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Hospital Reimbursement Price Cap for Cancer Drugs

The French Experience in Controlling Hospital Drug Expenditures

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Abstract

Background: In 2005, the French Government implemented a new way of financing high-cost drugs for hospitals in order to promote innovation. Such drugs are gathered on a positive list, established by the Ministry of Health, with a reimbursement price cap. Hospitals still negotiate with pharmaceutical firms, who set their prices freely, and then charge the national health insurance according to their consumption, without budgetary constraints, but on the condition of good use of care. They are not allowed to charge a price higher than this ceiling price, which is called the 'responsibility tariff' (RT). This measure is included in another, larger reform, which concerns hospital financing through allotted amounts at a specific diagnosis-based level. The purpose of this add-on payment on top of the health funds is firstly to avoid heterogeneity in costs per diagnostic-related group and secondly to avoid an uncontrolled increase of prices due to a lack of interest in negotiation from hospitals, as supplementary funding could reduce hospital price sensitivity.

Objectives: The aim of this work was to assess the bargaining power of hospitals with the pharmaceutical firms in the monopoly market of innovative cancer drugs since the implementation of this reimbursement price cap.

Methods: This study used data from the French Technical Agency of Information on Hospitals (ATIH; Agence Technique de l'Information sur l'Hospitalisation) and included 487 hospitals, which were public and non-profit private. The analysis was conducted on the cancer drugs of the regulated list. An index representing the ratio of the purchase prices to the RT was built from 2004 to 2007 in order to make a 'before-and-after' comparison.

Results: Results showed a transient price decrease in 2005 before an alignment of patented drugs with regulated prices in the context of a dynamic market with a 22.5% yearly growth rate in value between 2004 and 2007.

Conclusion: Hospitals are able to impose the RT for single-brand drugs. However, they are no longer able to negotiate below the RT except for generic drugs. Negotiations take place upstream for setting the RT between the public authorities and the firms.

Key points for decision makers

- High-cost hospital drugs, such as cancer drugs, are gathered on a positive list and are fully reimbursed to hospitals by the French national health insurance
- Meanwhile, in 2005 the French Government implemented a reimbursement price cap in order to limit the increase of expenditures on these drugs. In fact, pharmaceutical companies set their prices freely and negotiate directly with hospitals
- From the study results, if hospitals are able to impose the price cap for single-brand drugs, they are no longer able to negotiate lower than this except for generic drugs. Negotiations take place upstream for setting the price cap between the public authorities and the firms

Background

Healthcare spending is an increasing concern in industrialized countries. Pharmaceutical expenditures represent an average of 17% of the total health spending in most of the Organisation for Economic Co-operation and Development (OECD) countries, with a growth that exceeds the average growth of OECD economies.[1] In France in 2008, all expenditures attributed to health totalled €215 billion, accounting for 11.0% of GDP.[2] The sale of drugs by pharmaceutical companies to hospitals has been growing at an average rate of 9.7% per year in value for the last 20 years and totalled €5.304 billion in 2008.[3] The top ten drugs represent 30% of the hospital market share in value; seven of these are cancer drugs.[3] Since 1998, the cancer drugs sold to hospitals have been growing at an average rate of 20.3% per year, and in 2008, approximately €1.6 billion was spent on cancer drugs.[3]

Prior to 2004, public hospitals received fixed annual budgets for their overall expenses from the French national health insurance (NHI). In early 2004, the French Government introduced a new system to finance healthcare spending in the hospital setting with the establishment of the activity-based costing reform called '*Tarification à l'activité'* (T2A).[4] From then, NHI reimburses hospitals a fixed amount based on patient diagnosis codes; this amount covers both medical and pharmacy costs. Patients do not pay for the drugs administered in hospitals. Drugs are covered by the tariffs related to the 'homogeneous group of stay' (GHS; *groupe homogène de séjour*), based on the diagnosis-related group classification. In addition, on presentation of bills, hospitals receive funding for expensive drugs on the formulary list developed at the national level by the Ministry of Health (90 drugs in 2004), commonly referred to as the 'out-of-GHS list'. It is limited and subjected to regular updates. The purpose of this add-on payment on top of GHS is to ensure access to innovative drugs without creating significant heterogeneity in the cost per stay. All public and privately managed hospitals that provide services in the area of medicine, surgery and obstetrics are eligible for this supplementary financing. The local and psychiatric hospitals, and rehabilitation and long-term care facilities are initially excluded from T2A.

