

Drug price setting and regulation in France

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Summary

In France, drug prices have historically been regulated but approaches to setting and regulating prices have been evolving in recent years. In 2003, the prices of new outpatient drugs, which had hitherto been entirely regulated, were semi-liberalised, with drug companies setting prices in line with those in neighbouring countries; and in parallel with this in 2004, the prices of expensive drugs and/or drugs qualifying for reassignment must now also be set in line with European prices. In addition to this, price/volume regulation has recently been introduced. This document describes the price setting rules applicable to each drug category and discusses different measures for regulating drug price, particularly the conventional policies implemented under successive framework agreements. The regulatory path for medicines and the different actors involved are presented in an Appendix.

Keywords : Drugs, Regulation; Public Health

JEL classification: I18, L65

In 2005 drug expenditure in France amounted to 31 billion Euros, representing 20.4% of total health expenditure¹ and 2.11% of GDP. With a per capita expenditure of €500 of the €2 452 spent on health, France spends more on drugs than any other European country (Eco-Santé France 2006).

Drug expenditure is increasing rapidly in France: it has doubled since 1990 and the drug expenditure as a proportion of total health expenditure is also growing, increasing from 18.5% in 1995 to 20.4% in 2005 (Eco-Sante France 2006), underlining the increasing growth rate of the pharmaceutical sector. However there has historically been administrative control of drug prices in France and hence the overall level of prices in France is relatively low: the price level index² for French pharmaceutical products compared to the average price in 25 European countries is 91, compared to 128 in Germany, 118 in Italy, 93 in the UK and 77 in Spain (Eurostat 2007).

But the French drug sector has several national characteristics: demand is relatively insensitive to price because consumers pay for little or none of their consumption; in fact Sickness Insurance reimburses 76%³ of expenditure on reimbursable drugs (medic'AM 2006) and supplementary insurance, which covers 9 out of 10 people, in general meets the cost of any excess which is payable. The French, both patients and doctors, seem to prefer innovative and expensive drugs, even when less expensive ones are as effective. Furthermore, 90% of medical consultations result in a prescription, this percentage being higher than in other European country (CNAMTS, Ipsos Sante 2005). Clearly the French consume high volumes of drugs, and this, rather than high drug prices, explains the high level of pharmaceutical expenditure in France.

Given that administrative price setting had failed to control expenditure and demand regulation had not worked because of its insensitivity to expenditure, in the Nineties attempts to regulate supply took the form of different contributions requested from the pharmaceutical industry. Thus the State, through the Economic Committee for Drugs, and the industry, through its union, signed the first framework agreement in 1994. This set out their common objectives for the evolution of the market and defined the rules of financial regulation for the period 1994-1998. Three other agreements have been signed since then: 1999-2002, 2003-2006, extended in 2007 for the period 2007-2009.

Viewed from two opposing perspectives, drugs are an unusual consumption good: their growing importance within total health expenditure suggests the need to control this whereas the treatment benefits of new formulations represent public health capital. Furthermore because pharmaceuticals are an industrial good, they must be profitable; in particular the prices of drugs need to cover research costs.

¹ Total health expenditure (THE) is one of the aggregates of national health accounts which analyses total expenditure on medical goods and services each year in France. THE in 2005 was 153 billion euros.

² This is for the total price of production, whoever is financing this.

³ This percentage is calculated by dividing the sum of the reimbursed amounts by the sum of the basis for reimbursement; it therefore includes 100% reimbursements to persons exempt from copayment.

Since 2003, the historical control of prices has left little room for the control of volume: the prices of innovatory specialties have been liberalised but subject to clauses concerning the volume of sales with the objective of encouraging innovation. The possibility of higher prices for innovative specialties makes France an attractive location for the early commercialisation of innovative therapies.

Medicines are today one of the essential elements of the Sickness Insurance reform begun in 2004 and the Government chose to reinforce its actions in a “drug plan” implemented between 2005 and 2007. This involves several types of action; increasing the consumption of generic medicines is a major lever of pharmaceutical policy because it enables costs to be reduced without affecting drug prescribing structure. This approach is of greatest benefit to the Sickness Insurance Funds. Medical control of expenditure aims to optimise prescribing while maintaining efficacy and patient safety; various agreements between doctors, pharmacists and Sickness Insurance have addressed this, as well as various public information campaigns (Grandfils and Sermet 2006). Finally, we have grouped together more measurable actions under the label “conventional policy”; this encompasses drug price setting at the point of registration, and the range of government-industry agreements which exist, in particular those concerning sales volumes. In this article we discuss this range of measures.

The paper is divided into three sections: in the first we discuss approaches to drug price setting, in the second conventional regulation mechanisms are described and the final section discusses other French price regulation measures. The regulatory path for medicines and the different actors involved are presented in an Appendix.

1. Approaches to drug price setting in France

In France, we have a mixture of unregulated prices for certain specialties and controlled price for others. Prices and distribution margins for non-reimbursable specialties have historically been completely unregulated. The prices of reimbursable ambulatory drugs were controlled until 2003 and were determined by negotiation between the pharmaceutical company and the Economic Committee for Health Products (CEPS). Since 2003, the price of innovative specialties has been semi-controlled – it is proposed by the company and co-opted by CEPS. Finally, the price of hospital drugs was completely uncontrolled until 2003 and was determined by negotiation between pharmaceutical companies and hospitals. With the introduction of activity-based costing in hospitals, rules have been established for reassigned drugs and for expensive drugs.

The European Directive 89/102/CEE of 21 December 1988, known as the transparency directive, imposed a regulatory framework for price setting in European countries; these measures for the most part apply to the regulators who must set out the criteria used to determine the price of drugs, adhere to deadlines and justify any decision they make in terms of price regulation. AMM holders must provide adequate information for the regulator to make a decision.

A regulation at the beginning of the lifecycle of a product applies to the manufacturer's price before tax (PFHT). The margins of wholesalers and pharmacists need to be added to arrive at the public price. These margins consist of a small fixed price and most importantly a variable margin which depends only on the price of the drug. These margins are based on a sliding scale, which means that the margin coefficients, fixed by the regulator, reduce as the brands price increase⁴. Nevertheless the more expensive the drug, the higher is the pharmacist's margin .

