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# Governing the Market Through Prices: The State and Controls on the Price of Medicines in France

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This article brings together two streams of research which have had important developments over the past years without coming together around a single empirical object. The first of these streams has developed in economic sociology around questions of valuation and pricing (Aspers and Beckert, 2011; Hegelsson and Muniesa, 2013; Vatin, 2013). If the majority of these works are more interested in processes of qualification than in processes of pricing, this gap tends to be filled by studies that are primarily focused on the formation, the circulation and the social uses of prices (Beckert, 2011; Chauvin, 2011 and previous issue). However, as Beckert (2011) emphasizes, these works have often neglected the role of institutions in general, and of the State in particular, in the determination of prices. The second stream of research has developed in the policy analysis around "government instruments" (Hood, 1983; Lascoumes and Le Galès, 2004) used by the State to govern different social spheres, and in particular the market (Hall, 1986; Dobbin, 1994; Jullien and Smith, 2008). These works have often emphasized the use of the tax system and public expenditure (Lascoumes and Le Galès, 2004; Bézès and Siné, 2011) as classic government instruments, but on the other hand they have given little attention to control of prices by the State.

However, according to the analysis of Dobbin (1994) on the development of the railway industry in the 19th century, the fixing of rates was a central issue in industrial policy, not only in France but also in the United States and the United Kingdom. Fixing the rates of rail transport allowed for the promotion of equality between territories and persons, for the regulation of competition between rail companies, and for influencing the development of the rail lines in the directions preferred by the State. But price control is also an important instrument of macro-economic policy, which has been applied to many sectors, and not only in the Soviet Union; price control was the rule in France from 1936 to 1986, but also in the United States during the two world wars and under Nixon's presidency.

Hervé Dumez and Alain Jeunemaître (1989), who have studied closely price control policy, have noted the variety of ways it was used in France in terms of both eras and sectors: far from being a secondary or inefficient government instrument, price control has been shown to be, at least in the case of France, a powerful method of economic regulation by the State.

The French medicine market is one of the last representatives of this price control policy; since the 1930s until today the prices of reimbursable medicines have been fixed by the state. Relatively unusual both in the European and global contexts (Lecomte and Paris, 1998; Sermet, 2007), this administrative price fixing is justified in the case of medicines by the necessity of controlling socialized spending on health: the State represents the aggregated demand in the face of laboratories that have a quasi-monopolistic position. This State control over the price of medicines has nevertheless been the subject of numerous criticisms: for its interventionism (that prevents the establishment of any real price competition); for its lack of transparency (marked by arbitrariness and corruption); and its ineffectiveness (weak prices given to the medicines are "compensated for" by the laboratories through "artificial" strategies of innovation and incentives to doctors to prescribe higher amounts, therefore continuing to inflate health expenditures) (Jeunemaître, 1985; Chauveau, 1999). Within the framework of European harmonization, this policy underwent important reforms during the 1990s; from that point the fixing of prices was entrusted to the Economic Commission for Health Products (hereafter "the Commission"). Unofficially created in 1994 and formalized by decree in 1997, this Commission includes representatives of different ministerial departments (Health; Social Security; Consumerism, Competition and Fraud Prevention; Industry) and of (universal and complementary) health care organizations, and is responsible for negotiating with the pharmaceutical industry the prices of medicines reimbursed by health insurance around a number of objectives:

*The mission of the commission is to obtain the most advantageous price and the economic conditions for the health insurance service, taking into account both the global medicine market and the constraints of the National Target for Expend-*

*itures on Health Insurance, the requirements of public health and the need to treat enterprises equally. (Report of the Commission, 2004, p.60).*

In this article we examine in more detail the role played by the Commission in price fixing and regulation of the market. The fixing of prices by the Commission reaches across three different areas of political economy. First of all, the Commission presents itself as a valuer, responsible for translating in the prices of medicines a range of principles of value reflecting different definitions of public interest in terms of medicine. Then, the Commission appears as a planner, supposed to control, through the fixing of prices, the development of the volume and the structure of health expenses. Finally, the Commission also assumes, more or less overtly, a role as regulator of the market, using the prices to influence (or not) the investment and competitive strategies of pharmaceutical companies and, to a lesser degree, the prescription of medicines.

### Valuing the Public Interest

The Commission defines itself, first of all, as a representative of the interests of the aggregated demand for medicines, responsible for defining “collective preferences” in the area of public health and for negotiating, in the name of the payers, the fairest price with the pharmaceutical companies. But in order to determine these collective preferences, the Commission must balance three partially contradictory principles of valuation (Boltanski and Thévenot, 2006; Stark, 2009; Vatin, 2013): a public health rationale according to which the prices should value the health needs of patients and the therapeutic value of the medicines; a financial rationale according to which the price should value the financial imperatives of the Social Security; an industrial rationale according to which the price should value industrial development.

