Jean-Julien Lemonnier

White & Case, Paris

Email: jjlemonnier@whitecase.com

LIDC – Questionnaire A

Part 1 – Competition law context of the pharmaceutical industry

a) Which legislative provisions of your jurisdiction are most likely to be applied to a potential competition law infringement in the pharmaceutical sector? Please provide the text of the key provisions of this legislation.

The main legislative provisions applicable to competition law infringements in the pharmaceutical sector are the same as those applied to other sectors: those provisions are the articles L.420-1 and L.420-2 of the French Commercial Code, prohibiting on one hand anticompetitive agreements[1] and on the other hand the abuse of dominant position and of economic dependence[2].

b) Is market definition in the pharmaceutical sector any different, compared with market definition in other industries, as a matter of law or as a matter of practice in your jurisdiction? Please give a brief account of the main decisions of competition authorities or court judgments on market definition in this sector, or of any specific legislative provision dealing with this issue.

As pointed out by the French Competition Authority, *« the medical sector has* […] *a specific* feature, *since the decision of purchase is not taken by the final user but by the prescribing doctor, who is the one to choose the medication to be administered to his patient"*[3].

To define the relevant market in this particular sector, both the decision-making practice of the French Competition Authority and French case law apply the principles issued by the European decision-making practice based on the « *Anatomical Therapeutical Chemical* » classification system (hereinafter the « *ATC classification* ») recognised and used by the World Health Organisation to define the relevant market[4].

This system classifies pharmaceuticals products by levels according to their therapeutics indications.

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[1] *« Concerted actions, agreements, express or tacit undertakings or coalitions shall be prohibited, even through the direct or indirect intermediation of a company in the group established outside France, where they have the aim or may have the effect of preventing, restricting or distorting the free competition in a market, particularly where they are intended to: 1° Limit access to the market or the free exercise of competition by other undertakings; 2° Prevent price setting by the free play of market forces, by artificially encouraging the increase or reduction of prices; 3° Limit or control production, opportunities, investments or technical progress; 4° Share out markets or sources of supply»*

[2] "*The abuse of a dominant position by an undertaking or group of undertakings on the domestic market or a substantial part of the market is prohibited, pursuant to Article L. 420-1. This abuse may include a refusal to sell, a tie-in of sales or discriminatory terms of sale as well as the termination of established commercial relationships, for the sole reason that the partner is refusing to accept unjustified commercial terms. The abuse of the state of economic dependence of a client or supplier by an undertaking or group of undertakings is also prohibited, if it is likely to affect the functioning or structure of competition. This abuse may include a refusal to sell, tie-in sales or discriminatory practices mentioned in I of Article L. 442-6 or in product range agreements.*"

[3] Autorité de la concurrence, décision n° 13-D-11 du 14 mai 2013 relative à des pratiques mises en œuvre dans le secteur pharmaceutique (ci-après « affaire *Plavix* »), point 286.

[4] Voir, par exemple, l'arrêt de la Cour de cassation, Chambre commerciale, 15 juin 1999, n° 97-15185, publié au bulletin ; voir aussi la décision C (2005) 1757 final de la Commission européenne, du 15 juin 2005, relative à une procédure d'application de l'article 82 CE et de l'article 54 de l'accord EEE (affaire COMP/A.37.507/F3 – AstraZeneca)

The third level of the ATC classification, which allows combining medicines according to their use, constitutes the starting point for the analysis of the majority of the cases submitted to the French Competition Authority[5].

The Court of Cassation confirmed this approach in the « *Lilly France*[6] » judgment where it pointed out that "*if, to define the relevant market of a medicine, the third level of the ATC classification is useful, this classification might be too narrow or too broad for certain medicines*".

Therefore, following the European Commission, the French Competition Authority has been referring to narrower levels, thereby defining the perimeter of the relevant market to the fifth level of the ATC classification, notably in the "*Plavix*" case[7].

According to the European decision-making practice, other elements of differentiation justifying a stricter segmentation of the products market, have been taken into consideration by the decision making practice of the French Competition Authority, such as the distinction between medicines submitted to medical prescription and over-the-counter drugs, or medicines refunded totally or in part by the medical insurances and the ones that are not[8].

Furthermore, the decision making practice of the French Competition Authority traditionally distinguishes between two segments: the market for city distribution (pharmacy network) and the one for distribution at the hospital (hospital network)[9].