1.1 Completely unregulated prices for non-reimbursable drugs

There is no price regulation of non-reimbursable drugs other than that of supply and demand. These include drugs for which the manufacturer has not requested reimbursement from Sickness Insurance (the most common case) or drugs which have not been included in the list of products reimbursable in hospitals or ambulatory care. These may be one of three types of drug:

- Products not on the list, which may be obtained without prescription, and which even if they are prescribed will not be reimbursed ("Over the Counter" or OTC); hence their public price is completely unregulated.
- Products on the list for which a prescription is compulsory but which are not reimbursed; this is the case for drugs like Viagra®. The price is therefore completely unregulated.
- OTC versions of reimbursable products on the list for which the price is not regulated. This is the case for example for Virlix® (cetirizine), on the list and reimbursed at 35%, while Zyrtecset®, which contains the same molecule, is an OTC product; this is also the case for Imodium® (loperamide), on the list and reimbursed at 35%, while Imossel® (loperamide too) is an OTC product.

For these latter cases there is a real barrier to self-medication because patients will meet the entire cost themselves of a product which would be reimbursed if it has been prescribed and for which they would be charged far more by the pharmacist.

⁴ Since 2004, the wholesale margin is 10.3% of the manufacturer's price before tax (PFHT) up to €22.90, 6% between €22.90 and €150 and 2% above that; the retail margin is 26.1% of the PFHT up to €22.90, 10% between €22.90 and €150, and 6% above that , to which is added a forfeit of €0.53 per box.

1.2 Regulation of prices is steadily reducing for ambulatory reimbursable drugs

The approaches to price setting for reimbursable medicines are described in successive framework agreements in the Social Security code; article L. 162-16-4 of the Social Security code describes the rules for price setting for drugs reimbursed by Social Security: the sale price is fixed by agreement between the committee and the pharmaceutical company. Essentially the price is set taking into account improvement in medical benefit (ASMR; cf. Appendix) of the drug, the price of other drugs with the same indication, actual or forecast drug sales, and anticipated or actual conditions for use of the drug. It should be noted that at present the relative contribution of these different factors to the price is unknown; but an IRDES study to be published in 2008 will quantify their relative importance in the level of price obtained. Those drugs which neither improve medical benefit nor produce savings in the cost of medical treatment are not eligible for reimbursement by Social Security.

Since the general practice framework agreement of 2003-2006, **innovative outpatient drugs** are considered in an accelerated process; this applies to drugs which have obtained a level I⁵ or II ASMR for their principal indications, or a level III ASMR for orphan drugs only, for paediatric drugs and for those for which the sales volume forecast by the manufacturer for the third year following commercialisation does not exceed €40 million. The endorsement of the 2003 general practice framework agreement signed on January 29 2007, extends this procedure to all drugs with an ASMR III as well as some with an ASMR IV for which the daily treatment cost is below that of the comparator.

The principle behind this regulation is that of a price proposed by the pharmaceutical company, this price then acting as a ceiling for reimbursement by Sickness Insurance. This procedure is called "price registration". The company proposes a price to CEPS which must be in line with prices in neighbouring countries (Germany, Spain, Italy and the UK). This situation is monitored over time and the proposed price is modified if it differs from that in other European countries. Following this price registration, the company agrees on one hand to financial compensation by refunding any excess costs to the Sickness Insurance if sales exceed those forecast for the first four years following commercialisation, and on the other hand to provide CEPS with any complementary studies which may be requested on drugs which may be used by a large population, on drugs where there is a risk of inappropriate use, and on those which may have a significant impact on the organisation of the health system (article 6 of the framework agreement). If CEPS does not object to the price registration within 15 days, the price is fixed.

Setting the price of drugs and particularly innovative drugs may also involve clauses for price revision (cf. the third section of this paper on conventional regulation), particularly where there is a risk of inappropriate use.

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ASMR significance levels	I	II	III	IV	V
	major	important	modest	minor	inadequate

Drugs of low innovative value are those with an ASMR other than V and which are not eligible for the accelerated procedure. Until 2006 these consisted of drugs with ASMRs IV and these with an ASMR III for which the sales volume forecast by the company in the third year of commercialisation exceed €40 million. Since 2007, this category includes only drugs with an ASMR IV for which the daily treatment cost is greater than or equal to the comparator. It can also include drugs which can demonstrate improved efficacy (this is the case for Seroplex® which obtained an ASMR IV by demonstrating greater efficacy than Seropram®) or improved ease of use (for example slow-release Ritaline® obtained an ASMR IV vis a vis immediate-release Ritaline®).

For these products, the law states that the main factors to take into account are the ASMR and the price of comparator medicines. In general, the price is a little above that of comparator drugs, but the difference depends on the size and characteristics of the beneficiary population.

The maximum delay for setting a price during the registration of a new drug is 180 days. In 2005 the average was 164 days (CEPS 2005).

Non innovative drugs are those with an ASMR of V. This includes all generic medicines, additions to a range and me-too⁶ drugs when they are produced a long time after the first drug of the class. (When a me-too is commercialised very soon after the first drug in the class, it can obtain a share of the ASMR from the transparency commission where it considers that the research for the me-too took place in parallel with the first commercialised product.)

The law stipulates that drugs with no improved therapeutic value, nor savings in the cost of medical treatment, cannot be reimbursed by Social Security. These products must be commercialised at a price which will enable expenditure savings vis a vis comparable drugs on the market.

Generic medicines, copies of originator drugs, must be priced at least 40% below the brand-name drug⁷. For other drugs with an ASMR of V, there are two possibilities: either it is considered that the new product will only take part of the market of other products already in the market (in this case a small price difference would suffice to generate a saving), or it is estimated that the new product may increase consumption (in which case a reduced price will be imposed on the new entrant).

1.3 Increasingly regulated prices for hospital drugs

Between 1987 and 2003, there was no regulation of hospital drug prices; prices were unregulated and subject only to the laws of public markets. Hospitals issued invitations to tender which were concluded within the law of supply and demand with pharmaceutical companies. Hence there were big differences in purchasing price between hospitals related to volume and the classes of drugs which were needed. Public and private hospitals had to finance these purchases from their global budget or from

⁶ A me-too drug is one with the same therapeutic activity without being strictly identical.

