël RENAUDIN, Chairman

1.1. Medicines section

Bernard TEISSEIRE, Vice-chairman

Representatives of the Director for Social Security – Ministry of Work, Employment and Health:
Katia JULIENNE, Deputy Head, Healthcare Finance Department
Marine JEANTET, followed by Guillaume COUILLARD, Assistant Deputy Head, Healthcare Finance Department
Hedi BEN BRAHIM, followed by Pierre PRIBILE, Head, Healthcare Products Office
Isabelle CHEINEY, Deputy Head, Healthcare Products Office
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Representatives of the Director General for Health – Ministry of Work, Employment and Health:
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Danièle GOLINELLI, Deputy Head, Healthcare Products Policy Department
Nadine DAVID, Head, Medicines office
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Representatives of the Director for Care Provision – Ministry of Work, Employment and Health:
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Paule KUJAS, Hospital Pharmacist, Deputy Head – Healthcare products cluster, Department for healthcare establishment quality and operations
Anne L'HOSTIS, Chief Public Health Medical Examiner, Policy Officer

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Jean-Yves SAUSSOL, Head, Health office followed by Catherine RIOUX, Deputy Head, Health Office
Nolwenn DELARUELLE-LAPRIE followed by Delphine PIERSON, Health office

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François LHOSTE, Financial services officer, Department of Industry and Life sciences, Chemistry and Materials Technology
Catherine TRENQUE, Deputy Head, followed by Aristide SUN, Policy Head, Medicines Industry, Department of Industry and Life sciences, Chemistry and Materials Technology

Representatives of national health insurance bodies appointed by the Director General of CNAMTS (national health insurance fund for salaried workers)
Jean-Pierre ROBELET, followed by Philippe ULMANN, Director, Care Provision
Jocelyn COURTOIS, Head, Healthcare products departments
Thierry DEMERENS, Medical Examiner, Deputy Head, Healthcare products departments
Martine PIGEON, sous-directeur

Representatives of national health insurance jointly appointed by the Director of the Caisse nationale du régime social des indépendants (national health insurance fund for self-employed workers) and the Director of the Caisse nationale de la mutualité sociale agricole (national health insurance fund for agricultural workers):
Brigitte HEULS, Director, Deputy National Medical Examining Department, Caisse nationale du RSI (self-employed workers' fund)
Hélène BOURDEL, Senior consulting pharmacist, Caisse nationale du RSI

Representatives of the Union des organismes d'assurance complémentaire (union of top-up health insurance companies):
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Sébastien TRINQUARD, Health Economist

Representative of the Minister for Research:
Isabelle DIAZ, Health department – Directorate General for Research and Innovation

1.2. Medical devices section

André TANTI, Vice-chairman

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Hedi BEN BRAHIM, followed by Pierre PRIBILE, Head, Healthcare Products Office
Chrystelle GASTALDI-MENAGER, Healthcare Products office
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Representatives of the Director for Care Provision – Ministry of Work, Employment and Health:
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Jocelyn COURTOIS, Head, Healthcare products departments
Annie ARPIN-BARBIEUX, Medical Examiner, Head of Department
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Representatives of national health insurance jointly appointed by the Director of the Caisse nationale du régime social des indépendants (national health insurance fund for self-employed workers) and the Director of the Caisse nationale de la mutualité sociale agricole (national health insurance fund for agricultural workers):
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Representatives of top-up health insurance bodies:
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Sébastien TRINQUARD, Health Economist

Representative of the Minister for Research:
Régis BEUSCART, Health Department – Directorate General for Research and Innovation

Representative of the Caisse nationale de solidarité pour l'autonomie (independent living fund):
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Madame BRUN, Health Economist, Disability Support Department

Representative of the Directorate General for Social Action:
Chantal ERAULT, Head, Independent Living office, Disability Department

2. Committee rapporteurs

Monsieur Alex ALINE,
Madame Diane KARSENTY,
Monsieur Philippe LALANDE,
Madame Régine LEMEE-PECQUEUR,
Madame Catherine PHILIPPE,
Madame Marie-Odile PROY,
Monsieur Michel ROUSSEAU,
Monsieur Bruno STALLA,
Monsieur Franck SUDON

