The Fall of the French Drug Agency

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1. Introduction

One of the reasons for creating agencies is to enable experts to objectively decide on cases without political interference and thereby reduce decision making costs[3]. But at what costs? More than a ministry, an agency is exposed to the danger of capture by third parties, such as industrial corporations[4]. What possibilities do governments have when they have to keep their distance, but want to maintain independence in decision making by the agency? A medical scandal involving hundreds of fatal victims has resulted in the search for an organisational equilibrium where the advantages of an agency are kept, while keeping the industry at bay.

An anti-diabetic called Mediator caused a number of fatal victims among French users; estimates vary between 500 and 2000. Despite a number of warnings for negative side effects, the drug was allowed on the French market. The manufacturer of the drug, Servier Laboratories, was accused of 'capturing' the responsible agency for market authorizations. This paper examines the case and analyzes the responses of the French government during the aftermath of the scandal. We will elaborate on a description of the government's reaction and analyze whether the measures that were taken will be adequate to prevent future problems. The paper shows that the government has done as much as possible within structural constraints, but nevertheless, some of the structural weaknesses of the system governing drug authorizations were left intact. Although different actors argued in favour of a reministerialization or a repolitization of the task, the government did to go further than providing a 'regulatory toolkit' to the agency that should keep the industry at a distance. Fundamental change of the system would be too costly for the public budget.

The material on which this work is based is mostly constituted by the official reports written in the aftermath of the crisis in order to propose ways and means to restore confidence in the safety

[3] Majone, G. (2001) Two Logics of Delegation : Agency and Fiduciary Relations in EU Governance. *European Union Politics* 2: 103.

[4] See : Dal Bó, E. (2006). Regulatory Capture: A Review. *Oxford Review of Economic Policy*, *22*(2), 203 -225; Wilson , J. (1989) *Bureaucracy. What Government Agencies Do and Why They Do It.* New York : Basic Books.

of French sanitary system, either at the request of the government either at the own initiative the concerned authorities. This paper continues with four parts: a second part is dedicated to an analysis of the institutional framework of the French sanitary agencies system (2); a third briefly exposes the Mediator affair (3), and a fourth describes the examines the changes it caused, and analyzes why these changes occurred. (4). We will conclude the paper with a short discussion of the modifications that have been made to the agency.

2. The context: the French sanitary agencies system

This part describes the institutional context of the French system by addressing three points: the origins of the French sanitary agencies (2.1); the rationale and the (ir)rationale according to which the system was set up (2.2) and a presentation of the French Medicine Agency as it was at the moment the scandal erupted (2.3).

2.1 Origins of the French sanitary agency system

As in many other countries, there is a long tradition of public bodies concerned with public health in France. But the management of these bodies escaped the control of public managers; instead, it can be argued that the French sanitary system was mostly ruled by the medical profession. At the central level, the ministerial administration in charge of the general management of the system failed to establish its legitimacy vis-à-vis the medical community, which was traditionally very suspicious of any administrative action toward it and *a fortiori* to any kind of administrative supervision.

The situation changed in the 1980s. Public authorities realized that they had insufficient tools, not only to ensure epidemiological monitoring and investigating, but also to monitor public

health and to manage sanitary crises. Therefore, an expert agency was set up, working in close contact with the health sector.

The creation of agencies outside the central administration to deal with the lack of expertise and the capacity to react adequately seemed an excellent solution for at least two reasons. First, the agency was deemed more pertinent than ministerial administration to gather expertise and to build decision support service. Second, the agencies were considered as much more likely to associate the medical professions with the tasks than the ministry would, and to assure room for autonomy and self-regulation. In this respect, the French government closely followed the global trend to agencification in this sector.[5]

The system of sanitary agencies was under construction when, in the 1990s, serious health crises occurred, such as the contaminated blood crisis[6] or the "mad cow" crisis[7]. These crises reinforced the tendency to use agencies. It was argued that the ministry was responsible for mismanagement, as well as creating the conditions under which these scandals could occur. The ministry had failed in its duty to monitor and control public health, it failed in the way in which scientific expertise was formulated and circulated, and lastly, it let economic interests to prevail over public health goals. To all these shortcomings, creating an agency was considered to be the solution.