⁷ This 40% rate has been in place since February 1 2006 ; prior to this the price of generics had to be less than 30% of the brand-name drug.

daily tariffs. In parallel with this, the practice of reassigning medicine sales was not governed by any legal framework and Social Security expenditure on this activity increased greatly.

The implementation of activity-based costing in hospitals (T2A) has strengthened the link between actual activity rates in hospitals and the payment they receive for this activity. In this framework, the Social Security financing law of 2004 describes the regulation of hospital drugs in broad terms; the hospital framework agreement of March 2004, concluded between the French Pharmaceutical Companies Association (LEEM) and the Economic Committee for Health Products (CEPS) specifies the conditions of this regulation for **reassigned medicine sales** (see Box 1) as well as for **expensive hospital drugs not included in activity-based costing** (see Box 2). Drugs dispensed in hospital which are not in either of these two categories have a completely unregulated price. We also note that the price levels resulting from negotiations between hospitals and pharmaceutical companies are only known to the hospitals themselves or through ad hoc hospital surveys such as the survey of University Hospitals (CHU) and Cancer Research Centres (CLCC) carried out by the Directorate for Research, Studies, Evaluation and Statistics of the Ministry of Health (DREES) (CLERC M.E., HAURY B.,2007).

The principle behind this regulation is the same as for innovative ambulatory drugs: the price is proposed by the company, this price then serving as a ceiling for reimbursement by Social Security (price registration procedure). This registered price may be opposed by CEPS during the following 15 days. In cases of non declaration or of opposition by CEPS (the main grounds for refusal by CEPS are where prices are too high vis a vis the comparator drugs or prices elsewhere in Europe), the price is fixed by Ministerial decree. These specialties are then reimbursed on the basis of this fixed price, known as the “cession price” or the “responsibility price” (article R.5126-110 of the public health code).

<<see Box 1>>

<<See Box 2>>

Reassigned medicines and **expensive drugs** cannot be charged to sickness insurance above the cession price. If a health establishment buys a drug on the reassigned list or on the non T2A list at a higher price than the cession price, the difference in cost is covered by the health establishment. In this case there is no value for the establishment in practicing reassignment. On the contrary, if a health establishment buys one of the pharmaceutical specialties at a lower price than the declared price, it can charge for it on the basis of the declared sale price. In the case of reassigned medicines, the cost differential is absorbed by the establishment. For expensive drugs, the bonus is shared between Sickness Insurance and the establishment: the establishment is reimbursed by Sickness Insurance on the basis of the amount billed by the hospital with a mark up of part of the difference (profit-sharing margin fixed at 50% by the decree of May 9 2005).

In the framework of T2A, the reimbursement within health establishments of certain expensive drugs and medical devices within the DRG tariffs is subject to an “Good use of care agreement” (AcBus) between the health establishments and the Regional Hospital Agency (ARH) for a period of 3 to 5

years (Decree n° 2005-1023 of August 24 2005 concerning the appropriate use of expensive molecules). This establishes the implementation timetable and the quantitative and qualitative monitoring and outcome indicators (annual and final evaluations). Where there is no agreed good use of care agreement or where the contract is not adhered to, the reimbursement rate for expensive molecules may in theory be reduced to 70%.

<< See Box 3>>

Drugs with a cohort or nominative ATU not classified for hospital use only⁸ and destined for outpatients are included in the reassigned list (articles R. 5126-103 et R. 5126-104 of the public health code). They are subject to price registration as reassigned medicines. These reassigned ATU drugs are reimbursed at 100% by Sickness Insurance on the basis of their declared price.

When drugs are administered to a hospitalised patient, the cost of any cohort or nominative ATU drugs is met by the health establishment treating the patient. This expenditure is covered by the establishment's financial allowance for missions of general interest and by assistance for contracting (MIGAC). Otherwise the MIGAC allowance can be increased to cover exceptional or unanticipated expenditure related to the purchase of ATU drugs.

Summary of approaches to drug price setting

Which procedure?	For which drugs?	What are the main criteria?
Price registration by the pharmaceutical company	Innovative reimbursable outpatient drugs	Coherence with European prices
	Non T2A expensive hospital drugs	
	ATU drugs	
	Reassigned drugs	
Price set by CEPS	Reimbursable outpatient drugs with little or no innovative value	Estimated patient volume Price of comparator drugs
Unregulated price	Non reimbursable outpatient drugs	
	Hospital drugs included in T2A	

2 Conventional end of year regulation

The framework agreements state that all pharmaceutical companies selling drugs to be reimbursed by compulsory sickness insurance must make an agreement with CEPS. These agreements define, with respect to the rules established by the social security code and in agreement with any changes communicated by ministers to CEPS, the annual repayments which the pharmaceutical companies must make to the Central Agency for Social Security Organisations (ACOSS)⁹, where development objectives have not been met. These objectives are defined for each company and are based on the trigger rates fixed by Parliament in the Sickness Insurance financing law, known as K rates. K rates correspond to the rates of progression of the national objective for Sickness Insurance expenditure (ONDAM) rounded to the nearest decimal; this was 4% in 2003, 3% in 2004 and 1% for 2005, 2006

⁸ The hospital reserve consists of products to be used exclusively in hospitals.

⁹ ACOSS is the national fund of the Recovery branch of the General Social Security Regime

and 2007. This K rate which is very often exceeded, is not a means of increasing expenditure, but a threshold above which Parliament estimates that repayments are due. These repayments commonly known as rebates are calculated at three levels: rebates at the level of products, rebates at the level of therapeutic classes and rebates at the level of sales volumes.

Companies which decide not to enter into agreements with CEPS are subject to a much less transparent regulatory mechanism known as a “safeguard clause”.

2.1 The principle of the safeguard clause

Companies which do not sign agreements with CEPS are subject to this accounting mechanism, implemented by the social security financing law. This safeguard clause consists of a contribution to be paid by the companies when the pre-tax volume of French sales of reimbursable specialties or specialties with a license for group use, reaches a percentage exceeding the K rate described above. In 2005, only 6 out of 180 companies active in the French market did not make an agreement with CEPS; these were companies whose output was in decline and were not subject to any rebate at the end of the year.