As the European Commission, the French Competition Authority[10] defines the geographical market of pharmaceutical products as national.

c) Is there a "per se" or "object" infringement rule by which evidence assessment tends to be truncated in pharmaceutical cases in your jurisdiction? If there are cases or decisions of competition authorities showing this rule in operation, please provide brief summaries of them.

The French Competition Council (former denomination of the French Competition Authority), followed by the French Competition Authority, have already considered different practices such as market sharing or tying agreements as having an anticompetitive object.

In a number of cases, even if the Competition Authority considers a practice as having an anticompetitive object it also analyses its effects, leading the analysis to remain complete.

Indeed, in a decision of 2001[11], the Competition Council considered as having anticompetitive object and effects the practice of wholesale distributors which convened and agreed upon freezing their market shares at the national level and fixing in common the commercial conditions in the region of the Nord and in Seine-Maritime in order to prevent the development of competitors. The Council considered that the parties to the agreement implemented a coordination aiming to prevent the developing of a competitor in those regions.

Likewise, the coordination aiming to put pressure on the aforesaid competitor to make it refund the turnovers taken from one of the wholesale distributors party to the anticompetiting agreement, was

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5 Conseil de la concurrence, décision n° 07-D-09 du 14 mars 2007 relative à des pratiques mises en œuvre par le laboratoire GlaxoSmithKline France ; voir aussi Autorité de la concurrence, décision n° 10-D-37 du 17 décembre 2010 relative à des pratiques mises en œuvre sur le marché de la cétirizine en comprimés.

6 Cour de cassation, Chambre commerciale, 15 juin 1999, précité.

7 Autorité de la concurrence, décision n° 13-D-11 du 14 mai 2013, précitée : l'Autorité a ainsi considéré que les génériques de la molécule de clopidogrel étaient des concurrents directs du médicament princeps Plavix notamment parce qu'ils sont « *composés du même principe actif, ont un rapport efficacité/sécurité équivalent et peuvent traiter les mêmes pathologies* », point 299.

8 Commission européenne, *Hoffmann-La Roche / Boehringer Mannheim*, 4 février 1998, aff. IV/M.950, point 11.

9 Voir par exemple : Autorité de la concurrence, décision n° 10-D-02 du 14 janvier 2010 relative à des pratiques mises en œuvre dans le secteur des héparines à bas poids moléculaire, point 55.

10 Commission européenne, *Hoffmann-La Roche / Boehringer Mannheim*, 4 février 1998, aff. IV/M.950, précitée, point 17.

11 Conseil de la concurrence, décision n° 01-D-07 du 11 avril 2001 relative à des pratiques mises en œuvre sur le marché de la répartition pharmaceutique.

considered as having anticompetitive object and effects. Indeed, the Competition Council considered that: "*if it is not possible, in the light of the elements in the file, to determine precisely the anticompetitive effect of the agreement, the latter could have affect the entire market of the distribution of medicines in France; that agreement had potential anticompetitive object and effect and as such prohibited by article L.420-1 of the French Commercial Code".*

In a decision of 2009, in which the Basse Normandie Chamber of Pharmacists was accused to have send a letter encouraging a retiring home to deal with the nearest pharmacies of its sera, the French Competition Authority considered that « *such a measure, as it comes from a professional organization, is considered as a concerted action which has as its objet or potential effect, the distortion of competition, especially by limiting the access to the market and the free exercise of competition and by sharing markets and the source of supply*".[12]

The Competition Authority, which did not assess the effects of the practice, imposed a fine of EUR 5.000 to the pharmacist's chamber of the Basse Normandie Chamber of Pharmacists.

In 2013, the pharmaceutical laboratory Schering-Plough was condemned by the French Competition Authority to a financial penalty of EUR 15.3 million Euros due to an anticompetitive agreement and an abuse of a dominant position that prevented the entrance into the market of a generic of the Subutex princeps medicine made by the company Arrow[13].

In this case, the commercial denigration was made both through an agreement between the undertakings Schering-Plough, the retailer of the princeps Subutex, and his supplier, the company Reckitt Benckiser, and, by an abuse of its dominant position by Schering-Plough.

Assessing the anti-competitive agreement in its economic context, the French Competition Authority observed that those practices concerned about 2.000 pharmacies representing 40% of turnovers, the most important clients. It also considered, in the legal context of the practice, that the discounts proposed to the pharmacists exceeded the 2,5% threshold authorised by the legislation and, finally, that the separate services asked for in compensation were non-existent.