French hospitals purchase drugs directly from pharmaceutical companies and are reimbursed by NHI. The Government has not regulated the purchase price of drugs in hospitals since 1986. However, with the implementation of T2A, NHI

reimburses for medications on the out-of-GHS list up to a price agreed upon by the French Healthcare Products Pricing Committee (CEPS; Comité Économique des Produits de Santé) and the pharmaceutical companies. NHI does not reimburse any additional amount paid by the hospital on top of the CEPS-recommended price for out-of-GHS drugs. Therefore, it is up to the hospitals to negotiate a price with the pharmaceutical companies that is within the reimbursement price cap. This new system, implemented in early 2005, is called the 'responsibility tariff' (RT). Its purpose is to prevent uncontrolled price increases resulting from hospitals' failure to negotiate with pharmaceutical companies, as supplementary funding can reduce hospital price sensitivity. Moreover, if the negotiated price is less than the RT, hospitals receive half the difference between the actual purchase price and the RT as an incentive from NHI. In addition, the hospitals have to respect an agreement of 'good use of healthcare' with NHI in order for their services to be fully reimbursed. This new system encourages appropriate use of limited available resources.

Objective

The objective of this study was to assess the bargaining power of hospitals with the pharmaceutical companies within the French market of innovative cancer drugs since the implementation of the new Government health policy in 2005. The assumption tested was that the purchase prices of the cancer drugs under study would be equal to or lower than the RT.

Methods

Data Sources

This study was approved by the Dauphine University and the Technical Agency of Information on Hospitals (ATIH; Agence Technique de l'Information sur l'Hospitalisation). ATIH collects information related to drugs on the out-of-GHS list reported by hospitals. Hospitals report drug usage details to ATIH in order to receive reimbursement for their drug expenditures. From 2004 until 2007, the agency collected financial information related to hospital drug usage on a quarterly basis. Since April 2007, the agency has collected these data monthly.

This study evaluated data collected between 2004 and 2007 and included all cancer drugs, classified as L01-level drugs according to the Anatomical Therapeutic Chemical (ATC) Classification System defined by the World Health Organization. There are five subclasses of L01, as follows: L01A (alkylating agents); L01B (antimetabolites); L01C (plant alkaloids and other natural products); L01D (cytotoxic antibiotics and related substances); and L01X (other antineoplastic agents). In addition to the L01-level drugs, four other cancer drugs listed as out of GHS were included in this study for analysis.

The ATIH data included in this study were derived from public hospitals and non-profit private hospitals. Data from other private hospitals (for profit) were excluded from this analysis due to the fact that their reporting structure is not compatible with other collected data. The types of hospitals that contributed the data included in the study are categorized as follows: hospital centre (HC), regional university hospital (RUH), cancer centre (CC), private non-profit hospital (PNPH) and the public welfare hospitals of Paris (APHP; Assistance Publique – Hôpitaux de Paris). The information reported by these hospitals included drug names, quantities used, expenditures and purchase prices.