2.2 Rebates at the level of products: price revision clauses

Setting the price of ambulatory drugs and more specifically that of drugs with an ASMR other than zero often involves conventional clauses which define prices and/or sales volumes for a company's products.

Volume clauses are used where the ASMR for a drug has only changed for one of its indications; here sales volumes are monitored in order to ensure that the drug is only being used for the indications for which it has received its ASMR. If these volume clauses are not respected prices will be lowered or a rebate is due from the companies.

Cost clauses for daily dosages: these clauses are used where there is a range of dosages in the product range; the aim is to ensure the use of the most appropriate dose by controlling the average daily cost of the range of products. If the distribution of the consumption of different dosages is different from that forecast, the price is revised in order to re establish the daily treatment cost which was forecast initially.

Dosage clauses: the treatment cost is calculated initially on the base of the average dose; posology clauses result in a price reduction if the average stated dose is exceeded.

These price revision clauses are in general independent of the global evolution of the market with regard to the K rate: unless otherwise stated, these rebates are due whether the K rate is exceeded or not; in contrast, the rebates by class and the sales volume rebates are only due when evolution of the market passes a defined threshold.

2.3 Rebates by class

CEPS divides the drug market into classes (for 2005, 65 classes were defined ; CEPS 2006). For each class CEPS forecasts a “desirable” rate of evolution for the market; it then distributes these

forecasts in order to ensure an overall rate of evolution equal to the annual allocation under the social security financing law and called rate K. The different rates of evolution thus calculated constitute the table of rebate trigger thresholds. For example in 2005, the K rate was fixed at 1% by the social security financing law; the rate of evolution for the class of antidiabetics was 7% while that for protein pump inhibitors was -5% (CEPS 2006).

A company must make a rebate if the real rate of evolution exceeds the rate in the table of rebate trigger thresholds. This rebate is distributed among all companies who market a product in the class as follows: 65% of the rebate is distributed among all companies marketing a product in the class in proportion to their sales; 35% of the rebate total is distributed among those companies who have exceeded the forecast rate of evolution. The framework agreement fixes the level of the rebates: in 2005 this was equal to 40% of the total stated excess.

If the level of rebates by class exceeds that which the company would have paid under the safeguard clause, then it is not subject to a rebate under the sales volume clause. If the class rebates do not reach the total of the safeguard clause, the company is accountable for the rebate on the sales volume.

2.4 Rebates by sales volume

The sales volume rebate is only due where the total of rebates due by class do not exceed the total which would be payable under the safeguard clause. Hence the sales volume rebate is equal to the lowest of the two following values:

- 25% of the total theoretically due under the safeguard clause;
- 50% of the difference theoretically due under the safeguard clause and the class rebate clause.

The total rebates due (the sum of the rebates due under the three types of rebate described above) under agreements reached between the company and the State are capped by the total which the company would pay if it were subject to the safeguard clause. Hence, there is a strong incentive for companies to sign agreements with CEPS (in 2005, 174 out of 180 companies with sales in France and signed an agreement).

2.5 Exemptions from rebates

In order to encourage innovation, this regulatory system includes a certain number of exemptions. The drugs which are exonerated from rebates are drugs with an ASMR greater than zero at the moment of their registration or which have obtained an extension of an indication with an ASMR¹⁰, orphan drugs, paediatric drugs, generic drugs or those with a reference price¹¹ and for which the price is at most equal to the tariff, drugs for which a significant proportion of sales are not presented for reimbursement¹² as well as drugs transferred from the hospital to general practice¹³.

In total, exemptions from rebates are very important. In summary, following market authorisation, only originator drugs with an ASMR of V are subject to the rebate system.

2.6 Rebate credits

Rebate credits are sums resulting from deduction of rebates owed by the companies. Awarded punctually following specific events, they are designed to partially compensate for any loss of turnover following price reductions or delisting. These credits are also granted if they prepare patient information notes in Braille or if companies invest in Europe to maintain or increase their research activity in the pharmaceutical sector; the latter rebate credit was established at the end of 2005 at the request of the Health Industries Strategic Board (CSIS)¹⁴.

3 Other price regulation measures

3.1 The establishment of reference pricing

In parallel with the pricing framework and in the context of increasing consumption of generic medicines, the Social Security financing law of 2003 introduced reference prices in France called TFR. This mechanism which consists of reimbursing the originator drugs on the basis of the price of generics has in practice become an instrument of price regulation; in fact 70% of originator drugs subject to reference pricing have aligned their prices with the generics in order to keep some of the market.

¹⁰ Exoneration from rebates only applies to that part of the sales attributable to this indication ; for drugs with ASMR I and II there is complete exemption for 36 months and 24 months respectively from the date of market authorisation. For those with ASMR III, there is 50% exemption for 24 months following market authorisation and for ASMR IV, 25% exoneration for 24 months following market authorisation.

¹¹ Reference prices for reimbursement were established in 2003 and involve reimbursing originator drugs on the basis of the generic price.

¹² Rebates are reduced pro rata to the sales not presented for reimbursement, measured on the basis of data from MEDIC' Sickness Insurance.

¹³ These are drugs which hitherto were only available from hospital pharmacies and which since the decree on reassigned medicines are no longer reassigned: during the 12 months following their transfer from the hospital to general practice, these drugs are only subject to aggregate rebates for the part of the sales exceeding the transfer.

¹⁴ The CSIS was established in 2004 ; its mission is to improve the appeal of France for research and production activity, to monitor the competitiveness of the French industry, to encourage innovation and to facilitate investment in research.

Apart from TFR, following the arrival of generic drugs, pharmaceutical companies used every means at their disposal in the attempt to conserve market share for their originator drugs. Amongst the strategies used, reducing the price of originator drugs was used before and after the arrival of generics. Reducing prices before their arrival was perhaps an attempt to discourage the production of generics: if the price differential between originators and generics is small, generics manufacturers might consider the cost of market entry to be too high. Reducing the price after the arrival of the generic is designed to limit market loss.