As a consequence, at the turn of the century, the French sanitary system consisted of a ministerial administration in charge of policy design and the adoption of very few decisions, while most of the implementation was left to numerous and powerful agencies in charge of expertise and most of the sanitary regulation.

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[5] Pollitt, C., & Talbot, C. (Eds.). (2004). *Unbundled Government: A critical analysis of the global trend to agencies, quangos and contractualisation*. London Routledge.

[6] Feldman, E. (2000) Blood Justice: Courts, Conflict, and Compensation in Japan, France, and the United States, *Law and Society Review* 24(3): 660

[7] Ansell & Vogel (Eds). (2006) *What's the Beef? The Contested Governance of European Food Safety* Cambridge, MA: The MIT Press; Holland, D & Pope, H, (2004) *EU Food Law and Policy* The Hague: Kluwer International Law

2.2 The rationale and the irrationale of the French sanitary agencies system

The sanitary agencies system is based on three principles, even though these were never clearly formulated.

The first principle is the distinction between the bodies in charge of expertise and health risk regulation, and those in charge of health risk management. The bodies in charge of multidisciplinary expertise in health and regulation of the health risk are all agencies, while the bodies in charge of the risk management operate from within the ministry, i.e. not as an agency. Risk management is therefore the responsibility of the central government which, according to the advice given by the agencies, is responsible for taking appropriate decisions. Other systems, like the U.S. system, are different. In the U.S. risk assessment and risk management of food and health products are the competence of one single agency, the Food and Drug Administration.

The second principle is the distinction between risks and economic regulation. The evaluation and regulation of risks in a determined sanitary sector (especially the evaluation of the risks of food and health products for health) is assigned to certain agencies and the economic regulation of the same sector is assigned to others. It is argued that this distinction is a condition to ensure the impartiality of the health decisions: the agencies in charge of the assessments has no further competencies for setting the price of a medicine (if the medicine is submitted to a forced price) or setting the amount of its reimbursement by the social security. In short, the setting of the safety rules and their implementation is separated from the setting of social security rules and their implementation.

The context examined above and the implementation of the two first principles leads to the creation of several agencies. But the landscape of the agencies has not been designed as a comprehensive and structured system. In other words, between the structural context and the

very general principles on the one hand and the creation of the sanitary agencies from the other hand, an intermediary step (a roadmap for example) was missing.

The creation of agencies was sometimes made from scratch (as the National Agency for Research on AIDS and viral hepatitis), but has more often resulted from merging or modification of structures already existing. The result is a stack of institutions created, modified or merged at the whim of crises. The respective scopes are not always clearly identified and often overlapping one another. Their public financing comes under various missions' budgets[8].

A telling example of the absence of an structured design involves the estimation of the number of agencies involved in the sanitary sector. The website of the Ministry of Health says that there are about ten sanitary agencies financed through the budget's programme called *Prevention, sanitary safety and care delivery* (LOLF's Mission *Health*). Parliamentary reports dedicated to the Mediator issue considered a wider area and identified eighteen sanitary agencies or organizations. The public audit body for sanitary affairs identified fourteen sanitary agencies.

The third and last principle is that the sanitary agencies and especially the medicines agency rely on external expertise to issue their decisions and advices. The outsourcing of expertise is very rare amongst other national or European bodies in charge of the medicine expertise. Most of them rely on internal expertise. Internal expertise may have its limits (it is costly as the agencies have to hire experts at market price, or almost, and the public expertise may lead to closure from the market innovations or new approaches) but it is nevertheless less likely to be captured by the industry. The choice made by the French system is contrary to the traditional desire of the state to have internal expertise at its disposal in most of the policies.

The system is thus built upon a number of structural separations among different agencies that perform different tasks. At the same time, the knowledge needed is in contrast to practice in other countries, is found outside the agencies. Therefore, the system had several

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security mechanisms built in, yet was still exposed to capture by third parties. Before we elaborate on this exposure, we will first turn to the specific agencies involved.

2.3 The Drug Agency

Medicine regulation (or more exactly the health products regulation) is a subsector of the sanitary regulation. To examine the case, we investigate three agencies at the heart of this field: the French Agency for the Safety of Health Products (AFSSAPS), the High Authority of Health, and the Economic committee of health products. These three agencies constitute what is called the "medicine chain" which runs from the evaluation of any new medicine (or the reevaluation of older ones) according to several standards (scientific, risks for human health…) to the amount of its reimbursement by the public founding (the "social security") through its marketing authorization.