Analyses

Data were analysed using Microsoft® Excel 2004. The pre-intervention 2004 data served as the baseline and were compared with the post-intervention (2005–7) data. Results are presented by common unit of delivery (CUD) code, which represents the smallest unit of delivery and identifies a specific product packaging. In this study, the term CUD refers to packaging of a drug in unit dosage form. Data analyses included annual average unit price, AUPih (with n CUDs from $i = 1$ to n, and H hospitals from $h = 1$ to H), calculated from the ratio of the annual expenditures of a CUD by a hospital to the quantities consumed; ratio of annual average unit price to the

RT of a CUD; Paasche indices to see the change in the total purchase cost for the same bundle of drugs between two different time periods;[5] and 'contribution to the growth' of a product to take into account the influence of its market share on the growth rate of total expenditures.[6] The formulae used for the calculation of Paasche indices and contribution to the growth are as follows:

Paasche price indices are used between $t=0$ (the base period) and $t=1$ (the period for which the index is computed) with k products ($k=1$ to n), and p denotes price and q quantity:

$$P_{1/0}(p) = \frac{\sum_{k=1}^{n} q_1^{(k)} p_1^{(k)}}{\sum_{k=1}^{n} q_1^{(k)} p_0^{(k)}}$$

The contribution to the growth of a product (i) in a year (t) is defined as the product of the growth rate in (t) and its market share in ($t-1$):

$$\frac{Spending^{i,t} - Spending^{i,t-1}}{Spending^{i,t-1}} \times \frac{Spending^{i,t-1}}{Total\ spending^{t-1}} = \frac{Spending^{i,t} - Spending^{i,t-1}}{Total\ spending^{t-1}}$$

To clean the declarative data, the coefficient of variation of AUPih is calculated. Thresholds are chosen in an arbitrary manner to exclude data with obvious input errors (mainly wrong units). In addition, thresholds applied to the AUPih/RTi ratio are also used to detect reporting errors.

Results

A total of 37 924 CUD codes were collected from 487 French hospitals that received reimbursement for cancer drugs on the out-of-GHS list.

Overview of the Cancer Drug Market

The cancer drug market is highly concentrated as shown in table I. The top ten brand-name drugs represent approximately 90% of L01 class expenditures and 50% of overall expenditures of the out-of-GHS list. The trend seen for the expenditure on L01 drugs is an average annual growth increase of 22.5% in value between 2004 and 2007 (table II). The greatest increase in expenditures is observed between 2004 and 2005. The overall increase in drug expenditures during the 4-year study period is mainly due to the L01X subclass of drugs. This subclass includes, but is not limited to, all new cancer therapy drugs referred to as 'targeted therapies'. Its contribution to L01's growth reaches 76%, 98% and 97% in 2005, 2006 and 2007, respectively. The contribution of L01 to the growth of the out-of-GHS list reaches 66% in 2006 and 37% in 2007. Figure 1 illustrates that drugs launched since 2000 are primarily responsible for increasing cancer drug expenditures.

Analysis per Hospital

The average AUPih/RTi in each hospital, defined as AUPh/RTh, is summarized in table III. In 2004, nearly 90% of hospitals had an average purchase price above the RT, and from 2005 onwards, the trend observed is a decrease in purchase price, with the purchase price being equal to or less than the RT. However, in 2005, 38% of hospitals purchased drugs above the RT on average. This trend reverses significantly in 2007, when only 11% of hospitals have an average purchase price above the RT. The decline in prices is confirmed by an analysis with a Paasche index between 2004 and 2007. The results show an index at 0.93 and a majority of hospitals (90%) whose spending in 2007 would have been higher if 2004 prices were maintained. This price decrease occurs mainly between 2004 and 2005. Indeed, between 2005 and 2007, prices stabilize. The Paasche index between these two dates is 0.97.

There is a decrease in the ratio of average purchase price/RT among all types of hospitals from 2004 to 2007. The average AUPh/RTh for each type of hospital during the study period (defined by the ratio AUP/RTx for each regulatory hospital classification 'x') is shown in figure 2.