3.2 Price reductions imposed by CEPS

Apart from the usual types of price reduction, CEPS reserves the right to reduce the price of products in the following circumstances :

...when renewing a product registration: when looking at the market position of the product since its registration or its last renewal, CEPS may decide to lower the price of the product.

...at the point when a generic becomes available: the orientation letter of October 2006 sent by ministers to CEPS requests a reduction in price for the group of molecules in a class when one of these molecules loses its patent protection, including a price reduction for the other originators in the class still under patent.

...in existing generic groups: since 2006, price reduction measures were imposed on existing groups of generics; in generics older than 24 months, a price reduction of 25% was imposed on both the generics and the originators.

3.3 Price reduction sanctions....

...where demands for bulk packaging are not met by the end of 2005

The 2004 Sickness Insurance Reform proposes better packaging for prescriptions for chronic illnesses. The companies in question must deposit requests for market authorisation for packaging for 3 months treatment courses for 4 classes of drugs: antihypertensives, anticholesterols, oral antidiabetics and treatments for osteoporosis. CEPS set some conditions to encourage companies to file applications quickly for market authorisation for this new packaging: maintenance of the manufacturer's unit price for applications filed before 31/12/2005 (any savings made therefore result from a reduction in the pharmacists' margin), but a reduction of 5% for applications filed between January 1 and June 30 2006 and after that, a reduction in the price of products already authorised in order to compensate for savings not made on distribution margins.

...where the medical visit charter is not adhered to

At the end of 2004, a medical visit charter was signed between CEPS and LEEM; this text addresses qualitative aspects of medical visits: quality of information, professional ethics, the presentation of transparency advice, but also includes, since July 2005, some quantitative aspects, such as the an-

nual rate of change in the number of medical visits (amendment no 1 of the medical visit charter). If these rates of change are not adhered to for a given class of drugs, CEPS may impose a temporary or definitive price reduction on the specialties of the relevant class.

In conclusion, the level of improvement in medical benefit determined by the transparency commission is a central element of the approach to price setting for reimbursable outpatient drugs in France; in fact it determines on one hand the type of procedure which will apply to a drug in order to obtain a price, and on the other, and related to this, the time it will take to obtain a price. Hence it is the relative therapeutic value of a drug which is used to determine its price in France and not an economic evaluation and/or its absolute therapeutic value as in other countries (Sermet 2007).

The procedure for price registration established in 2003 for innovative outpatient drugs has liberalised the pricing of these products for which now the only requirement is coherence with prices in the UK, Spain, Italy and the UK. We note that in Germany and the UK prices are not regulated¹⁵ and that in Spain and Italy prices are fixed essentially in line with prices in other European countries, particularly France. In 2007 the expansion of this process speeded up the price registration for drugs with ASMR III and for some ASMR IV drugs restricted the regulator's intervention to cases of non-innovative drugs and some drugs with a very small increase in medical benefit. In contrast, establishing a price registration procedure for reassigned medicines and for hospital drugs excluded from activity based costing has capped the price of these hospital specialties. Nevertheless we note that in 2006, according to the report of CEPS, only 4 price registration processes, corresponding to 11 products, were dealt with while 705¹⁶ registration dossiers relating to 1448 products, were dealt with by CEPS.

The year 2006 saw a reduction in the growth rate of pharmaceutical expenditure by Social Security compared to 2005 (+1.4% in sums reimbursed by the general regime in 2006 compared to 4.7% in 2005¹⁷); it also saw a reduction in total drug sales in general practice compared to 2005. Although there were no severe epidemics in 2006, this slowdown is also the result of tough regulation measures such as the reduction of prices of molecules under patent but also measures which affect the patient more directly such as the delisting of March 2006 or measures involving medical management of expenditure such as increases in generic substitution. In fact, price reductions of originators and generics, estimated at €160 million in 2005, increased in 2006 to €1064 million (Commission for Social Security Accounts, 2007). The prices of drugs and the number of boxes sold decreased respectively by 4% and 5.7% in 2006 (CEPS 2007) but the structure of sales changed to the advantage of more expensive products, which led to an increase in sales of 0.7% between 2005 and 2006. Because of this, the K rate, set at 1% has not been exceeded; hence companies only had to make product rebates, not aggregate or turnover rebates.

¹⁵ In Germany the prices are not regulated but governed by reimbursement tariffs for drug classes ; in the UK prices are not regulated but are regulated ex-post through taxes on the pharmaceutical industry.

¹⁶ Of the 705 dossiers, 515 related to generic medicines.

¹⁷ According to the Sickness Insurance monthly information bulletin of June 7 2007

Companies paid a total of only €192 million to ACOSS in 2006 (CEPS 2007) corresponding to only 0.95% of Sickness Insurance drug expenditure. This percentage was 2% in 2005, rebates totalling €409 million, for Sickness Insurance expenditure equivalent to that for 2006¹⁸. We may therefore question the impact of this very complex conventional financial regulation because in 2006 the ratio of the value of rebates to the value of expenditure is less favourable for Sickness Insurance although expenditure is slowing down.

Nevertheless the trend observed in 2006 does not seem to be continuing in 2007 ; according to the Sickness Insurance conjuncture bulletin of August 2007, the reimbursements made in the first 7 months of 2007 were 4% higher than the reimbursements made in the first 7 months of 2006. In view of this, an excess of €0.5 per box will be levied in 2008 in order to regulate expenditure from the patient side. Limited to €50 per person for all excesses paid for general practitioner care, the excess for drugs alone should raise about €700 million per year. The last report of the Court of Accounts underlines the need for more vigorous measures than those already in use and anticipates stricter controls on admission to the list of expensive drugs as well as price/volume regulation of these drugs. The draft law of social security financing (PLFSS 2008), which appeared at the end of September 2007, anticipates an exceptional contribution from wholesalers' turnover which should raise €50 million and now a 1% tax on companies' turnover which is expected to generate €100 million.

¹⁸ According to the 6 June 2006 Sickness Insurance information bulletin, the amount reimbursed for drug expenditure by all the social security regimes, including reassigned medicines, was €20.2 billion in 2005.