Stating that the aim of the agreement was the saturation of the shelves of pharmacists, therefore having a restrictive effect on competition, the French Competition Authority considered the agreement to have an anticompetitive object by preventing the entering of Arrow's generic medicine in the market.

Before the Court of Appeal, the parties alleged that the practice of commercial denigration resulting from the agreement could not be considered as having an anticompetitive object since a commercial claim in order to be considered as commercial denigration must influence the structure of the sector, which implies that the practice should be evaluated regarding the effective or potential effects on the competitive structure and on the position of the competitors.

On this specific point, the Court of Appeal admitted that it was proper to at least analyse the expected effect of the practice by the authors of the information in cause but that *"agreeing to spread comments likely to create a doubt or an unjustified prejudice against a competitor in order to weaken its position on the market constitutes a competition restrictive practice by object*"[14]

The Court of Appeal, underlined that: "*the elaboration of a strategy aiming to delay the entrance onto the market of generic medicines that, once their patents are expired, lead to a reinstatement of effective competition, until then non-existent, has a particular economic harmfulness.*"[15] [16].

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[12] Autorité de la concurrence, décision n° 09-D-17 du 22 avril 2009 relative à des pratiques mises en œuvre par le conseil régional de l'Ordre des pharmaciens de Basse-Normandie.

[13] Autorité de la concurrence, décision n° 13-D-21 du 18 décembre 2013 relative à des pratiques mises en œuvre sur le marché français de la buprénorphine haut dosage commercialisée en ville (ci-après « Affaire Subutex »).

[14] Cour d'appel de Paris, arrêt du 26 mars 2015, précité, , page 14.

[15] Cour d'appel de Paris, 26 mars 2015, précité, page 13.

[16] Cet arrêt a fait l'objet d'un pourvoi en cassation. L'affaire est en cours.

d) Is there difference in the scope to argue justification of restrictions of competition in pharmaceutical competition law cases in your jurisdiction, such as specific legislation or guidance? Is there any limitation tending to limit the scope to argue justifications for potentially restrictive conduct, such as a "per se" or "hard-core" rule?

Under French law, there is no specific justification to restrictions of competition in the pharmaceutical sector.

However, a system of exemptions does exist, provided for by article L. 420-4 of the French Commercial Code comparable to the individual exemption set forth in article 101 § 3 TFEU. This system allows to exempt agreements between market operators, particularly active in the pharmaceutical sector (*i.e.*R&D agreements), when certain conditions are fulfilled.

It is true that the pharmaceutical sector remains nevertheless specific as prices are regulated. However, this price regulation does not allow the avoidance of the application of competition law provisions as it was underlined by the Competition Council. : « *the criteria to qualify a commercial practice as abusive and so, in a certain measure, abnormal are necessarily different if this practice was implemented on a market for which the normal mechanisms of competition are not working*"[17].

In another decision related to parallel trade of medicines, the Competition Council considered that the practices of quotas system of laboratories in dominant position could have been accepted "*at the condition that the restrictions induced by this regulation would have been limited to what is strictly necessary to a reliable and optimal supplying of the national market*"[18].

e) Is there any special legislation defining excessive or discriminatory pharmaceutical pricing in your jurisdiction, differentiating it from "ordinary" excessive or discriminatory pricing cases?

In France, there is no specific legislation defining discriminatory or excessive pricing practices for pharmaceutical products.

However, if the price of non-refunded medicines by the social security is free in France, the price of the refunded ones and the profits of retailers of those medicines are strictly regulated as the legislation settles precisely the maximum price of those medicines[19].

This regulation forbids indirectly all practices of excessive pricing and discriminatory pricing, insofar as the pharmacist doesn't have in principle any interest to divert from the price settled accordingly to the law.

Thus in France: « *The public sale price of each medicine mentioned at the first paragraph of the article L. 162-17 (refundable medicines) is set by an agreement between the company exploiting the medication and the Economic Comity of health products*."[20]

"*This price setting process takes mainly into account the improvement of the provided medical service, if need be the results of the medial-economic evaluation prices of medicines with the same therapeutic use, planned or observed volumes of sale and the foreseeable and real conditions of the medication use*." [21]

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17 Conseil de la concurrence, décision n° 05-D-72 du 20 décembre 2005, relative à des pratiques mises en œuvre par divers laboratoires dans le secteur des exportations parallèles de médicaments, point 269.