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4. Declarations of interest

	Nature of interest			
Name (section)	*Type of contract*	*Paid work done (participation in clinical trials, studies, consultations, research, etc.)*	*Financial stake in any company capital*	*Other declared interests*
Committee members and participants in committee meetings				
Comité économique des produits de santé				
Noël RENAUDIN	none	none	none	none
Bernard TEISSEIRE (M)	none	none	none	none
André TANTI (DM)	none	none	none	none
Sylvette LAPLANCHE	none	none	none	none
Claire OGET-GENDRE (DM)	none	none	none	none
Christophe TREMOUREUX (DM)	none	none	none	none
Carine FERRETTI	none	none	none	none
Marc DURAND (M)	none	none	none	none
Yvan LE MANACH (M)	none	none	none	none
Hilaire PANDOR (M)	none	none	none	none
Direction de la sécurité sociale – Directorate for Social Security				
Katia JULIENNE	none	none	none	none
Marine JEANTET	none	none	none	none
Guillaume COUILLARD	none	none	none	none
Hedi BEN BRAHIM	none	none	none	none
Pierre PRIBILE	none	none	none	none
Isabelle CHEINEY (M)	none	none	none	none
Chrystelle GASTALDI-MENAGER (DM)	none	none	none	none
Mourad SAM (M)	none	none	none	none
Olivier VERNEY (DM)	none	none	none	none
Direction générale de la santé – Directorate General for Health				
Catherine LEFRANC	none	none	none	none
Catherine CHOMA	none	none	none	none
Danièle GOLINELLI	none	none	none	none
Nadine DAVID (M)	none	none	none	none
Stéphan LUDOT (DM)	none	none	none	none
Alexandre BARNA (M) puis (DM)	none	none	none	none
Arlette MEYER (M)	none	none	none	none
Anne DE SAUNIERE (M)	none	none	none	none
Joëlle SCHACHMANN (DM)	none	none	none	none
Séverine BERGON (DM)	none	none	none	none
Directorate General for care provision				
Yannick LE GUEN	none	none	none	none
Paule KUJAS (M)	none	none	none	none
Anne L'HOSTIS (DM)	none	none	none	none

	Nature of interest			
Name (section)	*Employed*	*Paid work done (participation in clinical trials, studies, consultations, research, etc.)*	*Financial stake in any company capital*	*Other declared interests*
Direction générale de la concurrence, de la consommation et de la répression des fraudes - Directorate General for Competition, Consumer affairs and Combating fraud				
Marie-Thérèse MARCHAND	none	none	none	none
Jean-Yves SAUSSOL	none	none	none	none
Catherine RIOUX	none	none	none	none
Nolwenn DELARUELLE-LAPRIE (M)	none	none	none	none
Delphine PIERSON	none	none	none	none
Dominique MONAVON (M)	none	none	none	none
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Marie-Caroline FURON (DM)	none	none	none	none
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Philippe PARMENTIER (DM)	none	none	none	none
Catherine TRENQUE (M)	none	none	none	none
Aristide SUN (M)	none	none	none	none
Assurance maladie obligatoire – compulsory health insurance agency				
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Jocelyn COURTOIS	none	none	none	none
Thierry DEMERENS	none	none	none	Sister and brother-in-law working in pharmaceutical industry
Martine PIGEON (M)	none	none	none	Daughter-in-law working in pharmaceutical industry
Christine VAULONT (DM)	none	none	none	On the board of directors of a Patients' Association
Annie ARPIN-BARBIEUX (DM)	none	none	none	none
Brigitte HEULS	none	none	none	none
Hélène BOURDEL	none	none	none	none
Caroline BOULANGER (DM)	none	none	none	none
Ministry for Research - Directorate General for Research & Innovation				
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Régis BEUSCART (DM)	none	none	none	none
Union of top-up health insurance bodies				
Martine STERN	none	none	none	none
Sébastien TRINQUARD	none	none	none	none
Directorate General for Social Action				
Chantal ERAULT	none	none	none	none
Caisse nationale de solidarité pour l'autonomie – national independent living fund				
Annie RICHART-LEBRUN	none	none	none	none

	Nature of interest			
Name (section)	*Employed*	*Paid work done (participation in clinical trials, studies, consultations, research, etc.)*	*Financial stake in any company capital*	*Other declared interests*
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Philippe LALANDE	none	none	none	none
Régine LEMEE-PECQUEUR	none	none	none	none
Claire OGET-GENDRE	none	none	none	none
Catherine PHILIPPE	none	none	none	none
Marie-Odile PROY	none	none	none	none
Michel ROUSSEAU	none	none	none	none
Bruno STALLA	none	none	none	none
Franck SUDON	none	none	none	none