This compromise is established around the assessment of the therapeutic value of the medicine by the Commission of Transparency. This commission, which used to fall under the French Drug Agency and was integrated in 2004 to the “Haute Autorité de Santé”, is composed of doctors, pharmacists, and specialists in medical research and epidemiology. It uses clinical data provided by laboratories to assess the Improvement in Medical Service (IMS/ASMR in French) of a drug, the therapeutic “value-added” of this medicine compared to others in the same therapeutic class. There are five levels of IMS, ranging from I for a major therapeutic advance to V for a lack of improvement. The Improve-

ment in Medical Service plays a central role in the negotiations between the Commission and the laboratories, since it will determine the “acceptable” price range for both parties and legitimize the final price.

According to the agreement signed between the Commission and the union of the pharmaceutical industry, the medicines which have been ranked IMS I to III (major to moderate) are supposed to receive a price “coherent” with those used in four other European countries, of which two (Germany and the United Kingdom) have unregulated, elevated prices and two (Italy and Spain) have fixed, weaker prices. Granting in this way higher prices to medicines having greater therapeutic benefit both indicates the importance of these treatments for public health and “compensates” innovative laboratories, while taking care not to strain the budgets of the health insurance service. For all that, the “fair price” is never completely self-evident, as is regularly shown by the case of “orphan drugs.” As these medicines affect only a very small number of people suffering from problems which are often serious<sup>1</sup>, access for these patients is crucial; but the few laboratories that invest in research on these medicines face limited markets to profit from them and therefore often demand extremely high prices. The negotiations within the Commission and between the Commission and the firms are often therefore very difficult.

Another example of these difficulties of “assessment” relates to the medicines rated as IMS IV (minor), for which the therapeutic value is not high enough to include the medicine within a European price bracket, nor weak enough for the company to accept a price lower than that of comparable medicines. It is therefore not unheard of for a company to demand a price ten to twenty times higher than that of equivalent drugs for a new form of one of its medications which has a grade of IMS IV. In this case, matching therapeutic benefit with price can prove to be particularly problematic, with the representatives of the Health Ministry hoping to offer patients the benefit of this new medicine while the representatives of Social Security or of the healthcare organizations refusing to pay a high price for a minor innovation.

Financial considerations are even more evident in the case of the medications that do not offer an improvement (IMS V), which represented 60 to 80% of the medications evaluated by the Transparency Commission from 2000 to 2006. The Social Security Code stipulates that in the absence of therapeutic value, a medication should not be

included on the list of reimbursable medicines unless it allows for savings for Social Security. However, the Commission elaborates in one of its reports that *"the expected savings are not measured by the unit price gap between the new medicine and those, already included, with which the Transparency Commission compared it, but as savings in expenditures, which is the product of gaps in the price per volume"* (Annex 1, Report 2002, p.40). Moreover, the arrival of a new medicine modifies the competitive structure within the market of that therapeutic class, which affects at the same time the global volume of sales and the structure of market shares. For the Commission, then, the issue consists of fixing a price for this new medicine which takes into consideration the probable evolution of its sales volumes but also those of other medicines and therefore integrates market regulation and expenditure planning.

The Commission's approach to assessing medicines has recently been criticized as inflationist by both politicians and economists. For example, in a recent study of the *"determinants of price gaps between similar medicines and the first on the market of a therapeutic class,"* some researchers (Sorasith et al., 2012) find *"the existence of occasionally important price gaps between similar medicines, which have the same indications and which are therefore postulated to be a priori equivalent"* (p.30). While these gaps result from the principles governing price fixing in France (the date of market launch and IMS), the researchers question the foundations of these principles since *"the majority of minor innovations lead to these price gaps within a class [...although] for the doctor who prescribes them or the patient who consumes them, they are in most cases interchangeable"* (p.30). These researchers therefore find that it would be wise to question the role of the criteria of innovation in the assessment of medicines to offer more weight to financial imperatives.

This critique appears to be well founded as long as it reduces the activity of the Commission to an assessment of the therapeutic innovation offered by a medication. But in reality, the Commission is not content to just value the therapeutic interest of these medicines; it also aims to use its control over prices to plan the evolution of health expenditures.