The AFSSAPS is at the core of the process. Its two main tasks are first to evaluate the safety of the drug on the basis of risk / benefit ratio in order to deliver marketing authorizations (limited to the domestic territory), and second, to evaluate the effects of the medicines authorized (pharmacovigilance or drug monitoring). As to the first task, a technical commission (CTCAMM) is in charge of evaluating the benefices / risks ratio of the pharmaceuticals according to three criteria (quality, security, effectiveness) without any economic consideration. The marketing decisions are adopted by the general director of the agency under CTCAMM advices. The authorization may be subjected to conditions. As to the drug monitoring tasks, the Medicine Agency is the final recipient of the information related to the adverse effects of medicines observed by medical doctors and other medical professionals. Such information, gathered by a network of thirty bodies distributed throughout the country, is examined first by technical committees and second by a national commission. The general director of the agency decides, upon the above advices, to maintain, suspend, withhold or modify marketing authorizations.

The agency employs almost 1000 FTE. It relies on more than 2000 external experts (regular or occasional) spread in eleven commissions, two committees and 47 working groups. Its internal organization counts five scientific directions, three management directions and two transversal units. The agency adopts some 80 000 administrative decisions yearly, 2000 of which are marketing authorizations of medicines. Every year, it starts 1 900 clinical trials, leads 800 investigations and controls 10 000 advertisings. Its budget of around 120 million euros is financed at 80% by fees and charges levied in connection with its main decisions and therefore paid by the industry.

The second agency is the High Health Authority. Among several tasks, it is in charge, through its Transparency Commission, to assess the medical benefit (SMR) of pharmaceuticals and possibly their improved medical benefit (AMSR), according to several criteria (such as the severity of the disease the product is aimed at, its side effects, its position in therapy strategy, etc.). According to its advice, the ministry formally lists the pharmaceutical as reimbursed.

The third agency is the Economic committee of health products, an inter-ministerial body under the joint supervision of ministers responsible for health, social security and the economy. It sets drug prices, after negotiation with pharmaceutical industry and after consultation with other stakeholders.

3. The Mediator affair

In the fall of 2010, a medicine called Mediator became increasingly suspected to be the cause of hundreds of deaths in France (estimates vary from 500 to 2000) during the past thirty years. Mediator was admitted to the market as an anti-diabetic in 1973. But both public and private investigations brought to light that Mediator was subjected to warnings and adverse evidence under routine drug monitoring and during the process of authorization renewal and that none of these warnings led to the prohibition of the drug. In the meantime, Mediator was withdrawn

from other markets (e.g. Italy and Spain). Apparently, the security mechanisms at the core of the agency mission had not worked. In November 2009, the amount and the pertinence of evidence gathered *outside* the Agency (by a research team of a Brest's public hospital and by the National Fund of Health Insurance) lead the Agency to suspend the marketing authorization of the Mediator, 33 years after the authorization was released.

The public audit body for sanitary affairs (IGAS) reported that the "agency's incomprehensible tolerance toward Mediator" was due to the inside influence of the pharmaceutical firm which created the Mediator's active substance, the Servier Laboratories. This influence took two forms. The first was a "legal" one, but stretched to its extreme, and probably constituting an abuse of process. The drug monitoring processes and the renewal of marketing authorization processes (the former being conditioned by the latter) are characterized by the pursuit of scientific consensus. Consequently, facing the growing doubts about its pharmaceutical, the Servier Laboratories repeated the pharmaceutical trials (for which it legally paid for) and used any "defense's rights" legally available in order to create doubts about the reservations toward Mediator's "side effects". Even if an increasing number of experts were concerned, the lack of consensus hindered the suspension or the withdrawal of the authorisation. The second form of influence was much more proactive and probably illegal: the public audit body for sanitary affairs evoked falsified documents submitted to the Agency's commissions.[9]

4. Aftermath: a way to redemption?

In this section, the modifications made to the system will be discussed. In the first part, we will describe the methods of data collection (4.1). The second part addresses the constraints that were caused by the institutional context (4.2), followed by the modifications in the relation with the

[9] Reference follows

ministry (4.3). Finally, in the fourth part, we discuss the provisions made that should lead to a greater distance between the agency and the industry (4.4).