Appendix : The administrative path of a drug

The administrative procedure for market authorisation and registration for reimbursement for drugs consists of a series of stages involving different actors. In the first instance any drug must receive market authorisation from the French or European authorities; then, if it is to be covered by Sickness Insurance or distributed in hospitals, a dossier must be filed with the transparency commission which will issue scientific advice on the product's place in the treatment strategy and on whether it should be used in general practice or in hospitals. Primary care drugs as well as some hospital drugs must then negotiate a price with the Economic Committee for Health Products. Finally, the National Union of Sickness Insurance Funds (UNCAM) fixes the rate at which outpatient drugs will be covered within conditions and limits set by the State; but it is the Minister of Health who decides whether a drug will be accepted for use in general practice or in hospitals.

1. Market authorisation

In order to be commercialised a drug must obtain market authorisation (AMM). Currently three market authorisation procedures are used in the European Union : two procedures are European, one decentralised, the other decentralised and the third is national. The centralised European procedure is compulsory for a number of products, particularly biomedicines¹⁹; it involves filing a unique dossier valid in all countries and processed by the European Medicines Agency (EMA); hence it is the European Commission which grants market authorisation based on the scientific advice issued by the Committee for Medicinal Products for Human Use (CHMP). The decentralised procedure involves filing a request for market authorisation in one country, and then making this authorisation known in other countries; hence it is also known as a mutual recognition procedure.

The national procedure consists of filing a dossier in each country where the company wishes to market the product; in France it is the French Agency for the Health Safety of Health Products (Afssaps) which awards market authorisation following advice from the Market Authorisation Commission (AMM Commission). This Commission, made up of scientific experts and directors from the different commissions of Afssaps, carries out a scientific and technical analysis of the data submitted by the pharmaceutical company filing the request with the AMM. Whichever procedure is used, the dossier includes the results of pharmaceutical, biological, pharmacological and toxicological studies as well as clinical trials. This evaluation is based on criteria of quality, efficacy and security of use of the drug. Based on the benefit/cost ratio, the conditions of prescription of the drug are defined: the drug will be available under medical prescription only - in which case the drug is registered on the list - or available without prescription as an Over the Counter drug (OTC). Some drugs may have restricted prescribing conditions, for example requiring prescription by hospital doctors or by certain specialists.

¹⁹ Biomedicines are specialties made from living organisms or cellular components such as insulin, growth hormone, interferons etc.)

The AMM also defines the hospital reserve ; in France unlike in other countries, pharmacists have a monopoly on the distribution of drugs, including OTC products; however, for safety reasons, some drugs may only be used in hospital: these are known as hospital reserve drugs.

Market authorisation is reassessed five yearly. It can be modified, suspended or revoked by the Director General of Afssaps on advice from the AMM Commission.

2 Request for cover by Sickness Insurance

If a company does not wish its product to be covered by Sickness Insurance, the product may be marketed as soon as it obtains its AMM. However if it is to be covered, a dossier must be filed with the transparency commission.

The transparency commission is a consultative scientific entity composed of independent experts: general practitioners and medical specialists, pharmacists, methodological and epidemiological experts. Since 2004, this commission has been part of the High health Commission (HAS).

The transparency commission gets involved following the initial request for inclusion of a product in the list of reimbursable drugs; and also for extensions of indications of products already included and for five yearly reviews. The transparency commission reviews data submitted by the manufacturer as well as existing literature.

In particular the transparency commission evaluates the drug's position in the treatment strategy, on the basis of two indicators, the medical benefit (SMR) and improvement in medical benefit (ASMR) compared with existing treatments.

The SMR measures, for each indication of the product, the « absolute » medical benefit of the drug; this evaluation takes into account the severity of the illness, the effectiveness of the product and any side effects, whether the product is curative, preventive or designed for symptom relief, and its importance for public health. The impact on public health (ISP) takes into account the size of the population affected by the product's indications (target population), but also its impact on the organisation of care. There are five levels of SMR (major, important, moderate, weak and inadequate). Together with the severity of the illness, the SMR determines the rate of reimbursement for ambulatory drugs according to the table below (decree n° 99-915 of 27 October 1999 in the JO n° 253 of 30 October 1999 and article R.163-3 of the Social Security Code). It should be noted that an inadequate SMR does not indicate that the product is ineffective but that its coverage by Social Security is not a priority.

Reimbursement rates for ambulatory drugs as a function of the level of medical benefit and the severity of illness

Medical benefit	Serious illness	Non serious illness
Major or important	65 %	35 %
Moderate	35 %	35 %
Weak	35 %	35 %
Inadequate	0 %	0 %

Some ambulatory drugs are recognised as irreplaceable and particularly expensive by the Ministry of Health and the Ministry of Social Security; in which case they are reimbursed at 100%.

The ASMR measures the progress in treatment or added value which the drug represents. This assessment is made for each of the therapeutic indications defined when AMM is granted. Assessing the ASMR is difficult at present, partly because the dossiers filed by the pharmaceutical companies include few scientific results comparing different treatments, and because the indications for the comparator medicines are often not equivalent. There are five levels of ASMR: an ASMR I is for products representing a major therapeutic advance; an ASMR II indicates important progress in terms of effectiveness or reduced side effects; an ASMR III is for a modest improvement; an ASMR IV represents little improvement and an ASMR V represents no treatment benefit.

The transparency commission also advises the Ministry of Health on whether a drug should be approved for use in primary care or hospitals; if a drug is licensed for group use, it is authorised for purchase by and use in hospitals; if it is licensed for primary care use, it may be used in general practice and also in hospitals; however some products, either due to their packaging or their dosage, are only licensed for group use. Drugs classified in the hospital reserve when they obtain AMM may only request a group licence. All of this information is published in the Advice of the Transparency Commission; this advice is transmitted to the Economic Committee for Health Products (CEPS) which then uses it to negotiate the drug price with the pharmaceutical company, and also to the Union of Sickness Funds (UNCAM) in order to set the reimbursement rate. At this point the administrative process ends for most hospital drugs which are not subject to price regulation (non reassigned and inexpensive drugs cf. section 2 and Boxes 1 and 2).

