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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from France

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- France ¹--

Introduction

1. The Autorité de la concurrence (hereinafter “the Autorité”) has a well-fuelled contentious and consultative practice in the healthcare sector. This practice was consolidated by the Conseil de la concurrence, which the Autorité succeeded in 2009, in a thematic study published in its 2008 annual report.

2. Since then, several decisions and important guidelines have been adopted by the Autorité in the healthcare sector, and in that of medicines in particular.

3. The following developments are based on the Autorité’s recent consultative and contentious practices within this sector. The sectoral opinion recently published by the Autorité is set out first². This is followed by a discussion of the recent cases of denigration of generics by Plavix®³ and Subutex®⁴.

1. The sectoral inquiry into medicines

4. For some years now, the health sector has been undergoing changes in terms of both innovation and the reorientation of research towards biotechnologies, the development of generic and bio-similar medicines, the budgetary constraints of the Assurance-Maladie (the French State Health Insurance Fund) and the new challenges faced by *officines*, or dispensing chemist’s.

5. These changes, along with the impact of healthcare expenditure on the national economy⁵ and the questions raised by ongoing disputes and the development of the legislative and regulatory framework led the Autorité to begin an ex officio investigation on 25 February 2013 into the sector of the distribution of non-hospital medicines for human use. The first results of this sector enquiry led to the publication on 10 July 2013 of a public consultation document, inviting players in the sector to give their reactions to the Autorité’s interim findings. The public consultation came to an end on 16 September 2013 and the

¹ The Autorité de la concurrence is an independent authority and the opinions expressed in this contribution are its own personal ones.

² Opinion 13-D-24 of 19 December 2013 on the functioning of competition in the sector of distribution of prescription medicine for human use. The final text of the Autorité’s opinion is available online via the following link: <http://www.autoritedelaconcurrence.fr/user/avisdec.php?numero=13-A-24>.

³ Decision 13-D-11 of 14 May 2013 on practices in the pharmaceutical sector, available online via the following link: <http://www.autoritedelaconcurrence.fr/user/avisdec.php?numero=13-D-11>.

⁴ Decision 13-D-21 of 18 December 2013 on practices in relation to high-dosage buprenorphine sold on the French market via private practice, available online via the following link: <http://www.autoritedelaconcurrence.fr/user/avisdec.php?numero=13-D-21>.

⁵ Current healthcare expenditure totalled 243 billion euros in 2012, namely 12% of GDP. The consumption of medicines per French person in 2012 amounted to 525 euros, with the reimbursement of prescription medications by the Health-Insurance Fund over this period totalling 22.66 billion euros.

Autorité's final opinion was published on 19 December 2013. This sectoral opinion falls within the scope of the Autorité's consultative practice and its role in relation to the promotion of competition policy. Its aim was exclusively to carry out a diagnosis of competition, without the Autorité seeking, within this framework, to establish breaches of competition rules.

6. The Autorité's conclusions are in particular based on an analysis of the regulations in force within the sector, along with a monitoring of the economic and sectoral issues to which the players in question are subject, and on a reminder of the decision-making practices of both the Autorité and other European and American competition authorities.

7. These conclusions are set out below for each category of stakeholder involved in the distribution of non-hospital medicines for human use, namely pharmaceutical laboratories, intermediaries and dispensing chemists.

1.1 The pharmaceutical laboratories

8. Within the context of the aforementioned sectoral opinion, the Autorité stressed the importance of innovation in the pharmaceutical field, a factor which strengthens competition between companies and constitutes a source of employment in the sector. It also stressed the role that generics can play, by encouraging the originator companies to maintain sustained research and development activity (hereinafter "R&D"). It specified in its conclusions that generics allow the State Health Insurance Fund to make savings and thus offer higher payment or reimbursement for innovative medicines.

9. Taking into account the current economic context in which the pharmaceutical laboratories are operating, the Autorité has issued a series of guidelines aimed at identifying the areas of exercise of its competence in the sector.

1.1.1 The report to the authorities

10. The medicine channel is regulated in France from the granting of marketing authorisations (hereinafter "MA") to the fixing of the price and reimbursement rate (for medicines reimbursed by State Health Insurance Fund).

11. Within this administrative process, the Autorité has nevertheless identified a series of areas where competition can be exercised and in which it could theoretically become involved, should any of the players demonstrate anticompetitive behaviour.

- The procedure for establishing prices

The price of each reimbursable medicine is established in an agreement entered into between the Interministerial *Comité Économique des Produits de Santé* (Economic Committee for Healthcare Products - hereinafter "CEPS"), and the laboratory selling the proprietary medicine in question. These negotiations are based on an assessment of a set of criteria, and in particular the improvement of actual benefit offered by the medicine in question. The costs incurred by the laboratory are, to a certain degree, likewise taken into account by the CEPS in its assessment of the product's price.