## Planning Health Expenditures

In his study of railway policy in the 19th century, Dobbin (1994) tends to separate planning policy from pricing policy. However, price fixing has been an important instrument

in French planning (Fourquet, 1980 ; Dumez and Jeunemaître, 1989). In the 1990s, administrative price fixing of medicines was the subject of numerous critiques (Jeunemaître, 1985 ; Chauveau, 1999). It did not seem, in fact, able to curb the growth of medical expenses without strict controls on the volumes sold and therefore on prescriptions. The equilibrium resting on fixed, weak prices and free, high volumes was not satisfying in terms of finances, since it did not allow limitations on medical expenses, nor in terms of health care, since overconsumption of medicines entailed iatrogenic risks for the patients, nor even in terms of industrial development, since the weak and relatively homogenous pricing did not encourage the pharmaceutical companies to invest in the research and development of truly innovative medications. The creation of the Commission in 1994 and the establishment of the *"Plan Juppé"* in 1996 aimed to address this problematic situation by making the Commission a true planning authority, empowered to control the evolution of medical expenses by acting not only on the prices but also on the volumes of medicines sold.

The Commission therefore has the mission of ensuring that the growth of reimbursable medical expenses is consistent with the National Target of Health Insurance Expenditures, voted on by the Parliament every year since 1996 within the framework of the Social Security Financing Law. To achieve this consistency, the Commission applies the *"K rate"* of growth of Health Insurance Expenditures defined by the Social Security Financing Law at a different rate for each of 65 pharmacotherapeutic groups, grouping together medicines considered therapeutically equivalent. The first step is evaluating the perspectives of a *"normal"* evolution of sales within each therapeutic class starting from the demand for the drugs (prevalence of the illness to be treated and public health priorities) and their promise (predicted development of innovations or generic medicines). A second stage aims then to *"identify the classes within which [the Commission] calculates that, at the currently observed levels of sales, the prices are – at least relatively, considering the global constraint on expenditures set by the Parliament – too high"* (Annex 2, Report 2002, p.46-47) in terms of the assessment of the interest in that therapeutic class, the length of time that the medicine has been on the market and the volumes of sales. In this sense, the Commission plays a central role in planning through its capacity to control not only the levels but also the structure of medical expenditures, based on its evaluation of public health needs, public finances, and the growth of the markets.

To “execute the plan,” the Commission can act not only on the prices of medicines but also on the volumes and structure of sales. First, the Commission can modify prices based on the observed sales volumes of the medicines. In the case of older therapeutic classes for which generic medicines are widely available, the Commission has, on the request of Parliament, implemented important price cuts between 2000 and 2012, in order to get the sales price as close as possible to the cost of production. Otherwise, the prices granted to innovative medications are usually accompanied by provisions under which passing a certain volume (of global sales or daily treatment) can lead to the lowering of the price of the medicine. These provisions aim to ensure that the laboratories do not pressure doctors to prescribe the medications unless indicated, jeopardizing not only the balance of health expenditures but also public health. In cases that significantly exceed the sales targets fixed in these provisions, the Commission can theoretically lower the official price of the medicine. In fact, lowering prices in this way provokes the hostility of the pharmaceutical companies, since it threatens not only the price established in the French market, but also more broadly that of the European market, via the system of cross-referencing among European countries.

A second instrument is therefore preferred both by the companies and by the Commission: the end-of-year rebates. These rebates, paid by laboratories to the health insurance system in the case of exceeding the volumes “authorised” by the Commission, permit the health insurance system to get a real price lower than the official price without changing the latter. Finally, a third instrument aims to act from a distance on medical prescriptions by regulating the amount of doctor visits by pharmaceutical representatives. In 2004 a “doctor visit quality chart” was agreed between the Commission and the pharmaceutical industry union in order to “*promote the quality of medical treatment by avoiding the misuse of medicines and unnecessary expenditures and by participating in informing doctors*” (Medical Visit Charter signed by the Commission and medical companies in 2004). While this Charter only relates to the content of medical visits, the Commission has moreover negotiated with the laboratories to fix the number of doctor visits they can make within therapeutic classes; passing this number can lead to sanctions (price lowering or rebates). By this logic, actors in the health field (doctors, patients, pharmacists) appear almost negligible since the Commission and the laboratories agree to fix the “acceptable” prices and volumes of sales and of medical visits, without considering doctors’ actions or opinions.