3 Setting the price of drugs

Setting drug prices is one of the tasks of the Economic Committee for Health Products (CEPS) ; CEPS is a decision-making body bringing together representatives from different Ministries: the Ministry of Economy and Finance, the Ministry of Industry, the Ministry of health and representatives of national sickness insurance organisations and the National Union of Supplementary Insurance Organisations. In order to set prices, the committee negotiates with the pharmaceutical industry and reaches agreements with the companies about drug prices and their regulation (conditions of use of the drug, rebates due at the end of the year, agreements with the companies about appropriate use of drugs and sales volumes, what companies will do to implement Ministerial directives). It should be noted that the French pharmaceutical industry is in a strong negotiating position because of its strategic economic position: France is the biggest European pharmaceutical producer with a turnover of €33 billion in 2005; in addition, the pharmaceutical industry employs 100,000 people in France and represents 2.2% of GDP in 2005. It is therefore a key sector in the French economy.

4 Setting the rate of reimbursement

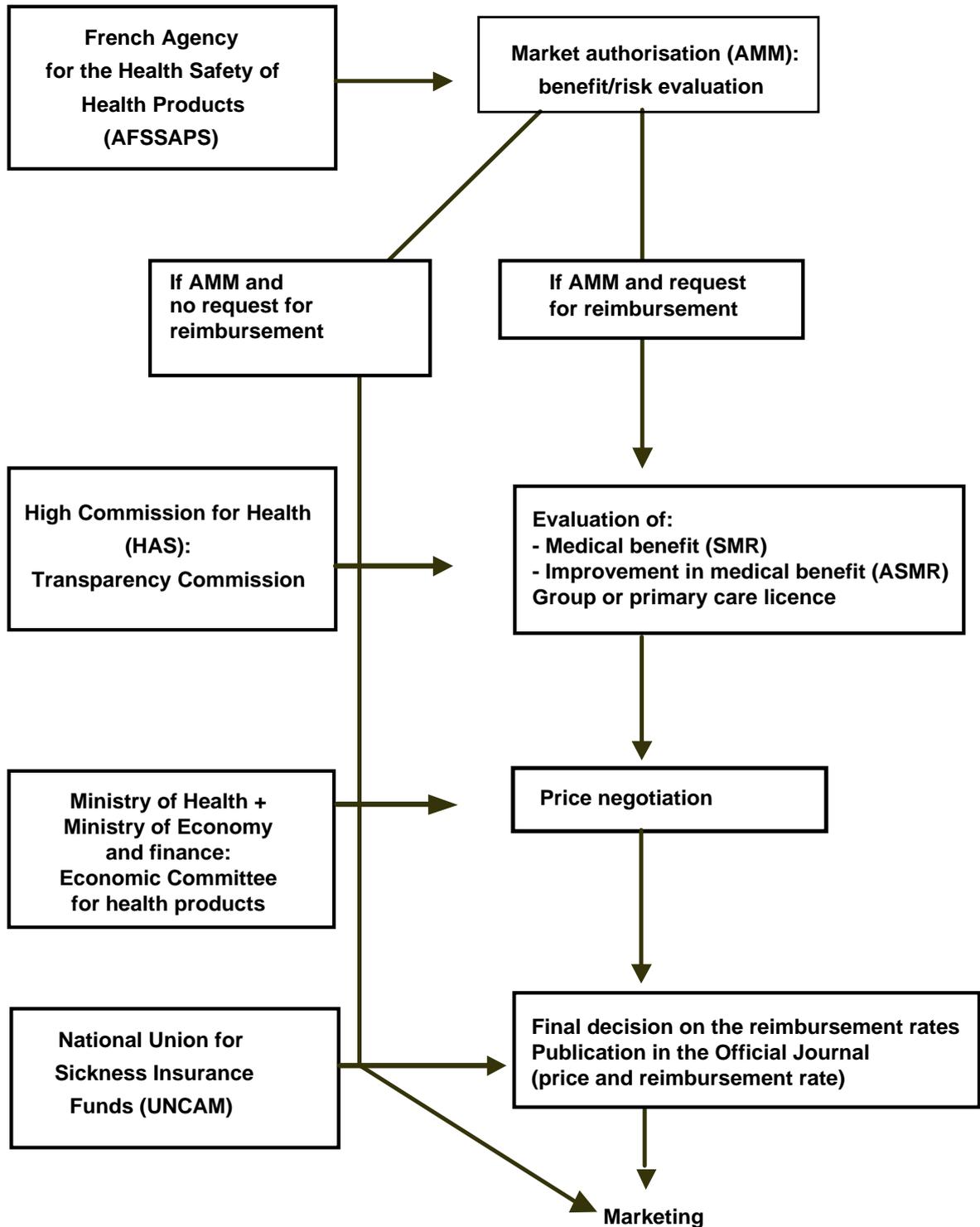
Since 2004, the rate of reimbursement has been determined by UNCAM (National Union of Sickness insurance Funds). This organisation gets involved in parallel with the price setting negotiations, following advice from the transparency commission. UNCAM's room for manoeuvre is limited because it must set the rate of reimbursement within a fairly narrow range for participation defined by decree²⁰. Finally, it is the Minister of Health who decides whether a drug will be included in the list of reimbursable drugs.

Glossary of acronyms in French and in English

AcBus	Accord de bon usage des soins Good use of care agreement
ACOSS	Agence centrale des organismes de sécurité sociale Central agency for social security organisations
AFSSAPS	Agence française de sécurité sanitaire des produits de santé French agency for the health safety of health products
AMM	Autorisation de mise sur le marché Market authorisation
ASMR	Amélioration du service médical rendu Improvement in medical benefit
ATU	Autorisation temporaire d'utilisation Temporary authorisation for use
CEPS	Comité économique des produits de santé Economic committee for health products
CHMP	Committee for medicinal products for human use
CHU	Centre hospitalier Universitaire University hospital
CLCC	Centre de lutte contre le cancer Cancer research centre
CSIS	Conseil stratégique des industries de santé Strategic Board for Health Industries
EMA	European medicines agency
GHS	Groupe homogène de séjour Diagnostic related group
HAS	Haute autorité de santé High Health Authority
ISP	Impact sur la santé publique Impact on public health
LEEM	Les entreprises du médicament French Pharmaceutical Companies Association
MIGAC	Missions d'intérêt général et de l'aide à la contractualisation Missions of general interest and assistance with contracting
ONDAM	Objectif national des dépenses de l'assurance maladie National objective of health insurance expenditure
OTC	Over the counter
PIB	Produit intérieur brut Gross domestic product
PLFSS	Projet de loi de financement de la sécurité sociale Draft law for social security financing
SMR	Service médical rendu Medical benefit
T2A	Tarification à l'activité Activity based costing
UNCAM	Union nationale des caisses d'assurance maladie National union of sickness insurance funds

²⁰ Decree 2004-1490 of December 30 2004 relating to participation by the insured person foreseen in article L322-2 of the Social Security code sets a range of 10 points : from 60 to 70% or from 30 to 40% depending on the medical benefit level of the drug.