However, the Autorité has observed that upstream of this procedure of negotiation with the authorities, some laboratories selling competing proprietary medicines, which may for example belong to the same therapeutic class or the same group of generic medicines, could, in certain cases, work together on the parameters for establishing the prices of their proprietary medicines. For example they might reach agreement on their manufacturing cost levels, with a view to

getting higher prices in their negotiation with the CEPS. Such coordination might be liable to constitute anticompetitive practice.

- The procedure for granting MA

While the Autorité does not consider itself competent to pass judgement on disputes of a scientific nature, where responsibility lies with the health authorities, it has nonetheless indicated that its competence should not be excluded when it comes to looking into coordination between laboratories in relation to the details of their MA applications. It could for example take action in situations where proprietary medicines sold by two laboratories have partially equivalent therapeutic scope. If the laboratories in question were to reach an agreement in order not to compete in the shared therapeutic domain, the Autorité could then consider such an agreement as equivalent to the dividing up of a market between competitors.

- The duration of the procedures

Delays in the procedures for granting MA or establishing prices are often of administrative origin. However, the Autorité has pointed out that its competence should not be excluded when assessing behaviour adopted by undertakings aimed at slowing down administrative procedures and consequently delaying the entry of competitors (for example generics) onto the market⁶.

- The strengthening of exchanges between authorities

Inspired by existing practice between the FTC and the FDA in the United States, the Autorité has stated that it would be in favour of strengthening its exchanges with healthcare authorities, and in particular with the *Agence nationale de sécurité du médicament et des produits de santé* (National Agency for the safety of medicines and healthcare products, hereinafter “ANSM”), which is in charge of granting MAs at a national level.

1.1.2 *The risk of denigration of generic medicines*

12. In France generics suffer from a degree of suspicion on the part of patients and some healthcare professionals, which certain institutions and private players sometimes help to maintain. This suspicion can in some specific circumstances constitute an essential support device for the implementation of a denigration strategy spearheaded by a pharmaceutical laboratory against generics that provide competition for an originator whose patent is set to expire.

13. This then becomes a case of anticompetitive denigration. Such behaviour is liable to constitute the abuse of a dominant position.

14. In this area, the Autorité recently condemned practices of denigration in two cases concerning the Plavix® and Subutex® generics referred to above (these cases are presented in detail in the second part of this document).

15. The Autorité has consequently put forward a number of recommendations within the context of its sectoral opinion, aimed at preventing denigration strategies. In them, the Autorité suggests that public campaigns are regularly held to highlight the effectiveness of generics, that the training of doctors in pharmacopeia is increased and that pharmaceutical laboratories adopt good practices (in particular through

⁶ See case T-321/05, *AstraZeneca v/ Commission*, judgement of 1 July 2010 and Case C-457/10, *AstraZeneca AB and AstraZeneca v/ Commission*, order of 6 December 2012.

their competition law compliance programmes) aimed at preventing the adoption of denigration strategies by their sales teams, etc.

1.1.3 Prices and reimbursement of generics

16. The Autorité has also denounced the systematic exceeding by generic laboratories of the level of maximum discounts authorised by law. The fact that they do this can be attributed to exacerbated competition between the numerous generic laboratories that exist in France. Dispensing chemists have low stock capacity; on average they do not hold more than one or two ranges of generics. The laboratories with the most attractive discounts therefore have more chance of being chosen by a dispensing chemist.

17. However, these major discount rates can be indicators that prices of generic medicines are too high and could consequently be renegotiated at a lower rate by the CEPS. There has been a legislative response to the Autorité's concerns on this subject by introducing an obligation on the part of generics laboratories to declare to the CEPS the levels of discounts offered to dispensing chemists and allowing an increase by law to the legal level of these discounts, up to a maximum of 50%⁷. Monitoring these measures will make it possible to establish their real effect on the prices of generics.

18. Furthermore, the Autorité has also issued some reservations with regard to the generalisation of identical reimbursement for an originator and its generics. Indeed, the much lower prices of generics constitute their main attraction from the point of view of consumers. In the case of identical reimbursement, it is observed that the prices of originators and generics tend to align. In this situation, consumers favour the originator, particularly on the basis of its brand reputation.

19. It may therefore be, in the case of such a generalisation, that the originator's market share may rise, to the detriment of the generics that could not then hope to enter certain markets. The originator would then find itself in a monopoly situation on these markets, which would allow it to impose higher prices on CEPS, and consequently on the end consumer.

1.1.4 Repertoires of generics and bio-similar drugs

20. In order for an originator and its generics to be substitutable and substituted by a chemist, they must have been registered in the relevant group in the repertoire of generics kept by the ANSM. The Autorité found that this repertoire was still quite narrow, with the generics' share of reimbursable medicines being much lower in France than in Germany or the United Kingdom for example.