Analysis per Drug

The distribution of the AUPi/RTi ratio for each CUD (which corresponds to the average AUPih/RTi per CUD) between 2004 and 2007 confirms that there is a decrease in drug prices after implementation of the new Government

Table I. The top ten single-brand cancer drugs with the highest expenditures on the out-of-GHS list[a,b]

Rank	2004			2005			2006			2007		
	Drug	ATC subclass	Spending (€ mill.)	Drug	ATC subclass	Spending (€ mill.)	Drug	ATC subclass	Spending (€ mill.)	Drug	ATC subclass	Spending (€ mill.)
1	Taxotere®	L01C	78.0	Taxotere®	L01C	103.7	Mabthera®	L01X	120.1	Mabthera®	L01X	136.0
2	Mabthera®	L01X	74.9	Mabthera®	L01X	99.1	Taxotere®	L01C	111.8	Herceptin®	L01X	128.1
3	Taxol®	L01C	62.4	Eloxatine®	L01X	63.8	Herceptin®	L01X	109.3	Taxotere®	L01C	117.9
4	Eloxatine®	L01X	49.8	Herceptin®	L01X	59.7	Eloxatine®	L01X	65.6	Avastin®	L01X	73.7
5	Gemzar®	L01B	43.0	Gemzar®	L01B	45.1	Campto®	L01X	49.1	Eloxatine®	L01X	64.2
6	Campto®	L01X	37.6	Campto®	L01X	43.3	Gemzar®	L01B	46.0	Erbitux®	L01X	52.5
7	Herceptin®	L01X	35.4	Taxol®	L01C	37.0	Erbitux®	L01X	44.8	Campto®	L01X	50.6
8	Farmorubicine®	L01D	19.8	Erbitux®	L01X	32.2	Avastin®	L01X	38.9	Gemzar®	L01B	47.2
9	Navelbine®	L01C	9.3	Alimta®	L01B	29.9	Alimta®	L01B	37.7	Velcade®	L01X	43.3
10	Caelyx®	L01D	9.1	Velcade®	L01X	22.0	Velcade®	L01X	32.8	Alimta®	L01B	43.0
Total (€ mill.)			**419.3**			**535.7**			**656.1**			**756.4**
Top ten drugs share in:												
the L01 class on the list			91.0%			87.3%			87.6%			89.9%
the out-of-GHS list			NA			47.1%			48.9%			47.5%

a Corresponding international non-proprietary names for the drugs presented in this table are as follows: Taxotere® (docetaxel), Mabthera® (rituximab), Taxol® (paclitaxel), Eloxatine® (oxaliplatin), Gemzar® (gemcitabine), Campto® (irinotecan), Herceptin® (trastuzumab), Farmorubicine® (epirubicin), Navelbine® (vinorelbine), Caelyx® (doxorubicin), Erbitux® (cetuximab), Alimta® (pemetrexed), Velcade® (bortezomib), and Avastin® (bevacizumab).

b See the Data Sources section for ATC subclass definitions.

ATC = Anatomical Therapeutic Chemical; **GHS** = homogeneous group of stay; **L01** = antineoplastic drugs (ATC classification); **mill.** = millions; **NA** = not available.

Table II. Consumption of the L01-level drugs on the out-of-GHS list (in quantities and value) between 2004 and 2007

	2004		2005		2006		2007	
	No. of CUDs consumed	Spending [€ mill.]	No. of CUDs consumed	Spending [€ mill.] (%)	No. of CUDs consumed	Spending [€ mill.] (%)	No. of CUDs consumed	Spending [€ mill.] (%)
All out-of-GHS drugs	NA	NA	NA	1138.0 (100)	NA	1342.1 (100)	NA	1591.0 (100)
L01 class[a]	1 563 036	460.7	1 859 668	613.9 (53.9)	2 104 246	748.6 (55.8)	2 183 690	841.3 (52.9)
L01A	19 482	3.5	21 430	5.0 (0.4)	21 754	6.3 (0.5)	23 191	7.3 (0.5)
L01B	358 539	51.6	375 300	79.6 (7.0)	396 396	88.2 (6.6)	394 879	97.1 (6.1)
L01C	438 235	151.3	473 850	157.1 (13.8)	458 951	148.5 (11.1)	433 543	140.5 (8.8)
L01D	194 559	32.1	167 670	33.4 (2.9)	157 296	34.5 (2.6)	147 561	35.6 (2.2)
L01X	552 221	222.2	821 418	338.8 (29.8)	1 069 849	471.1 (35.1)	1 184 517	560.8 (35.2)

a See the Data Sources section for ATC subclass definitions.