18 Conseil de la concurrence, décision n° 07-D-22 du 5 juillet 2007 relative à des pratiques mises en œuvre dans le secteur de la distribution des produits pharmaceutiques, point 100 (décision annulée par : Cour d'appel de Paris, 26 novembre 2008, RG n° 2007/13915, lui-même cassé par : Cour de cassation, Chambre commerciale, 2 février 2010, n° 08-70449).

19 Article L. 5123-1 du Code de la santé publique : *« Les médicaments et produits mentionnés à l'article L. 5121-8 ne peuvent être vendus à un prix supérieur à celui qui résulte de la réglementation des prix. Les autres médicaments et produits dont la vente est réservée aux pharmaciens ne peuvent être vendus à un prix supérieur à celui qui résulte du tarif pharmaceutique national. […] »*

20 Article L. 162-16-4 du Code de la sécurité sociale.

21 Article L. 162-16-4 du Code de la sécurité sociale.

In the context of the estimation of the improvement of the medical-economic service, the price of the innovative and intermediary products could not be lower than the lower price implemented under a period of five years in Germany, Spain, Italy and UK.[22].

f) Please comment on any other aspects that you consider to be relevant in which the legal treatment of pharmaceutical sector cases tends to be differentiated in your jurisdiction, compared with other competition law cases.

Here, it should be mentioned the recent approach of the Competition Authority regarding commercial denigration on the pharmaceutical sector.

Indeed, the Competition Authority tends to deal with the issues concerning commercial denigration in the light of article L. 420-2 of the French Commercial Code, regarding the abuse of dominant position, when instead commercial denigration is traditionally considered by the commercial judge as a practice of unfair competition.

In the pharmaceutical sector, this tendency is even more blatant according to the recent judgements *Plavix*[23] and *Subutex*[24]in which the French Competition Authority followed by the Court of Appeal of Paris[25], adopted a strict approach regarding commercial denigration. It will now suffice to establish a doubt among health operators to characterise the commercial denigration[26].

Part 2 – Enforcement mechanisms, remedies and consumer protection / Les mesures d'application, les remèdes et la protection du consommateur

a) **Is there any pattern by which pharmaceutical competition law issues in your jurisdiction tend to be dealt with primarily by laws against restrictive agreements, laws against monopoly, or by merger review?**

The legislation doesn't lead to a priority treatment by one or the other of these rules. The cases heard by the French Competition Authority in the pharmaceutical sector essentially concern the abuse of dominant position.

However, an evolution of the decision-making practice of the French Competition Authority during these last year can be identified. In the early 2000 the issue of the quota system of medecines for the wholesalers-exporters by the pharmaceutical laboratories was of first importance, with about seven decisions.

Recently, the French Competition Authority is more focused on the problematic related to the entrance onto the market of generic medicines. A majority of cases focus on commercial denigration (a French specificity as these practices are analysed under competition law by administrative authorities) or others squeezing-out strategies implemented by the originator companies against the generic's companies. Five recent decisions, of which two rejected a request of precautionary measures,[27]

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22 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013 relatif au fonctionnement de la concurrence dans le secteur de la distribution du médicament à usage humain en ville, point 73.

23 Autorité de la concurrence, décision n° 13-D-11 du 14 mai 2013, précitée.

24 Autorité de la concurrence, décision n° 13-D-21, du 18 décembre 2013, précitée.

25 Cour d'Appel de Paris, Pole 5 – Chambre 5-7, 26 mars 2015, RG n° 2014/03330 dans l'affaire Plavix ; Cour d'Appel de Paris, Pole 5- Chambre 5-7, 18 décembre 2014, RG n° 2013/12370 dans l'affaire Subutex.

26 Autorité de la concurrence, décision n° 13-D-11 du 14 mai 2013, précitée, point 376 : *« dès lors, la diffusion d'une information négative, voire l'instillation d'un doute sur les qualités intrinsèques d'un médicament peut suffire à le discréditer immédiatement auprès des professionnels de la santé. En effet, si ceux-ci s'interrogent sur son efficacité thérapeutique voire sur son innocuité, du fait de la présentation qui leur en a été faite ou des réponses qui ont été données à leurs interrogations à cet égard, ils ne prendront pas le risque de le prescrire ou de le délivrer* ».