4.1 Data Collection

The following analysis is based on a set of reports that has been written during the aftermath of the scandal. A first set of reports was written by the French public audit body for sanitary affairs (Inspection générale des affaires sociales, IGAS) at the request of the health ministry: Investigation on the Mediator, 15 January 2011[10]; and Sanitary expertise, April 2001 and Drug monitoring and drug's chain, 21 June 2011[11].

The President of Republic asked two medicine professors to write a report on the overhaul of the French system of monitoring the effectiveness and the safety of medicines[12]

Both chambers of Parliament used their own investigative powers and gathered information on the Mediator and the drug monitoring. The Chamber and the Senate published their reports respectively on the 22 June 2011[13] and the 28 June 2011[14]. Another Chamber's investigation was especially dedicated to investigate the sanitary agencies and released its report on 6 July 2011[15].

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[10] « Enquête sur le Médiator® » http://www.igas.gouv.fr/spip.php?article162

[11] pharmacovigilance et gouvernance de la chaîne du médicament http://www.igas.gouv.fr/IMG/pdf/RM2011-103P_pharmacovigilance-2.pdf

[12] Rapport de la mission sur la refonte du système français de contrôle de l'efficacité et de la sécurité des médicaments du Pr Debré, député de Paris, et du Pr Even, Président de l'Institut Necker remis au Président de la République le 16 mars 2011.
http://docs.google.com/viewer?url=http://www.institutnecker.fr/images/stories/institutnecker/documents/rapport2011.pdf

[13] Rapport de la mission d'information de l'Assemblée Nationale sur le Médiator® et la pharmacovigilance du 22 juin 2011 http://www.assemblee-nationale.fr/13/rap-info/i3552.asp

[14] Le rapport du Sénat fait au nom de la mission commune d'information : « Médiator® : évaluation et contrôle des médicaments » du 28 juin 2011 http://www.senat.fr/rap/r10-675-1/r10-675-11.pdf

[15] Le rapport de l'Assemblée nationale en conclusion des travaux de la mission sur les agences sanitaires du 6 juillet 2011 http://www.assemblee-nationale.fr/13/pdf/rap-info/i3627.pdf

After the release of the above mentioned IGAS reports, the Minister for Health launched a broad consultation on the overhaul of the safety system of health care products. The consultation, called "drugs' forum" (*assises du médicament*) brought together health professionals, patient groups, regulators, whistleblowers, academic expertise, healthcare industries and qualified persons. A synthesis report was made public on 23 June 2011[16].

Other material used includes two sets of parliamentary reports: first the parliamentary reports (including the impact study) accompanying the adoption of law n° 2011-2012, 29 December 2011 on strengthening the safety of the drugs and of the health products which revamped the French medicine agency[17] and second the parliamentary reports accompanying the adoption of the 2012 (general state) budget act[18] and of the 2012 (social security) budget act[19]. Both acts profoundly change how the agency is founded.

4.2 Answering the scandal in a constrained framework

The Mediator scandal caught the French administrative system unprepared. It also hit it at its deepest core.

During the last two years, the French State engaged itself in a reform aimed at strengthening the management of its agencies and at reshaping its relationships with them[20]. All the agencies are concerned even if the reform is more incisive towards the executive agencies than the independent (fully regulatory) agencies. The aim is to settle a better balance between autonomy and control: enough autonomy to ensure improved efficiency but enough control to

[16] Le rapport de synthèse des Assises du médicament du 23 juin 2011. http://www.sante.gouv.fr/rapport-de-synthese-des-assises-du-medicament.html

[17] Loi n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé publiée au Journal Officiel du 30 décembre 2011

[18] Loi n° 2011-1977 du 28 décembre 2011 de finances pour 2012.

[19] La loi n° 2011-1906 du 21 décembre 2011 de financement de la sécurité sociale pour 2012.