ATC = Anatomical Therapeutic Chemical; **CUD** = common unit of delivery; **GHS** = homogeneous group of stay; **L01** = antineoplastic drugs (ATC classification); **mill.** = millions; **NA** = not available; **no.** = number.

policy on drug reimbursement price (table III). The number of CUDs whose average purchase price exceeds the reimbursement cap decreases over time and accounts for only ~25% of drugs in 2007. The Paasche index analysis confirms the decline in prices between 2004 and 2007 with an index at 0.9. However, 34% of CUDs have seen their prices raised conversely.

Figure 3 shows the average of the ratio AUPi/RTi for three categories of drugs ('y'; generic, single-brand and multi-brand drugs) between 2004 and 2007. Generic drugs are primarily responsible for the decline in overall purchase price. Hospitals purchase single-brand drugs at prices equal to the RT on average. However, in 2007, many hospitals paid more than the RT-recommended price for single-brand drugs (24/55). Following the launch of numerous generic drugs in 2007 and the decrease by 50% of the RT of paclitaxel, the AUP/RTy ratio for generic drugs increased in 2007.

Discussion

In this study, the impact of a new Government policy on pharmaceutical spending in the hospital setting was evaluated by assessing purchase prices of cancer drugs pre- and post-implementation of the Government policy. Since the establishment of the RT, hospitals are no longer able to negotiate prices for single-brand drugs. This new Government policy has led to a decrease in single-brand drug prices mainly in the first year, reflecting the wish of the Government to set up an RT below the historical prices. Then, prices reflect the general policy pursued by the public authority, and prices of single-brand cancer drugs equal to the RT in a context of a concentrated cancer drug market where only a few drugs drive the costs and are accountable for the dynamic growth rate.

According to the 2007 data,[3] nearly 45% of hospital drug expenditures are due to drugs on the out-of-GHS list. This study shows that consumption of and expenditures for antineoplastic drugs (L01) on the out-of-GHS list, which repre-

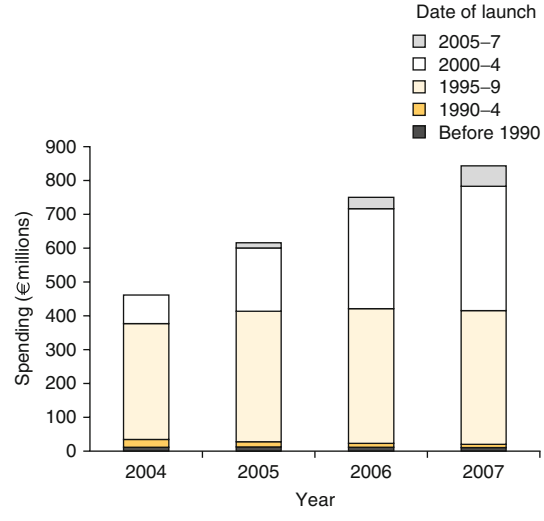

Fig. 1. Expenditures of cancer drugs on the out-of-GHS list between 2004 and 2007 by date of launch to the market. **GHS** = homogenous group of stay.

sent 90% of cancer drugs,[7] increased during the study period. The strongest growth in consumption was observed between 2004 and 2005; this was followed by more moderate growth between 2005 and 2007. It is likely that the dramatic increase in consumption and expenditures in 2005 was mainly due to the launch of several single-brand innovative drugs. Prior to the implementation of T2A, these expensive drugs may not have been provided to all eligible cancer patients due to hospital budget constraints. Following implementation of T2A, hospitals were able to provide access to all new cancer drugs for all eligible patients. In addition, the number of patients treated by chemotherapy is increasing every year.[8] Between 2006 and 2007, no new cancer drug had been added to the L01X subclass. Therefore, no sudden increase in expenditures was observed during this period. Since the cancer market is a concentrated market of innovative new drugs that are expensive and single brand, the launch of each new drug will change the overall landscape of expenditures and consumption of cancer products.