21. Several factors could explain the narrowness of this repertoire and in particular the absence of the creation of groups of generics for certain proprietary medicines, including paracetamol and acetylsalicylic acid. Prescription is still carried out a great deal by brand name in France; the consequent absence of the creation of groups of generics means that an order referring to a brand of paracetamol may not lead to the issue of a generic, even though it is cheaper. This is significant given that one of the makes of paracetamol prescribed in France (Doliprane®) is the medicine with the fifth highest rate of reimbursement by the State Health Insurance Fund.

22. The Autorité has however praised the initiative taken recently by the ANSM to create a group of dry oral forms of paracetamol in the repertoire of generics and it hopes that the Health Agency will continue this expansion effort.

⁷ See law 2013-1203 of 23 December 2013 on social security financing for 2014.

23. As far as biosimilar medicines are concerned, their substitution within a repertoire and at the start of treatment has recently been introduced in law⁸. The Autorité has noted this initiative and calls on operators to avoid any anticompetitive behaviour comparable to that which has been observed in relation to generics in the past (in particular the use of denigration tactics).

1.1.5 *The protection of intellectual property*

24. The Autorité has highlighted the importance of innovation in the pharmaceutical sector, which goes hand in hand with adequate protection of the patents held by the pharmaceutical laboratories. Tools such as infringement proceedings thus ensure that a laboratory maintains its exclusivity throughout the term of the patent.

25. However, the practice of European and American competition authorities reveals that some behaviour aimed in principle at protecting patents, can in reality lead to an increase in anticompetitive strategy aimed at preventing or delaying the entry of competitors (generics or others) onto a given market. There are, for example, “*pay-for-delay*” tactics – agreements under which originator and generic laboratories agree to delay the entry of generics onto a given market, in exchange for payment⁹. Likewise worth mentioning are the practices by which a laboratory issues erroneous information to a patent office, with a view to preventing or delaying the entry of generics onto the market¹⁰.

26. Finally, some studies allege that laboratories in France attempt to bring multiple proceedings for patent infringement solely with a view to creating a dissuasive cost of entry for the generic laboratories in question. Legal action has already been taken against such manoeuvres in the United States¹¹. The Autorité could likewise declare that it is competent to take action against such behaviour.

1.1.6 *Non-reimbursable medicines*

27. Non-reimbursable medicines can be freely priced in France. The Autorité has established in this area that all laboratories tend to offer much higher discounts on the non-reimbursable medicines sold by direct sale (namely made directly between the laboratory and the dispensing chemist) than by sale to intermediaries, even though the latter tend to order significantly higher quantities of boxes than those ordered by directly by a dispensing chemist.

28. On this matter the Autorité stressed that it is competent to rule on possible agreements between laboratories on their discounts, as well as any pricing discriminations that may be made by a laboratory that also holds a dominant position.

1.2 *The intermediaries*

29. There are several categories of intermediaries active in the distribution of prescription medicine, with varying statuses and obligations. In particular they include wholesalers, who provide the logistics for

⁸ *Ibid.*

⁹ See on this subject the European Commission judgements in the cases Lundbeck (http://europa.eu/rapid/press-release_IP-13-563_fr.htm?locale=FR) and Johnson & Johnson (http://europa.eu/rapid/press-release_IP-13-1233_en.htm?locale=FR). See also the order of the Supreme Court of the US: 570 U.S. *FTC v. ACTAVIS, INC.* (2013).

¹⁰ Case T-321/05, *AstraZeneca v/ Commission*, judgement of 1 July 2010 and Case C-457/10, *AstraZeneca AB and AstraZeneca v/ Commission*, order of 6 December 2012.

¹¹ Case *Bristol-Myers Squibb Company*, 135 F.T.C. 444 (2003).

direct sales from the laboratory to the dispensing chemist, wholesale distributors, *structures de groupement à l'achat* (bulk-buying associations, hereinafter “SRA”) and *centrales d'achat pharmaceutique* (pharmaceutical purchasing organisations, hereinafter “CAP”). Wholesalers and wholesale distributors can be involved in the distribution of reimbursable and non-reimbursable medicines. The SRAs and CAPs cannot, however, be involved in the distribution of non-reimbursable medicines.

1.2.1 *An unbalanced competitive relationship*

30. The Autorité has observed that unlike other intermediaries involved in the distribution of prescription medicine for human use, wholesale distributors are subject by law to what are known as “public service” obligations, which include delivering dispensing chemists within twenty-four hours and holding a two-week stock including at least nine-tenths of the proprietary medicines sold in France. These obligations represent a fixed cost for the wholesale distributors, to which other intermediaries are not subject.

1.2.2 *An absence of compensatory purchasing power for non-reimbursable medicines*

31. As stated previously, laboratories tend to grant higher discounts to dispensing chemists than to intermediaries. The Autorité considers that the intermediaries’ inability to obtain higher discounts on non-reimbursable medicines, even though the amounts ordered by them are greater than those ordered even by the largest dispensing chemists, indicates the low level of their compensatory purchasing power.