[20] Ref on the reform

ensure the implementation of the public policies and to avoid "usual" agencies' problems such as, for example, inefficiency. But none deals with the place and the role of the regulated sectors within the agencies and even less faces the cases of capture by the industry. The Mediator scandal imposes to tackle the agencies' issue from a different perspective. The main problem is no longer the independence of the agency from parent ministry but a matter of independence –from the industry.

In France, from a theoretical point of view, the public interest should be prioritized above the other interests, and especially, above the private interests. From a practical point of view, the French administrative system should enforce this supremacy. The report of the Public audit body for sanitary affairs (IGAS) on the Mediator scandal pointed to the inability of the French Agency to produce scientific expertise that was independent from the expertise developed by the laboratories. The report describes the agency as "structurally and culturally in a conflict of interest [originating from] an institutional cooperation with the pharmaceutical industry leading to a form of institutional co-production of expertise and of the resulting decisions"[21].

In the aftermath of the outrage, many voices called, therefore, for major changes in the agency based medicine regulation. The debates lasted throughout the year 2011. They were fuelled by the many reports quoted above (part 1), even if, without waiting the publication of all of them, the government introduced a bill on the 1st of August 2011. The project was amended on several aspects by the Parliament but not profoundly modified. Eventually, on 29 December 2011, the law n° 2011-2012 *on strengthening the safety of the drugs and of the health products* was adopted. The reform is large and complex. Here, only the aspects related to the use of the agency formula are analyzed. The numerous other provisions related to other aspects of the reform (protection of whistleblowers, reinforcement of drug monitoring, etc.) are not taken into consideration.

The government made the 'choice' to stay within the structural limits of the existing system, that is, to rely on the industry's money and expertise to regulate the sector. This was

21

contrary to the recommendation of the Public audit body on sanitary affairs (IGAS) and to the wish of many MPs who advocated the creation of a true in-house expertise for the evaluation of the medicines[22]. But the government had no other possibility, for it would be too large a burden on the public budget. Especially, the introduction of the radical change auspicated, the setting up a true internal expertise within the agency, was not taken into consideration, except on a very limited scale (see point 4.4.2). A larger extent of internal expertise by hiring more civil servants would have resulted in an unbearable burden for the public budget as the industry's funding of the agency would have to be substituted by public funding. In this constrained framework, the government and Parliament nevertheless tried to limit the industry's influence. The first modification was a symbolic one. To mark its willingness to introduce deep changes, the government proposed to recreate the old AFSSAPS under the new name National Agency for the Safety of Medicines and health products, Agence nationale de sécurité du médicament et des produits de santé (ANSM).

Under French constitutional law, the powers of the parliament are limited regarding administrative organizations. Only some main aspects can be dealt with, including the global design, the coercive powers and the powers to impose sanctions and penalties attributed (if any), and the funding. Legal power over the other elements is attributed to the executive branch. In order to politicize the scandal, parliament used its power at the maximum (and even further). Consequently, the law creating the newly created drug agency ANSM contains more elements than laws that create other executive agencies. Yet, the implementation margin left to the executive remains wide. The scope of the reform will be more precisely analyzed after the adoption of the implementing decrees[23]. It is clear, though, that the main solution to the problem is the provision of more policy instruments to the agency, in order to prevent future scandals

22

23 These decrees are expected in early 2012

from happening. In the following sections we will describe in greater detail what structural and functional changes were implemented.

4.3 Unchanged distance from ministry level

As explained above, the relationship between the Agency and its parent ministry and also the relationship between the three agencies involved in the medicine regulation were not at the core of the discussion. So the attempts made by some to bring the agency back in the ministry and closer top the political level were limited. Most of the reports estimated that the general architecture of the agencies was consistent and that the changes should focus within the agencies and especially within the Medicine Agency. The report issued by the National Assembly asked not "for a global institutional remodelling but for an internal renewal of the agencies involved"[24][25].

4.3.1 No (Re)ministerialisation

A radical solution would be the (re)ministerialisation of the medicines regulation, as it offered no possibility to closely associate the stakeholders and the industry. However, this option did not receive any serious attention. Moving away from the agency idea was out of the question.