Beyond these different instruments, a “contractual” framework contributes to assuring the planning of health expenditures. Almost all of the pharmaceutical companies have chosen to sign contracts and support a policy of negotiations, not so much for financial reasons as because this policy gives them the opportunity to negotiate prices directly with the State, mediated by stable rules which engage both parties. The policy offers the companies a handhold in the fixing of prices through the devices and rules established by the Commission, and gives the State influence over the conduct of companies and doctors. Moreover, by engaging the Commission and the companies on the basis of a five-year contract, this policy allows both stakeholders to plan the evolution of medical expenditures over the medium-term: the Commission can protect itself from a sharp drop in sales (and therefore in medical expenditures) and the companies can protect themselves against any temptation by the government implement short-term savings by unilaterally changing the prices.

The Commission therefore plays a planning role responsible for guiding the evolution of medical expenses based on objectives and priorities fixed by the government and by commitments with the pharmaceutical companies. We are left with a third role that implies relatively contradictory arguments: should the Commission also use the prices to regulate the market?

## Regulating Health Industries

Neo-institutionalist works have emphasized the key role of the state in the structuring of markets and the organisation of company strategies (Dobbin, 1994; Fligstein, 2001). Based on the laws that have been adopted, the State is able to promote strategies of cooperation, of price competition, or of merger among companies (Dobbin and Dowd, 2000). Through its decisions whether to fix a single rate or leave companies free to fix their own rates within the railway sector, the State either promoted the establishment of a substantial margin for the enterprises in the sector or on the other hand allowed an unbridled and ruinous price competition to take root (Dobbin 1994). In the French Case, two questions have been particularly important in the debate around market regulation. Should the Commission use its control over prices to subsidise the French and European pharmaceutical industry or should it respect equality of treatment across companies? Should the Commission use its control over prices to encourage price competition among enterprises and in this way “sacrifice” the

pharmaceutical industry in the search for lower health insurance expenditure?

The first question has been raised recently by two professors of medicine (one of whom is a member of Parliament), Philippe Even and Bernard Debré. From a table showing the price gaps between "similar" French and foreign medicines, the two authors accused the Commission of privileging *"first French firms, then foreign firms established and producing in France, and, finally, foreign firms producing elsewhere and without plans to establish themselves in France"* (p.61). According to them, this "national" or "European preference" is a result of the strong influence that the Ministers of Finance and of Industry have over the decisions of the Commission, which lead it to privilege an industrial logic over a public health or a financial rationale in fixing prices. The two authors note an important ambiguity in the political economy of medicine in France: should the Commission use the price fixing of medicines as a tool of industrial policy or should it observe a strict principle of neutrality towards different companies?

While each of the annual activity reports published since 1999 contain the reminder that the Commission intends to respect a perfect equality in the treatment of companies and a set of rules have been progressively enacted to translate this principle into price decisions, the relations of the Commission with the companies seems to have evolved the according to the involved branches of government (and in particular the weight of the Ministry of Industry), the economic conditions, and the positions of its presidents. In this way, the policy initiated by the first president of the Commission, Jean Marmot, and theorised in a 2004 report (Marmot, 2004), had a clear industrialist angle: the issue was to use price fixing to promote the development of a competitive French industry and to take into consideration the objectives of growth and employment alongside the objectives of controlling health insurance expenditures and the needs of public health. On the other hand, Noël Renaudin, who presided over the Commission from 1999 to 2011, defended a principle of neutrality on industrial issues. He considered that the protection of employment and growth in France should not be part of the criteria for price fixing and that equality of treatment across enterprises, *"as much for the legal certainty it provides as for the rational expectations that it makes possible, constitutes a significantly attractive element"* (Commission Report 2009, p.44).

The positions of Jean Marmot and Noël Renaudin offer an illustration of two opposing conceptions, protectionist and

liberal, of industrial policy. The political economy of medicine, as it is designed in the rules and price fixing instruments utilised by the Commission, constitute a unique compromise between these two extreme positions. The principle of equality of treatment and of respect for competition among enterprises appears in the system of distribution of "rebates" at the end of the year. The rebate paid by each company is based partially on the sales rate within the pharmacotherapeutic group concerned (65%) and partially on the growth of this sales rate (35%). The competitive neutrality principle of pricing policy would have the rebates based exclusively on the sales rate, but at the same time, the contracts discourage the systematic penalization of the same enterprises through the rebate system, because otherwise the companies would prefer the non-contract route. This system seems therefore to be a method of taxing all the companies without "distorting" the competition within the different therapeutic classes.