32. Several solutions aimed at strengthening their compensatory purchasing power have been put forward by the players in the sector and relayed by the Autorité within the scope of its final opinion. The Autorité has established its position, with regard to the current system of medicine distribution for which responsibility lies with the authorities alone. It would involve for example looking again at regulations on how the wholesale distributor’s margin is established, with a view to removing the possibility of redistributing its margin between the laboratory and the dispensing chemist within the framework of direct sales. Alternatively, it has also proposed looking again at the obligations of all intermediaries active in the distribution of medicine in order to ensure they are all subject to the same obligations and costs.

33. Finally, legislature has brought in a form of taxation on direct sales¹². This tax should make it possible to strengthen the process via intermediaries and in particular via wholesale distributors, which are currently weakened by a lower recourse to their involvement. Without pronouncing on this measure, the Autorité has nevertheless recalled French and European case law on this type of tax measure¹³.

1.2.3 *The parallel trade in medicines*

34. As far as the parallel trade in medicines within the European Economic Space is concerned, the Autorité had already had occasion to express itself on this subject within the scope of an opinion it issued on a draft decree on the supply of medicines for human use, which was aimed at avoiding the possibility of breaks in supply in French territory¹⁴. The Autorité had the opportunity on this occasion of referring to jurisprudence of the Court of Justice of the European Communities on the behaviour of companies aimed at limiting the parallel trade in medicines¹⁵.

¹² See law 2013-1203 of 23 December 2013 on financing social security for 2014.

¹³ Versailles, 2 September 2010, URSSAF of Rhône v/ Boiron S.A. CJCE, C-526/04, Laboratoires Boiron S.A. v/ URSSAF of Lyon.

¹⁴ Opinion 12-A-18 of 20 July 2012 on a draft decree on the supply of medicines for human use.

¹⁵ Joined cases C-468/06 to 478/06, judgement of 16 September 2008, *Sot. Lélos kai Sia* and joined cases C-501/06P, C-513/06P, C-515/06P and C-519/06P, *GlaxoSmithKline Services e.a. / Commission e.a.*

35. Furthermore, as regards quotas imposed by pharmaceutical laboratories on the wholesale distributors in the national territory, the Conseil de la concurrence stated in a decision in 2007 “*that a pharmaceutical laboratory can organise the distribution of its products in accordance with a legitimate aim of optimal supply of different national markets and in accordance with the quantified needs of these markets. Specific constraints are imposed on laboratories on the French market within the double framework of the security of supply and the policy of controlling healthcare expenses*”¹⁶. However, the Council had also specified that if quotas could be justified, it was only “*on the condition that the restrictions arising from this regulation are limited to what is strictly necessary for the reliable and optimal supply of the national market*”¹⁷.

36. The sectoral opinion on the distribution of prescription medicines for human use also made reference to the competitive role that parallel trade can play. Indeed, during the patent-protection period, parallel import is the only form of competition that can be exercised over an originator laboratory. It serves as an indication of the price levels practised in other Member States, which can provide the CEPS with the possibility of negotiating a decrease in the price of proprietary medicines that are the subject of parallel imports into France.

1.2.4 The authority’s contentious practice in relation to intermediaries

37. It should finally be noted that the Autorité has already adopted a decision to fine wholesale distributors for having coordinated their prices and sales conditions, contrary to Article L.420-1 of the Commercial Code and the current article 101 of the Treaty on the functioning of the European Union¹⁸.

1.3 Dispensing chemists

1.3.1 Regulatory framework

38. In France there are three pillars on which the retail distribution of prescription medicines rests: the monopoly of pharmacists and dispensing chemists, the territorial distribution of dispensing chemists in accordance with population quotas and the fact that only pharmacists can be the owners of the dispensing chemist’s establishments they run. In addition, pharmacists are themselves subject to strict regulation of the profession, the central tenet of which is that they must be registered with the *Ordre professionnel des pharmaciens* [Professional Order of Pharmacists] to be able to practice and dispense medicines.

39. Thus in France, unlike in some European Union countries, only pharmacists can dispense the medicines and other products listed in the public health code, via dispensing chemists. Therefore there is a double monopoly in France based on both the function (pharmacist’s monopoly) and location (dispensing chemists).

40. Finally, dispensing chemists have several missions, the main one being that of dispensing medicines. There are around 22,500 dispensing chemists in France. Their pre-tax turnover can be broken down as follows: 76% is generated by the sale of medicines reimbursed by the State Health Insurance Fund, 16% by the sale of parapharmaceutical products and 8% by non-reimbursable medicines.

¹⁶ Decision 07-D-22 of the Conseil de la concurrence, paragraph 99.

¹⁷ *Ibid*, paragraph 100.

¹⁸ Decision 01-D-07 of 11 April 2001 on practices implemented on the pharmaceutical distribution market.