APPENDIX 7: Glossary of acronyms and abbreviations

AFSSAPS: Agence française de sécurité sanitaire des produits de santé – France's regulatory agency for healthcare products
AMM: Autorisation de mise sur le marché – marketing authorisation
AMO: Assurance maladie obligatoire – compulsory health insurance
ASA: Amélioration du service attendu – improvement in expected service
ASMR: Amélioration du service médical rendu – 'added medical benefit': price rate bands for medicines, based on the added medical benefit compared to existing treatments for the same condition
ASR: Amélioration du service rendu – 'improvement in service': price rate bands for medical devices, based on their added benefit compared to the existing products on offer
ATIH: Agence technique de l'information sur l'hospitalisation - Technical hospital information agency
ATU: Autorisation temporaire d'utilisation – temporary licence granted to unlicensed medicines in specific circumstances

CEESP: Commission évaluation économique et de santé publique – economic evaluation and public health committee
CEPP: Commission d'évaluation des produits et prestations – medical device and service assessment committee
CEPS: Comité économique des produits de santé – healthcare products pricing committee
CNAMTS: Caisse nationale d'assurance maladie des travailleurs salariés – national employed workers' health insurance fund
CNEDiMTS: Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé – national medical device and health technologies assessment committee (formerly CEPP: *Decree n°2009-1088 of 02 September 2009*)
CSIS: Conseil stratégique des industries de santé – Strategic council of the health industry
CSP: Code de la Santé publique – Public Health code
CSS: Code de la Sécurité sociale – Social Security Code

DGCCRF: Direction générale de la concurrence, de la consommation et de la répression des fraudes - Directorate General for Competition, Consumer affairs and Combating fraud
DGCIS: Directorate General for competitiveness in industry and services
DGOS: Directorate General for care provision
DGS: Direction générale de la santé – Directorate General for Health
DSS: Direction de la sécurité sociale – Directorate for Social Security

EHPAD: établissements hébergeant des personnes âgées dépendantes – care homes for dependent elderly people

GAO: grand appareillage orthopédique - large orthotic and prosthetic devices
GERS: an economic interest group of pharmaceutical companies, which produces market statistics
GHS: Groupe homogène de séjours – 'standard hospital stay group' (similar to diagnosis-related group)

HAS: Haute Autorité de Santé – the 'High Health Authority'

LEEM: Les entreprises du médicament – the pharmaceutical companies' representative body
LFSS: Loi de financement de la Sécurité sociale – annual social security funding act
LPPR: Liste des produits et des prestations remboursables – reimbursable medical device and services list

MIGAC: Mission d'intérêt général et d'aide à la contractualisation – funding for work 'in the general interest' and for implementing contracts with regional health agencies

MINEFI: Ministère de l'Economie des Finances et de l'Industrie – Ministry for the Economy, Finance and Industry
MSA: Mutualité sociale agricole – a mutual health insurance fund for agricultural workers

ONDAM: Objectif National Dépenses de l'Assurance Maladie - the target annual national health insurance budget

RSI: Régime Social des Indépendants – self-employed workers' health insurance plan

SMR: Service médical rendu – medical service rendered (used in assessment of medical devices and services)
SNITEM: Syndicat national de l'industrie des technologies médicales – national medical technologies industry trade association

TAA-T2A: Tarification à l'activité – 'activity-based pricing': state funding based on the services provided by the establishment, as opposed to a blanket grant.
TFR: Tarif forfaitaire de responsabilité – 'fixed accountability tariff'

UCD: Unité commune de dispensation – common dispensing unit
UFAT: Union des fabricants d'aides techniques – medical aid manufacturers' union
UFOP: Union française des orthoprothésistes – French orthotic and prosthetic device manufacturers' association
UNCAM: Union nationale des caisses d'assurance maladie – national association of health insurance funds (CNAMTS, MSA and RSI)
UNOCAM: Union nationale des organismes complémentaires d'assurance maladie – national association of top-up health insurance organisations (FFSA, FNMF and CTIP)
URSSAF: Union de recouvrement des cotisations de Sécurité sociale et d'allocations familiales – social security contributions collecting body

VPH: véhicules pour personnes handicapées – disability-adapted vehicles (and other mobility equipment)