27 Parmi ces décisions refusant les mesures conservatoires, une a abouti à une décision de sanction et une est toujours en cours. Voir Autorité de la concurrence, décision n° 13-D-11 du 14 mai 2013, précitée ; et , Décision n° 13-D-21 du 18 décembre 2013, précitée. Ces deux décisions ont été confirmées en appel, mais font l'objet de pourvoi devant la Cour de cassation. L'Autorité de la concurrencea condamné Sanofi-Aventis pour dénigrement à une amende de 40,6 millions d'euros, après la décision n° 10-D-16 qui a rejeté les mesures conservatoires demandées.

underline the recent will of the Authority to fight against this kind of practices, which according to the Authority, took benefits from the mistrusts surrounding generics.

The simples practices of « *pay-for-delay* » (or postponement agreements), that represent the majority of recent cases of anticompetitive agreements at the EU level on the pharmaceutical sector, have not been examined yet by the French jurisdictions or authorities.

Finally, the Court of Appeal of Paris[28] quashed a sentencing to a fine of the Competition Council[29] for practices of « prédation par signal ». The Court considered that the link between the non-dominant market on which the practices have been implemented and the dominant market on which the effects were supposed to take place, was not sufficiently established[30].

Regarding mergers, only four operations have been analysed by the Competition Authority during the last six years. Between those four operations, two have been authorised according to the simplified procedure[31], and two under the normal procedure but with a very summary analysis.[32] The size of the companies and the magnitude of the operations on the sector ensure that the majority of the mergers on this sector are notified at EU level.

b) Does competition law interact with consumer protection law in your jurisdiction? If so, please provide examples of the interaction of consumer protection law and competition law.

The interaction between competition law and consumer protection appears indirectly through considerations of public health and security of medicines that can, in some cases, interfere or have an impact on the application of competition rules.

The French Competition Authority, in its opinion n°13-A-24 dealing with the functioning of competition in the sector of the distribution of medicines for human use in town, pointed out several times the imperatives of protection of public health in the formulation of its recommendations, for example when it advocated the widening of the repertory of generic medicines or the sale of certain non-medical products outside dispensatory[33].

Similarly, when it expresses recommendations advocating for the opening of the online sale of non - prescription medicinal products, it specifies that this should be done "*by fulfilling the requirements relating to protection of public health*"[34], and it equally considers that a cautious approach of public powers reserving this activity only to pharmacists already owning a dispensatory " *guarantees already the appropriate level of security of the products, the protection of public health and the reliance of patients.*"[35].

As part of the exercise of its advisory powers, by analysing potential restrictions of competition into the project of legislatives or statutory acts of which it is seized, the French Competition Authority can also analyse the alleged justifications holding the protection of public health, such as the security of supply

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28 Une politique de prix bas sur un marché non dominé de manière à dissuader l'entrée des rivaux sur le marché dominé.

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30 Cour d'Appel de Paris (1ère chambre, section H), 8 avril 2008, RG n° 2007/07008, confirmé par Cour de cassation, Chambre commerciale, 17 mars 2009, p n° 08-14.503.

31 Autorité de la concurrence, écision n° 14-DCC-61 du 25 avril 2014 relative à la prise de contrôle exclusif des sociétés Imarko SA et Laboratoires Arkopharma SA par la société Apharma Capital SAS ; et Autorité de la concurrence, décision n° 13-DCC-187 du 10 décembre 2013 relative à la prise de contrôle exclusif de la société Omnium Synerlab par la société 21 Centrale Partners.

32 Autorité de la concurrence, décisions n° 13-DCC-106 du 6 août 2013 relative à la prise de contrôle exclusif de la société Warner Chilcott plc par la société Actavis, Inc, ; Autorité de la concurrence, décision n° 10-DCC-191 du 20 décembre 2010 relative à la prise de contrôle exclusif des sociétés du groupe Théramex par le groupe Teva.

33 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013 relatif au fonctionnement de la concurrence dans le secteur de la distribution du médicament à usage humain en ville, points 569 et 722.

34 Autorité de la concurrence, avis n° 13-A-12 du 10 avril 2013 relatif à un projet d'arrêté de la ministre des affaires sociales et de la santé relatif aux bonnes pratiques de dispensation des médicaments par voie électronique, point 24.