1.3.2 *The financial situation of dispensing chemists*

41. Dispensing chemists do not enjoy such a favourable financial situation as previously. This is in particular due to the drop in prices for medicines reimbursed by the State Health Insurance Fund, the strengthening of the “third-party payment for generics” measure and the removal of numerous medicines from reimbursement lists, for which the first consequences is a drop in sales volume. The network of dispensing chemists is strongly concentrated in densely populated areas. France ranks third in the OECD in terms of the density of pharmacists with 1.13 pharmacists per 1,000 inhabitants.

42. The price of reimbursed medicines and the pharmacist’s margin on their sale is the subject of public regulation. Consequently, to the extent that the level of a pharmacy’s revenue depends essentially on the volumes of boxes of medicines that it sells, it is strongly dependent on the evolution of regulated prices and margins which remain limited in terms of the budgetary constraints of the social security systems. This is why the authorities have assigned pharmacists new jobs, paid for by the State Health Insurance Fund, and aimed at providing patient support services (law 2009-879 of 21 July 2009 on hospital reform and in relation to patients, health and territories). By performing these tasks, pharmacists are therefore returning to their essential role as a primary healthcare provider.

1.3.3 *Competitive analysis*

1.3.3.1 *The Autorité’s decision-making practice*

43. Other than opinion 13-A-24, the Autorité has adopted various decisions and opinions on the retail distribution of medicine, the most recent of which are as follows: decision 09-D-17 of 22 April 2009 on practices implemented by the regional council of the Order of Pharmacists of Basse-Normandie, opinion 10-A-15 of 6 July 2010 on a request from the Minister of Health and Sports on a draft decree regarding the roles of dispensing chemists and opinion 13-A-12 of 10 April 2013 on a draft order of the Minister of Social Affairs and Health on good practice in the dispensing of medicines on-line.

1.3.3.2 *Towards a controlled opening up of the retail sale of certain “borderline products” and over-the-counter medicines*

- The need for a reasonable transition

The retail sale of medicines, particularly over-the-counter medicine, is currently undergoing major upheavals which are provoking drastic changes in the competitive situation. Firstly, confronted by the removal of medicines from the reimbursement lists, patients have recourse more and more frequently to over-the-counter medicines. Secondly, the authorisation of online sales of medicines or the creation of new roles for pharmacists constitute real changes that offer dispensing chemists the opportunity to become full players in terms of competition, from the point of view of both price and the quality of services rendered to the patient.

Consequently the Autorité is convinced that the maintenance of the *status quo* does not constitute an effective option, either for consumers or dispensing chemists. It is therefore necessary to shed the constraints and examine the conditions under which an opening up of the distribution of prescription medicine can be envisaged in France.

- The example of the Italian model

The Autorité is particularly interested in the situation in Italy, where the sale of over-the-counter medicines was liberalised in 2006, and the effects of liberalisation which make it possible to assess the consequences of a partial abandonment of the dispensing chemists’ monopoly. Wholesale distribution has, since that date, been able to sell these medicines under the control of

a person qualified in pharmacy. The consequence of this limited opening up has not endangered the financial sustainability of pharmacies. In addition, as a result of the presence of persons qualified in pharmacy, not a single public health problem has been recorded. However, a major decrease in sales prices was initially recorded (20 to 30-35%) and even though prices then rose again, a difference of 15 to 20% remains between dispensing chemists and large and medium-sized retailers.

- Some arguments in favour of controlled opening up in France: price and availability

The Autorité is of the opinion that access to some medicines by certain parapharmacy or major retail chains would, due to their purchasing power and margins policy, make it possible to bring down their prices for consumers. The French consumer association UFC-Que Choisir and the federation of trade and distribution consider for example that a drop in prices of around 15% is a foreseeable option. In France, the opening up to competition of over-the-counter medicines will certainly have a beneficial impact on consumers because its result would be an increase of around 10% in the number of points of sale, and a decrease in prices of between 11 and 16%, all without casting any doubt on the sustainability of the dispensing chemists' network.

Furthermore, the proposed opening up should not jeopardise the maintaining of a high-quality network of dispensing chemists. In fact, since the over-the-counter medicines market is relatively restricted (representing around 7% of the turnover of a dispensing chemist), the liberalisation of distribution will probably not have a substantial impact on the number of dispensing chemists existing in France. In any case, given the financial difficulties currently faced by dispensing chemists, potential losses of revenue due to the generalisation of the sale of over-the-counter medicines could be offset by the new methods of payment discussed above.

- A limited opening up

The Autorité proposes to authorise the sale of certain products and medicines, currently sold exclusively in pharmacies, to other distribution channels. This opening up would be limited to over-the-counter medicines and certain "borderline" products, namely non-medicinal products sold exclusively in dispensing chemists such as pregnancy- and blood glucose-testing kits.