4.3.2 No reintroduction of a political dimension in the policy field

The reintroduction of a political dimension in the policy field was more seriously prospected. The health affairs ministry and parliamentary reports openly evoked it. The Senate's report insisted on

24

25 Besides, the calls for better coordination with the other agencies and improved supervision from the ministry will probably be taken into account in the futures implementing decrees.

the outmost importance to create information circuits making the ministry aware as quickly as possible of serious medicine related health problem[26]. The ministry itself declared in front of the social commission affairs of the Assembly that political responsibility cannot be delegated to the agency[27].

Two possibilities were taken into consideration but eventually given up. The first was to provide the ministry with a possibility to make an appeal to the decisions made by the agency. But the amount of the decisions adopted by the agency (especially the 2000 marketing decisions issued every year) made the idea not practicable. The problem was no much the number in itself, which would reduced by filtering important decisions, but the possibility for stakeholders to consider it as the last stage of the decision making process, rather than a mechanism to repair special decisions only.

The second was to introduce MP in the board of the agency. This solution didn't last for long either. The main *contra* argument was that the Medicines Agency was an executive agency under the joint supervision (*tutelle*) of several ministries and not an independent regulatory agency. Therefore the presence of MP into the board could have been interpreted as breach of separation of powers principle. In a similar vein, it was also advanced that if MP nevertheless serve on such boards, parliamentary internal regulations obliges them to serve as "members" of their assemblies and not "representatives" of their assemblies.

4.4 Greater distance from the industry

The efforts made by the government and the legislator to drive the influence of the pharmaceutical industry away from the work of the Agency took two directions: procedural

26

27 September 2011.

changes at all levels of the Agency functioning (4.3.1) and procedural change for the Agency's funding (4.3.2).

4.4.1 Functional and procedural changes

The new legislation contents four major procedural changes: the withdrawal of industry's representatives from the board of the Agency; increased transparency requirements of agency's activities; overhaul of the Agency's committees and of their advices or decisions making procedures; new and extended power to sanction the violation of the Agency's regulations.

The government proposal modified the composition of the board of the agency by augmenting the representatives of the medical professions and of users. But, during parliamentary work an MP's amendment withdrew the representation of the industry from the board. The government made no attempt to restore it. This measure is more symbolic than substantive as the capture by the industry was merely made at committee level rather than at board level.

Increased transparency is required for almost all the activities of the agency. The lack of transparency of many of the agency's activities was heavily criticised, even if internal transparency regulations were nevertheless in force. Some commentators noted that these regulations may well have included shortcomings, but the scandal would probably not have happened if they had been met. Yet the government and the legislator chose to put in place new transparency rules much stricter in two areas.

The first is the reinforcement of the statements of interest and of the conflicts of interest provisions. Public statements of interest are made compulsory and systematic for all the health stakeholders concerned: health professionals, external experts, internal experts, patients' groups, the staff of the Agency. A single and common form has to be used by all health agencies. The statements must be available through on line databases. An ethics resource group is created to

manage these issues. Negative consequences are also set in case of breach of interests provisions. Failure to report interest may, amongst other things, lead to penalties, inability to be committee member, illegality of the committees' decisions the expert was associated with.

The second is the introduction of a sunshine clause: agreements between companies on the one hand, and other health professionals, associations of health professionals, medical students, patients associations, foundations, academic associations, specialised publishers involved in these sectors on the other hand have to be made public by the industry. The agency may impose sanctions if these reporting requirements are not met. Transparency requirements do not apply in limitedly enumerated cases (such as commercial confidentiality). Commentators made clear that if the exceptions are too loosely interpreted, they may restrict the scope of the general principle of transparency in a way not contemplated by the government and the Parliament[28].

The many and often overlapping committees of the Agency are profoundly revisited in their structure and their functioning. The composition of the agency's committees is modified and open to non-specialists. These include medical doctors specialized in a different field from whom the health product concerns and qualified individuals such as representatives of patients associations. The number of committee members is reduced and their memberships are limited to a duration of 4 or 5 years. The new committees are also submitted to increased transparency requirements: publication of agendas and minutes of meetings within two weeks, collection and publication of minority opinions, video recording of the meetings. More clarification of the respective roles, missions, and coordination arrangements will be indicated in the implementing decrees.