35 Autorité de la concurrence, avis n° 13-A-12, précité, points 101, 172 et 178.

of sensitive medicines.[36] The French Competition Authority also takes into considerations those interests when it analyses the online sale of medicines.[37]

c) Are there any specialist bodies with responsibilities relating to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical regulation with a competition law competence, or a consumer protection body with specialist pharmaceutical competence? If so, please provide a brief description of the body and its powers.

In France, there is no specific institution or body with a competence on the application of pharmaceutical competition law. Anticompetitive practices in the pharmaceutical sectors are a matter of the French Competition Authority's jurisdiction. Obviously, civil and commercial jurisdictions remain competent to address the litigation between individuals.[38]

d) Please provide details of any sector-specific reviews of competition law in the pharmaceutical sector. Have any such reviews led to increased enforcement activities?

Recently, the French Competition Authority led a study of the pharmaceutical market that was published in December 2013, the opinion n°13-A-24, concerning the functioning of competition in the sector of distribution of medicines for human use in town. In this opinion the Authority underlines the importance of competition to implement the innovation and the competitiveness of pharmaceutical companies.

The French Competition Authority particularly insisted on the very frequent use of commercial denigration in France[39]. According to her, this commercial denigration has an impact on the general mistrust in France concerning generic medicines and has an indirect negative effect on the incentives to innovate.[40] The opinion is relatively recent and at our knowledge no case directly related to this matter has been referred yet. However, the French Competition Authority makes reference to the opinion in certain case concerning commercial denigration against generics: three decision rulings on precautionary measures before 2013 and two important decisions in 2013. One case is still pending, since the French Competition Authority rejected the parties' request for precautionary measures[41].

The functioning of intermediaries on the pharmaceutical market ended up being the object of an accurate exam. The Authority considers that the wholesalers-distributors, that play a decisive role, have found difficulties to distribute at competitive prices the self-medication's medicines.

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36 Autorité de la concurrence, avis n° 12-A-18 du 20 juillet 2012 portant sur un projet de décret relatif à l'approvisionnement en médicaments à usage humain, point 129.

37 Dans un récent avis (Avis n° 16-A-09 du 26 avril 2016 relatif à deux projets d'arrêtés concernant le commerce électronique de médicaments) l'Autorité de la concurrence a émis un avis favorable sur deux projets d'arrêtés visant à réglementer la vente en lignes de médicaments, estimant que les obligations imposées aux pharmaciens par ces projets sont disproportionnées par rapport aux objectifs de santé publique poursuivis. Ainsi, les nouvelles dispositions, qui ajoutent un grand nombre de formalités supplémentaires quant à l'analyse et au conseil pharmaceutique, « *n'apparaissent pas justifiées par des motifs de santé publique propres à la spécificité de ce mode de dispensation* » (point 83) De plus, ces contraintes supplémentaires ne concernent que les pharmacies exclusivement en ligne, et ne s'imposent pas aux pharmacies d'officines, constituant ainsi une discrimination à l'encontre de la vente en ligne qui peut avoir de lourdes conséquences « *d'un point de vue juridique et économique mais aussi de santé publique* » (point 84). L'Autorité estime que ces projets d'arrêtés conduiront à limiter l'attractivité et la compétitivité de l'offre française face à celles de sites étrangers, avec comme conséquence importante le risque de voir les patients français recourir à des sites non autorisés, beaucoup plus souples dans leur utilisation, et pouvant commercialiser des contrefaçons de médicaments (points 87 à 89).

38 Voir par exemple : Cour de cassation, Chambre commerciale, 23 avril 2003, n° 00-17.166, dans lequel Smithkline Beecham a assigné Lilly France pour concurrence déloyale du fait d'une publicité comparative qu'elle estimait dénigrant ;et Cour de cassation, Chambre commerciale, 22 mars 2011, n° 10-17.814, dans lequel la société Ferlux estimait subir des actes de dénigrement de la part d'une société concurrente.

39 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, point 461

40 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, page 11.

41 Autorité de la concurrence, décision n° 09-D-28 du 31 juillet 2009, précitée : la demande de mesures conservatoires a été rejeté faute d'une atteinte grave et immédiate à l'entreprise plaignante ou à l'économie générale, au secteur intéressé ou à l'intérêt des consommateurs.