- A controlled opening up of the retail distribution of medicines

However, the Autorité is of the opinion that a framework of strict regulations is required for such sales, which would guarantee the quality and safety of distribution, in particular the compulsory presence in all new places of sale of a qualified pharmacist with the obligation to provide advice, together with the creation of a dedicated sales space and the guarantee that medicines will not be trivialised in these new points of sale. Likewise, respect of the rules in relation to supply, storage and traceability, which are already incumbent upon dispensing chemists, is essential. In its opinion, consequently, the Autorité recommended a phased evolution of the current system that would first and foremost be an adaptation to new market realities, and in particularly to the consequences of the authorisation of online sales of over-the-counter medicine. This evolution must allow the advent of a French model in line with the times.

- Opening up accompanied by the retail distribution of medicines

At the same time, this opening up must be accompanied by a set of measures aimed at consolidating the role of dispensing chemists and strengthening their ability to be a fully-fledged competitive player.

Firstly, the rapid development of the new roles of dispensing chemists should be supported, in order for them to underpin their position as fully-fledged players in the health sector. Not only do these new services fulfil an important role in the organisation of the national health system,

but they also offer dispensing chemists a new form of income that allows them to decrease their dependence on the sale of medicines.

Secondly, the Autorité supports the online sale of over-the-counter medicines in the secure framework provided by the law. This new form of sale, which constitutes a vector of competition in the sector, is such that it will improve distribution and generate lower prices. It is still necessary however to limit as far as possible regulatory restrictions to the development of online trade.

- Dysfunctions in competition

A certain number of dysfunctions in competition remain and could slow down developments favourable to the market and consumers, in terms of diversification of offer and decrease in prices.

- Increasing transparency of conditions of purchase

First of all, the Autorité envisages increasing transparency with regard to the remuneration of dispensing chemists. On account of the financial difficulties that they have been facing, and their lower purchasing power in relation to the laboratories, pharmacists seek to benefit from advantageous sales conditions from their suppliers, in the form of big discounts on direct sales for the largest of them or payment by way of commercial cooperation on non-reimbursable medicines when they are buying generics¹⁹.

However, it is necessary to support the legal forms of grouping such as the SRAs and CAPs which find it difficult to flourish to the extent that it would be advisable, in the event of a failure to set up these structures, to favour legalisation of “selling on” between dispensing chemists which would allow some of them to benefit from commercial advantages with laboratories.

- A lack of information and publicity on the price of over-the-counter medicine

French patients’ use of over-the-counter medicine is becoming ever greater and in this context consumers need to be empowered so they can make a fully-informed choice of the best medicine for their needs. In this respect, information and advertising for non-reimbursable medicines are crucial. The Autorité has noted a lack of information about these medicines and their prices. Consumers are not therefore in a position to make price comparisons and use the leverage of competition between dispensing chemists.

As regards medicines that are not *vignettés* (bearing a price label for reimbursement by the State Health Insurance Fund), the Autorité has highlighted even greater price differences – up to four times – confirmed by all the studies on this subject. Thus, without denying the existence of a degree of competition in terms of price, the extent of these price differences bear witness to the absence of real pressure of competition between dispensing chemists. Furthermore, these price differences are indicators of the significant diversity in situations of dispensing chemists in terms of their purchasing conditions. This could also be the result of a lack of information with regard to the prices of these medicines.

Finally, the Autorité is in favour both of relaxing the rules on the advertising of prices as detailed in the Public Health Code and strengthening the rules on the displaying of prices, with the aim of promoting better competition between online pharmacies but also between traditional dispensing chemists, and indeed with new forms of trade if the distribution of over-the-counter medicines is opened up.

¹⁹ .

These payments are made on the basis of commercial cooperation on non-reimbursable medicines in order to get round the legal rebate ceiling on purchases of generic medicines, which is 17% on the manufacturer price before tax of these medicines, any form of commercial cooperation being included in the calculation of how far the cap has been exceeded (cf. article L. 138-9 of the Social Security code).

2. Contentious practice: Recent cases of denigration

2.1 *The case of Plavix®*

44. On 14 May 2013, the Autorité published judgement 13-D-11, under which it fined Sanofi-Aventis for having abused its dominant position by putting into place a strategy of denigration of the generics of Plavix®, one of its flagship products. This judgement, which was brought against the fourth biggest pharmaceutical group in the world, and the sector's leader on the French market, censured the practice of denigration of generic medicines for the first time.

45. An appeal has been filed against this judgement with the Appeal Court of Paris.

2.1.1 *The generification of Plavix: a major challenge for the medicines sector in France*

46. The practices condemned by the Autorité concern Plavix®, a pharmaceutical industry "blockbuster". It is the fourth most sold medicine in the world and in 2008 represented more than 550 million euros of turnover on French territory alone. Plavix®, whose main active ingredient is clopidogrel, is used for the prevention of relapses of serious cardiovascular illnesses.