On the other hand, the principle of the promotion and protection of French and/or European industry is applied through two instruments. The first of these is the valuing of innovation by "European" prices and the establishment of partial or complete exemptions from the rebates over the course of several years for medicines with high IMSs. This principle has crucial implications for the pharmaceutical industry, since it reinforces the separation between the (large, international) companies which innovate and access European prices but don't necessarily develop their research and production activities on French or European territories, and the (smaller, national) firms which concentrate on the exploitation of older or generic medicines and which often guarantee operation of their industrial sites on French territory. The second instrument aims to strengthen the attractiveness of France and the European Union for pharmaceutical research, development, and production activities. Based on the recommendations of the Marmot Report in 2004, a Strategic Council of Health Industries (SCHI, CSIS in French) met in 2005 under the auspices of the Prime Minister and entrusted the Commission with the distribution of credits (reaching a global annual sum of around 50 million euros) intended to finance "hard" investments (production factories, research centers, distribution platforms of headquarters) already implemented or under construction. While ostensibly recognizing the importance of industrial development within medical policy, the SCHI credits in reality enable the separation of industrial development policy from the price fixing of medicines.

The second problematic concerns the use of price controls to promote price competition among firms. The generic medicines policy which has been developed in France since the 1990s has led the government to construct a “price competition market” while at the same time maintaining the administration of prices and the socialization of health expenses (Nouguez, 2010; forthcoming). In the absence of micro-economic devices of price competition, the Commission has played the role of a Walrasian Price Commissioner groping to establish by trial and error a “perfect competitive price” that approaches the production cost of generic medicines: the price of a generic medicine, which is fixed by the Commission, has in this way gone from 80% of the price of the original medicine in 1994 to 40% in 2012; at the same time, the prices of original medications now competing with generics were lowered by the Commission from 80% of their original prices in 2006 and to 70% by 2012. Finally, on the request of the government, the Commission has developed since 2010 a policy of price convergence within therapeutic classes in which generic medicines were strongly present but did not manage to compete with certain patented medicines because of the marketing strategies of laboratories (Nouguez, 2007). Rather than leaving it to market actors (laboratories, doctors, patients) to organize a true price competition, the Commission has therefore used its control over the prices to “mimic” the effects of price competition. In this sense, it plays a major role in the regulation of the market and the industry.

The use of prices as an instrument of market and industry regulation has therefore been an important issue of conflict, muted but real, raising the question of the autonomy of the Commission from ministerial “guidance” and industrial “influence.” The economic crisis and the growth of unemployment can be seen as factors reinforcing the industrial logic within the decisions of the Commission, but they also contribute to strengthening the financial perspective and the pressure to lower the prices of medicines and optimize the savings of the health insurance system. Thus the balance between public health, financial, and industrial rationales in the assessment of medicines, far from being static, evolves notably based on ministerial guidance, rules elaborated by the Commission, and their use by public and private actors.

## Conclusion

Two conclusions in particular stand out from this study of the pricing policy conducted by the Economic Commission

for Health Products. The first is consistent with the work that has been done in economic sociology on the architecture of prices (Chauvin, 2011 and 2013). In the French medicine market a multiplicity of prices can be seen, the form, the status and the use of which vary significantly. We have seen that the system of rebates leads to a differentiation between the official price, written on the box, and the price actually paid by the health insurance system (Aspers and Beckert, 2011). This gap between the two prices is explained both by the capacity of the Commission to negotiate rebates with the laboratories, and by the eagerness of the latter to display a consistent (if not unique) price across the European (if not global) markets. While price fixing remains a national prerogative within the framework of the European Union, decisions in terms of price increasingly fall into a network of cross-references that tend to homogenize them. But the policy adopted in France (as in the majority of European countries) tends to create a price hierarchy based on the degree of innovation of the medicine, since the medicines judged to be of little innovation or that have been on the market longer are subject to strong policies of price competition aiming to reduce their costs for the collective and for individuals.

Our second conclusion emphasizes the need to further refine research on price controls as an instrument of governing markets. Studying the activity of the Commission has allowed us to identify three methods of using prices to govern the market: a rationale of valuing public interest, a rationale of planning health expenses, and a rationale of regulating the market and the industry. But, if the Commission offers without a doubt an ideal-typical case of price fixing, the examples of direct or indirect State intervention in prices are numerous, whether in terms of salary policy (e.g. minimum wage), financial policy (e.g. interest rates on savings accounts), or tax policy on activities “in the public interest” (e.g. electricity, water, gas...) or again on highly symbolic goods (e.g. tobacco, books, bread...). The systematic study of price policies developed in these different sectors should allow for the refining of the typology that we have outlined here and for more thinking generally about prices as a significant instrument of governing markets.

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## Endnotes

<sup>1</sup>The term also refers to drugs aimed at treating diseases suffered primarily in poorer countries, where the potential return on investment is low. In the European context, it is the first definition which is more relevant.

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