According to this study, this is manly caused by laboratories which encourage the direct sale by large dispensaries. Furthermore, the entities of joint purchase and pharmaceuticals buying-in groups, created in order to encourage the joint purchase of small size or isolated pharmacies, are unable to develop themselves such as they don't take benefit of commercial advantages that laboratories grant to the dispensaries of a bigger size in the context of the direct sale.

Finally, the French Competition Authority also analysed the functioning of the downstream market and particularly of dispensaries. Recognising the weak intensity of competition between dispensaries, the French Competition Authority have recommended the sale of self-medicines and of certain products called "*boundaries*"[42] in drugstores or in hypermarkets, in order to make consumers benefit of the really strong capacity of negotiation of those structure of commerce. However, this opening should be regulated by strict rules, in order to guarantee the quality and the security of the sale of medicines[43].

e) Is there any set of guidelines particularly relevant to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical specific set of guidelines or a set of competition law guidelines addressing intellectual property issues?

There is no set of particular guidelines at national level concerning the application of competition law to the pharmaceutical sector or concerning the related issues of intellectual property.

However, the opinion n° 13-A-24, concerning the functioning of competition on the sector of distribution of medicines for human use in town, published by the French Competition Authority that details its analyse of specific problematic of competition in the pharmaceutical field, appears as one. This opinion specifies the elements that the Authority considers as important and to be taken into consideration when analysing anticompetitive practices on the sector but it also details its previous decisional practice.

f) Is enforcement in pharmaceutical cases primarily public or private in character? Does this differ from the situation in other industries?

In France, enforcement of competition law is essentially public, both in the pharmaceutical sector and on other sectors. The French Competition Authority is the source of all the penalties against pharmaceutical companies for a breach of competition law.

Only few actions for compensation of competitive damages were brought before national jurisdictions. However, this type of litigation might increase with the introduction in French law of the class actions with the Consumer Affair Act n°2014-344 of the 17th March 2014 also called "*Loi Hamon*"[44].

The class action was originally opened only for procedures regarding consumers and competition. Recently, a reform of the Act enabled user's associations that wish to obtain compensation for the prejudice suffered in the medical field[45] to resort to the aforesaid class action. However, the latter can only concern the compensation of the prejudice resulting from a physical injury suffered by users of health system[46].

g) Which remedies tend to be applied in pharmaceutical competition law cases in your jurisdiction, such as fines, disgorgement of profits, damages, or injunctions?

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42 Comme par exemple les tests de grossesse, les produits d'entretien pour lentilles de contact, etc…

43 Autorité de la concurrence, avis 13-A-24du 19 décembre 2013 précité, points 712 à 729.

44 Les actions de groupe sont cependant très encadrées et complexes à mettre en œuvre. En effet, seules des associations de consommateurs, représentatives au niveau national et agréées, peuvent lancer une procédure devant les juridictions civiles. Par ailleurs, une action de groupe ne peut être introduite avant qu'une décision de l'Autorité de la concurrence constatant les manquements concurrentiels ne soit devenue définitive sur ce point, ce qui peut conduire à des procédures très longues.

45 Article 184 de la loi n° 2016-41 du 26 janvier 2016 dite de « Modernisation de notre système de santé », codifiés aux articles L. 1143-1 à L. 1143-22 du Code de la santé publique.

46 Codifié à l'article L. 1143-1 du Code de la santé publique.

The penalties applied in pharmaceutical competition law cases, as in other areas, result mostly in fines imposed by the French Competition Authority. The calculation of fines is detailed in a press release of the French Competition Authority[47], and it takes into account the seriousness of the facts, the importance of the damage caused to economics, the situation of the sanctioned undertakings and eventually the reiteration of practices prohibited by competition law[48].

Nevertheless, the French Competition Authority tries more and more to pass compliance programs or commitments[49]. Indeed, in recent cases of commercial denigration, the French Competition Authority accepted the implementation of a compliance program in the context of commitments following the "no-challenge" of the SO in order to educate sale representatives on the prohibition of commercial denigration meanwhile many molecules of the sanctioned laboratory were about to fall into the public domain[50]. Moreover, the Authority stated on its opinion n°13-A-24 that the recovery of those commitments by all the pharmaceutical companies was desirable[51].