47. The regulatory protection of Plavix®'s pharmaceutical data came to end in Europe on 15 July 2008, and the first generic competitors were sold from October 2009 onwards. Due to the importance of this product, its generification constituted a major financial event for the medicines sector in France and particularly for social security accounts. Indeed in 2008 Plavix® was the item most reimbursed by the State Health Insurance Fund, amounting to 625 million dollars. A saving of 200 million euros was forecast for 2010.

2.1.2 *A strategy of structured denigration rolled out across the whole territory of France*

48. Just before the Plavix® generics were set to come out, Sanofi-Aventis implemented a communication strategy as regards the public and healthcare professionals, aimed at limiting the entry of generics competing with its product Plavix® and its own generic, Clopidogrel Winthrop®.

49. The discourse used by Sanofi-Aventis was based on negatively highlighting the differences between its own products and the competing generics. In fact, while all clopidogrel generics are bioequivalent to Plavix® and can be substituted by the pharmacist in all cases, there are two differences between the latter and the originators. The first is the use of a salt – to fix the active ingredient – different to the one contained in Plavix®, and the second involves the absence of any therapeutic indication on acute coronary syndrome, in combination with aspirin.

50. However these purely formal distinctions, following the existence of intellectual property ownership, were in no way linked to the therapeutic properties of the generics. They had no impact on the possibility of substituting Plavix® with a generic.

51. However, Sanofi-Aventis stressed these differences in order to instil doubt about clopidogrel generics. The raising of these matters took place right at the heart of considerations related to the sensitive nature of the pathologies concerned and the risks incurred by patients. The discourse concluded with clear incitements: for doctors, to hinder substitution by using the comment "not substitutable" and for pharmacists, to order Clopidogrel Winthrop®, which was presented by Sanofi-Aventis as the "authorised copy" of the originator.

52. Furthermore, on the basis of an in-depth field investigation, the Autorité obtained numerous direct witness statements from pharmacists and doctors, as well as extensive feedback from the network of

representatives of the National Health Insurance Fund. This corroborating evidence demonstrates that Sanofi-Aventis medical visitors and pharmaceutical sales representatives had directly stated to healthcare professionals that the generics constituted a risk to patients' health.

2.1.3 The specific context of the health sector

53. In order to better appreciate the impact of Sanofi-Aventis's practices, the Autorité also carried out an analysis of the specific nature of the health sector. It was predominantly a matter of ascertaining precise details of the level of professionals' knowledge, as well as the manner in which they receive information.

54. It became apparent that healthcare professionals only had a vague knowledge of matters related to medicine law, that doctors do not always have full and precise knowledge of pharmacological matters and that visits by medical sales staff constitute a major source of information for them.

55. Thus the discourse designed by Sanofi-Aventis took place in a context where it undoubtedly had the effect of generating doubts, and indeed concern, on the part of professionals as regards Plavix® generics. This concern was confirmed by the evidence gathered, which demonstrated a strong feeling of suspicion with regard to these products across the whole French territory.

2.1.4 The very atypical clopidogrel market

56. The impact of Sanofi's practices is particularly noticeable on the clopidogrel market. Indeed, despite very high turnover and volumes and a large number of laboratories producing generics on the market, the substitution rate of Plavix®, after an initial sharp increase when the generics were first introduced, then suffered a continuous fall over many months.

57. In its 2010 report, the State Health Insurance Fund highlighted that the "rate of effective penetration of clopidogrel at the end of December 2010 [was] 10 points lower than the target (64.6% against 75%)", thus confirming that the generification rate of Plavix® was abnormally low over a long period. For the period January 2010 – August 2011, the State Health Insurance Fund put losses related to unrealised savings at 38 million euros.

58. The practice in question also allowed Sanofi-Aventis's own generic, Clopidogrel Winthrop®, to enjoy a market share of more than 34% in the clopidogrel generics segment, namely a position four times greater than that normally held by the brand on the French generics market.

2.1.5 A fine in proportion to the seriousness of the loss

59. The Autorité therefore considered that Sanofi-Aventis had abused its dominant position on the French prescription-clopidogrel market, in violation of Article L.420-2 of the Commercial Code as well as Article 102 on the Treaty on the Functioning of the European Union, and imposed a fine of 40.62 million euros.

2.2 The case of Subutex®

60. On 18 December 2013, in Judgement 13-D-21, the Autorité fined the laboratory Schering Plough 15.3 million euros for having abusively hindered the entry of generics competing with its product Subutex®, firstly by awarding dispensing chemists' commercial advantages entailing brand loyalty and secondly, by denigrating the generics.

61. The Autorité also imposed a fine for an agreement between Schering-Plough and its supplier, Reckitt Benckiser, aimed at putting this eviction strategy into place. The fines imposed were respectively 414,000 euros (on the Schering-Plough parent company, Merck & Co) and 318,000 euros (for Reckitt Benckiser) for implementing the agreement.

62. Subutex® (a molecule of buprenorphine) is a medicine prescribed in the treatment of patients with an opiate dependency, particularly heroin. During the period of the events in question, the Subutex® market was around 100 million euros per year. In addition, it should be noted that Subutex® is reimbursed up to 65% by the National Health Insurance Fund.