The objective of implementing the RT was to control drug costs and to encourage hospitals to negotiate better prices. The establishment of the RT led to an overall decrease in purchase prices paid by hospitals. However, this detailed analysis revealed that greater decreases in purchase prices were seen among generic and multi-brand drugs than among single-brand drugs. The decrease in purchase price may be due to the competition that exists among different manufacturers to sell the cancer drugs to hospitals. Negotiations appear almost impossible for single-brand drugs. The price of these drugs, which represent almost all expenditures, are considered fixed by the manufacturers, who may fear a further decline of the RT if the prices of their products fall in hospitals. Actually, the RT measure does not constitute an incentive to negotiate. This study confirms the report published in 2007 by the financial court in charge of the control of the public accounts, Cour des Comptes ('Court of Accounts'), who suggest that this measure would have eliminated negotiations between firms and hospitals.[9] These conclusions were based on a survey from a sample of 50 public hospitals.

Placing a limit on reimbursement acts as a price control to the extent that demand is elastic when price is higher than this limit. However, in the context of new drugs without therapeutic alternatives, clinical considerations will probably overcome access restrictions. Hospitals are forced to pay the difference if prices exceed the RT. Therefore, a selling price cap should be established. This regulatory mechanism, developed in other countries and industries in recent years, provides an incentive for the firms to contain costs while maintaining the possibility of negotiation for buyers in case of a competitive market.[10]

Certain limitations should be considered when interpreting the results of this study. The data analysed were reported voluntarily by the hospitals, and it could not be determined whether the price reported was the actual price paid by the hospitals to the pharmaceutical manufacturers. Furthermore, in 2007, data from two RUH were absent and five generic drugs were unavailable yet were reported by three hospitals to have been consumed. Moreover, there may be a lag between reported purchase prices and negotiated prices

Table III. Characteristics of the distribution of the AUPh of hospitals and of the AUPi of drugs relative to the RT between 2004 and 2007

	2004	2005	2006	2007
Hospitals: AUPh/RTh				
Mean ± SD (range)	1.09 ± 0.27 (0.80–6.15)	1.00 ± 0.07 (0.71–1.56)	0.96 ± 0.13 (0.32–3.09)	0.95 ± 0.10 (0.59–2.47)
Number of hospitals with AUPh/RTh >1 (%)	365 (87.1)	160 (38.0)	53 (12.6)	46 (11.2)
Drugs: AUPi/RTi				
Mean ± SD (range)	1.09 ± 0.40 (0.73–3.79)	0.98 ± 0.14 (0.57–1.43)	0.88 ± 0.26 (0.23–1.23)	0.88 ± 0.23 (0.23–1.41)
Number of drugs with AUPi/RTi >1 (%)	39 (61.9)	37 (49.3)	35 (39.8)	29 (26.4)

AUP = average unit price; **i** = common unit of delivery; **h** = hospital; **RT** = responsibility tariff; **SD** = standard deviation

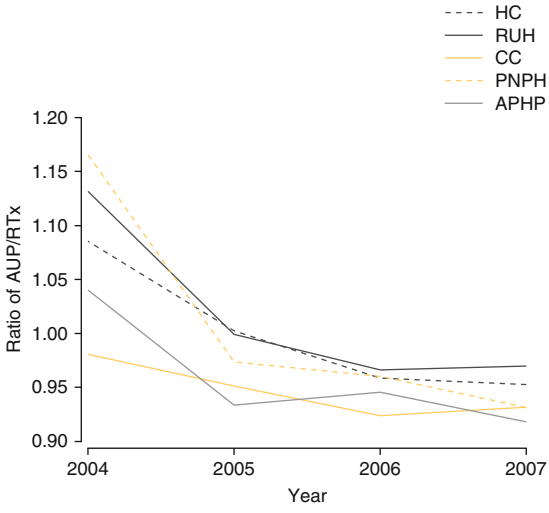

Fig. 2. Ratio of AUP to the RT of hospital categories between 2004 and 2007. **APHP** = public welfare hospitals of Paris; **AUP** = average unit price; **CC** = cancer centre; **HC** = hospital centre; **PNPH** = private non-profit hospital; **RT** = responsibility tariff; **RUH** = regional university hospital; **x** = hospital category.

due to a flow of stock from a former drug market. Finally, some hospitals reported their consumption of listed drugs even though they are temporarily excluded from T2A.