Administrative path for an outpatient drug



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Box 1 : reassigned medicine sales

Reassigning medicine sales is a very French practice: hospital pharmacies supply drugs to patients which are not available from external pharmacists because they only have a group agreement. Before the 2004 agreement which established the new approach to regulation of these specialties, these treatments, initiated by hospitals during an inpatient episode, were purchased by the hospitals at a price negotiated with the company following an invitation to tender and billed to the patient with no limitation on price; Sickness Insurance reimbursed the hospital pharmacy as a third party payer or the patient directly on the basis of this completely unregulated price. This situation was clearly highly advantageous for the hospitals and the pharmaceutical industry – the industry avoided the price registration process applicable to ambulatory drugs and hospitals benefited from the difference between the purchasing price and the price billed to Social Security – but was critical for Social Security which saw steep annual rises in this expenditure category²¹. The decree of 17/12/04 determined a restricted list of pharmaceutical specialities authorised for sale to the public from pharmacies in health establishments. This list is decreed by the Minister of Health on demand from the pharmaceutical companies. It takes into account the risks associated with using the products and makes it easier to control stocks. Companies commercialising hospital drugs not included in this list and which are used frequently in general practice are obliged to request certification for general practice and therefore have a price fixed by CEPS. In 2006, this list contained about 100 molecules. The establishment of this list was completed by setting a price ceiling for reimbursement of these products by Sickness Insurance.

Box 2 : Expensive hospital drugs not included in activity based costing

A certain number of drugs dispensed in hospital for which the list is defined at the national level are reimbursed by Social Security within diagnosis related group (DRG) tariffs set by activity based costing (T2A). The idea of this supplementary financing is to guarantee equitable access to the most innovative drugs which would introduce considerable variation in the distribution of DRG costs, either because of the very expensive nature of these drugs, or because the number of patients consuming these drugs is marginal within the DRG.

The 2004 Social Security financing law which implemented activity based costing (TA) in health establishments specifies that the State determines the list of pharmaceutical specialties authorised for sale in the market and which may be reimbursed on presentation of bills by the sickness insurance funds, to hospital services (this list is usually called “non T2A drugs”). An initial list of these drugs was established at the beginning of 2004 and has been regularly updated as new products have entered the market. As with the list for reassigned medicine sales, the Minister of Health authorises the inclusion of a drug in this list. However there is no formal procedure for inclusion in this list, in contrast to reassigned medicines where the pharmaceutical companies must make a request.

²¹ Between 2000 and 2001, expenditure on reassigned medicine sales increases by 16.7% ; this increase was by 30.7% between 2001 and 2002 (cf. the 2003 assessment of CNAMTS).

In 2007 this list contained about 100 active molecules, particularly anticancer drugs, blood products, orphan drugs and some treatments for rheumatoid arthritis. This list is regularly updated, with new entries as innovative and expensive drugs reach the market; in theory drugs should be removed from this list and put back into the DRG system when they begin to be used more widely and/or their cost decreases. As for reassigned medicines, this list was completed by establishing a price ceiling for reimbursement of these products by sickness insurance. If an expensive drug is reassigned, it is added to the reassigned list.

Box 3 : Drugs with temporary use authorisation (ATU)

Temporary authorisations for use were established in 1994 for purposes of enabling patients with very serious or rare illnesses to be treated as quickly as possible – with no administrative delays – using drugs still awaiting market authorisation, where no other treatment exists. There are two types of temporary use authorisation: nominated ATUs, provided for a single patient under the responsibility of the prescribing doctor, and cohort ATUs for groups of patients, established at the request of the manufacturer. A temporary use authorisation must be accompanied by a simultaneous demand for an AMM or an intention to file an AMM dossier in the near future.

Drug price setting and regulation in France

Nathalie Grandfils (Irdes)

In France, drug prices have historically been regulated but approaches to setting and regulating prices have been evolving in recent years. In 2003, the prices of new outpatient drugs, which had hitherto been entirely regulated, were semi-liberalised, with drug companies setting prices in line with those in neighbouring countries; and in parallel with this in 2004, the prices of expensive drugs and/or drugs qualifying for reassignment must now also be set in line with European prices. In addition to this, price/volume regulation has recently been introduced. This document describes the price setting rules applicable to each drug category and discusses different measures for regulating drug price, particularly the conventional policies implemented under successive framework agreements. The regulatory path for medicines and the different actors involved are presented in an Appendix.

Fixation et régulation des prix des médicaments en France

Nathalie Grandfils (Irdes)

En France, le prix des médicaments est historiquement régulé mais les modalités de fixation et de contrôle de ce prix a évolué ces dernières années. En 2003, les prix des médicaments ambulatoires innovants, auparavant entièrement régulés ont été semi-libéralisés, les laboratoires proposant un prix cohérent avec les prix pratiqués dans nos pays voisins ; en parallèle, en 2004, les prix des médicaments hospitaliers onéreux et / ou rétrocédables, auparavant entièrement libres, ont été soumis à cette même contrainte de cohérence avec les prix européens. Par ailleurs, une régulation prix/volume a récemment été introduite. Ce document expose les règles de fixation du prix propres à chaque catégorie de médicament et traite des différentes mesures de régulation des prix des médicaments, notamment de la politique conventionnelle instaurée par les accords cadre successifs. Une présentation du circuit réglementaire du médicament et des différents acteurs y prenant part est présentée en annexe.