63. The case originated in a complaint by a generics manufacturer, Arrow Laboratory, which was accompanied by an application for the imposition of protective measures. In a decision dated 11 December 2007, the Conseil de la Concurrence upheld this application and ordered Schering-Plough to publish an announcement in the specialist press, reminding doctors and pharmacists of the strict bio-equivalence of Subutex® with competing generics and the absence of risks to the health of patients from generic substitution²⁰.

64. Subutex® was first marketed France in 1997 by Schering-Plough (which became MSD France in 2011). The previous year it had reached an exclusive agreement with Reckitt Benckiser (the manufacturer of Subutex®) for distribution of the product in France. In exchange, Schering-Plough paid Reckitt Benckiser royalties (a percentage of the turnover achieved).

65. In March 2006, the Schering-Plough patent expired, and Arrow launched its equivalent generic. It was following the launch of its generic and the difficulties that it found in penetrating the market that Arrow referred the matter to the Autorité, maintaining that Schering-Plough was abusing its dominant position to drive it out of the market.

2.2.1 The comprehensive plan conceived by Schering-Plough and Reckitt Benckiser to counter the arrival of the Subutex® generics

66. Between October and December 2005, Schering-Plough and Reckitt Benckiser, anticipating the 2006 arrival of Subutex® generics, adopted a plan (“French plan against generics”) – aimed at “Delaying/Discouraging the entry of generics”.

67. This plan firstly envisaged setting up a system of direct sales to pharmacists, three months before the arrival of the generic, accompanied by client loyalty programmes, based in particular on discounts. Secondly, it upheld the need for communication instilling “fear” in the minds of doctors and pharmacists with regard to a change in treatment and in relation to the patient’s “psychiatric instability”, the risk of wrongful use and indeed the increase of “trafficking” with the Subutex® generic.

2.2.2 The implementation of the plan by Schering-Plough

68. Schering-Plough denigrated Arrow’s generic and gave pharmacists discounts with the aim of inundating their shelves with Subutex®.

- A global, structured denigration campaign

From mid-February to May 2006, Schering-Plough organised seminars and telephone meetings, as well as rolling out arguments in the form of questions/answers distributed to its medical sales

²⁰ See press release and decision 07-MC-06.

teams and pharmaceutical representatives so that they could propagate alarmist discourse among doctors and pharmacists on the risks of prescribing or issuing Arrow's generic, even though Schering-Plough did not have any specific medical studies at its disposal which could have justified its arguments.

- Commercial supplies aimed at inundating pharmacists' shelves with Subutex®

Schering-Plough completed its plan by offering pharmacists major reductions from January to August 2006, without any objective counterpart, with the sole aim of preventing them from buying supplies from Arrow. These reductions had the effect of inundating the pharmacies' shelves with boxes of Subutex® only.

Payment facilities (extended payment terms and discounts) were also granted to the pharmacists, beyond the facilities generally offered to them.

- Major effects on the rate of substitution and the public accounts

According to the managers of Schering-Plough themselves, these practices proved very effective.

By influencing both doctors and pharmacists, Schering-Plough placed an obstacle in the path of competition at the two key stages of generic substitution, namely at the prescription stage, by significantly increasing the number of "non-substitutable" specifications (67% of orders were marked thus), which made it possible to limit the rate of generification of Subutex® and at the dispensing stage, by persuading pharmacists not to substitute Subutex® even when the orders were not marked "not-substitutable".

In order to assess the loss to the economy, the Autorité used the 'range of evidence' method, which allowed it to measure the difference between the observed rate of substitution of Subutex® by its generic and the rate that would have normally been recorded. This method was based firstly on the reference comprised by the rate of substitution observed for one of three dosages of Subutex®, the 0.4 mg dosage, given that the practices were mainly linked to the other dosages (2 mg and 8 mg) and secondly, on the studies undertaken by Schering Plough itself, studies that had analysed the substitution rates of products known as "sensitive" compared to Subutex®, particularly Prozac®. Finally, it took as counterfactual the rate of penetration of 11-molecule generics in class-N, the class to which Subutex® belongs.

The Autorité thus estimated that the savings that the National Health Insurance Fund could have made would have been between 2 and 5 million euros per year.

2.2.3 *Schering-Plough's decision not to contest the facts and undertakings by Financière MSD and its parent company Merck & Co*

69. Schering-Plough, as well as Financière MSD which succeeded it and its parent company Merck & Co, did not contest the grievances brought by the Autorité. These companies made undertakings to conform with competition law in order to prevent such practices in the future. They particularly undertook to monitor planned commercial strategy prior to the arrival of generics and to provide training for their sales teams on the prohibitive nature of denigration. These major undertakings have been made at a time when numerous molecules of the laboratory are due to come into the public domain. The fines on these companies were reduced on this basis.