This study confirms that the increase in pharmaceutical spending is related to a structural effect and not to the conditions of purchase or consumption.[11] It raises the issue of a possible need for the establishment of a central purchasing process for out-of-GHS drugs. This systematic alignment poses the risk of discouraging negotiation settlements.[9] Educating hospital staff on the upcoming launch of single-brand, multi-brand and generic drugs that may affect overall drug expenditures is essential. As the out-of-GHS list was primarily established for high-cost drugs, the presence of generic drugs in the list should be considered. A regular review of the out-of-GHS list is necessary and measures to control the proper use of these drugs should be taken on the basis of scientific evidence.[8] Thus, several cancer drugs have been removed from the out-of-GHS list since 2010.

In 2009, a strict regulation of expenditures for out-of-GHS drugs was added to social security financing law,[12] and thus it falls within the logic of French health policy to control expenditures. From national analyses on changes of prescriptions of these drugs, a forecast growth rate in spending related to these specialties is being determined (10% in 2009, then 8% in 2010). Hospitals that exceed the rate without reason, according to the benchmarks and guidelines, will run the risk of having a refunding rate for out-of-GHS drugs decreased by 10%. The effects of this recent measure have to be assessed.

Conclusion

The results of this study reveal that the implementation of the new Government reimbursement policy for high-cost hospital drugs helped to prevent inflation of spending by an uncontrolled increase in drug purchase prices. However, it increases the risk for pharmaceutical companies that have no incentive to negotiate prices under the price fixed by the CEPS. For single-brand drugs, an alignment of prices with the RT is thus observed. The RT is part of a broader issue of rationalization of expenditures to avoid direct rationing of care. The originality of the T2A is that it combines a mechanism for macroeconomic regulation, with the RT, in addition to controlling the quality of care by a microeconomic device

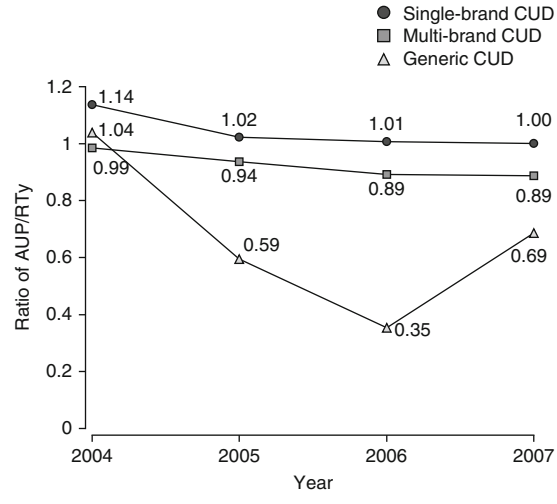

Fig. 3. Ratio of AUP to the RT of drug categories between 2004 and 2007. **AUP** = average unit price; **CUD** = common unit of delivery; **RT** = responsibility tariff; **y** = drug category.

with the 'good use of healthcare' agreement. Finally, the optimal level of innovation, compromise between the inputs of therapeutic progress and the ability to spread them out in a fair and egalitarian social way, is still debated.

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All authors have participated sufficiently to take responsibility for the entire content of the article. A. Degrassat-Théas conceived and planned the work, analysed and interpreted the data, wrote the manuscript, and is responsible for the work as a whole. M. Bensadon, C. Rieu, M. Angalakuditi, C. Le Pen and P. Paubel made significant contributions to the conception of the work, the analysis and interpretation of the data, and the revision of the manuscript, and approved the final submitted version.

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