Lastly, the government and the legislator granted the Agency with a new set of powers related to sanctions encompassing both administrative and financial penalties in the case of breach of the Agency regulations by pharmaceutical companies (by example for failing to report

[28] Reference needed

adverse reactions of pharmacological studies). It has to be noticed that the Medicine Agency is henceforth the only French executive agency endowed with so wide spread sanction powers. Usually such powers are more likely attributed to full legal regulatory agency (named *autorités administratives indépendantes*). But we can also argue that, according to functional approach, the new French medicine agency is provided with powers that make it a regulatory agency regardless of its formal ties with the executive.

4.4.2 New procedure for the funding: "dirty money from cleans hands"?

The general budget act for 2012 and social security budget act for 2012 introduced two other changes in the agency's new design.

The first is a budgetary effort to increase the amount of internal expertise of the agency by recruiting around twenty high-level experts (pharmacologists, epidemiologists, statisticians). This effort will be not sufficient, as it cannot create a critical mass of internal expertise vis-à-vis the external expertise that the new Agency still massively relies on (around 2000 experts).

The second is a major change in the funding structure of the agency. It may be considered as a technical trick but it is altogether a major step forward. In past years, the financial revenue of the agency have been characterized by an increasingly large share of the taxes and charges levied on the industry (annual tax on sales of drugs, annual tax on medical devices, progressive fees on the marketing authorisations, etc.), and a symmetric decrease of State subsidies[29]. The taxes and charges were directly paid to the Agency. It was acknowledged that this funding procedure was likely to introduce doubt about the independence of the agency vis-à-vis the pharmaceutical industry[30]. The reform reroutes the collection of the taxes and charges[31].

[29] Recall, in fact, no subsidy to support public service has been paid to the agency by the Finance Act 2011, unlike previous years: the state claiming that the revenue related to taxes permissions on the market enough to balance its budget.

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Their collection will no more be made by the Medicine agency but by another one, the National Fund for the Health Insurance of Salaried Workers, which has no relationship with the industry. In the meantime, the State subsidies assigned to this Fund (percentage of sector related VAT) are proportionally reduced. Lastly, the State directly subsidy the Medicine Agency with the equivalent of amount of the taxes and charges paid by the industry to which is added the financial effort reported above. As a result, State subsidy to the Agency was 9,8 million euros in 2010. It is expected to reach 134,9 million euros in 2012.

5. Conclusion

This paper was an effort to look into the possibilities for the government to react and find a solution after the Mediator crisis in France. It showed that changing the fundaments of the institutional structure that was built up around the drug agency comes with high costs. Although several members of parliament wanted a much more extensive reform, such as the reministerialization of the agency, these costs prevented such a solution. Yet, the nature of the agency was changed indeed. In contrast to other executive agencies, the new drug agency is provided with regulatory and sanction powers. This implies that the agency has *de facto* become a regulatory agency, despite its links to the ministry. The logic of delegation, lowering decision making costs, remains intact and became even more visible through this specific case.

Furthermore, the government and Parliament wanted to "disconnect the agency from the pharmaceutical industry"[32]. In order to do so, an impressive toolkit was provided at the disposal of the agency which could be adequate to prevent future scandals, provided that the contents of the implementing decrees go in the same direction. But with no true internal expertise and consequently with an industry that remains in the central position of co-regulator, the reform

[31] Law n ° 2011-1906 of 21 December 2011 financing of social security for 2012, Section 26.

[32] According to the expression of Jean-Yves Grall, director general of health at the ministry of social affairs.

didn't address the structural weaknesses of the system. Only a proactive implementation of the regulations and their toolkit by Agency's staff can conjure the sanitary safety of health products to be put at risk again.

The agency remains in a position where the power of the industry's money will have to be countered with regulation. Although some experts have argued that with the existing rules at its disposal, the agency could have been able to prevent the scandal from happening. However, armed with a more extensive toolkit of policy instruments, the agency might be more willing to use its capacities. Nevertheless, whether the agency will do so remains to belong to the organization's discretionary room.

At a more general level, it is open for future research whether arm's length control can actually be designed in such a way that capture will not happen. The present study indeed points to possible threats to agencies. At this moment, however, it remains unclear to what extent these threats can be generalized to other agencies in other countries and other policy fields. A greater distance from the parent ministry might also include less protection from outside pressures, and therefore, should increasing autonomy arguably be compensated with some sort of guarantee of independence – but: at what cost?