Also, the Authority can urge the author of the anticompetitive practice to stop the contested practice or to modify its behaviour in order to comply with competition law[52]. Finally, the Authority can "*take the demanded provisional measures or those it considers necessary* [53]" at the condition that the denounced practice "*lead to an imminent and serious injury to the general economy, to the economy of the concerned sector, to consumer interest or to the complainant's companies*"[54] .

In order to sufficiently advertise its decision, the French Competition Authority has also the faculty to impose its publication by way of press release in order to inform the companies of the sector and consumers of the harmfulness of the illicit behaviour[55]. However, the granting of damages is only a power of the judiciary order.

h) Is there a mechanism for the monitoring of patent settlements in the pharmaceutical sector, such as a register of patent settlements?

No, this kind of mechanism does not exist in France

i) Are pharmaceutical suppliers obliged in your jurisdiction to make available pharmaceutical products that they are licensed to sell? What is the extent of any such obligations?

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47 Communiqué de l'Autorité de la concurrence du 16 mai 2011 relatif à la méthode de détermination des sanctions pécuniaires.

48 Article L. 464-2 du Code de commerce.

49 Article L. 464-2, I du Code de commerce. Les propositions d'engagements sont généralement suivies d'un test de marché (publication des propositions d'engagements sur le site de l'Autorité afin de recueillir les observations des tiers intéressés), l'Autorité décide ensuite de les accepter et clore l'affaire ou non. L'Autorité peut également décider d'une réduction d'amende, pour inciter les entreprises à proposer des engagements et à souscrire à des programmes de conformité.

50 Par exemple: Autorité de la concurrence, décision n° 13-D-21 du 18 décembre 2013, précitée.

51 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013précité, point 529.

52 Article L. 464-2, I du Code de commerce. En cas de non-respect d'injonction, l'Autorité a la possibilité de prononcer une décision de sanction pour non-respect d'injonction, éventuellement accompagnée d'astreinte (article L. 464-3 du Code de commerce).

53 Article L. 464-1 du Code de commerce.

54 Par exemple, dans l'affaire 07-MC-06 qui concernait des pratiques de dénigrement, l'Autorité a imposé à Schering-Plough, auteur des pratiques alléguées, de publier un article réaffirmant la bio équivalence entre les médicaments génériques et le princeps, ainsi que l'innocuité de la substitution par les pharmaciens dès l'arrivée d'un générique sur le marché. L'Autorité a néanmoins plusieurs fois rejeté les demandes de mesures conservatoires, les conditions légales n'étant pas réunies, tout en poursuivant l'instruction au fond afin de qualifier les pratiques. Voir par exemple la décision n° 09-D-28 du 31 juillet 2009, dans laquelle l'Autorité refuse de conclure à ce stade de l'examen que les prix très bas, qui confinaient parfois à une quasi-gratuité, s'inscrivent dans le cadre d'une stratégie de prédation, et reconnait l'absence d'atteinte grave et immédiate à l'un des intérêts protégés par l'article L. 464-1 du Code de commerce, mais décide de poursuivre l'instruction au fond. Voir également Décisions 00-MC-16 du 7 novembre 2000, 02-MC-09 du 12 juin 2002 et 02-MC-07 du 15 mai 2002.

55 Article L. 464-2, I du Code de commerce. Généralement c'est un extrait de la décision expliquant la raison de la condamnation qui est publié. Les frais sont supportés par la personne intéressée.

The new law of 26th of January 2016 of modernisation of the health system provides in its article 151 that "*marketing authorisations holders and pharmaceutical companies exploiting medicines ensure an adequate and continuous supply of the national market in order to cover the needs of patients in France. For that purpose, they supply adequately and continuously all authorized establishments under a wholesaler-dispatcher activity in order to allow them to fulfil the obligations of public services stated at the first paragraph of the article L. 5124-17-2. They take all the necessary measures to prevent and mitigate all supply's difficulties and allow, in the case of stock shortage, the provisioning of the information of which they dispose to pharmacists of dispensatory, and to pharmacists of pharmacies for indoor use as defined at the article L. 5126-1 and to pharmacists responsible or delegates of wholesalers-dispatchers*"[56].

This provision was adopted after many stock shortages of various essential medicines. Hundreds of cases of supply shortages of health products were reported each year to the Agency of security of medicine[57]. During the parliamentary debates, an amendment tried to insert an obligation of production and of supply of medicines by the laboratories, with the possibility to entrust to a tiers the production of the medicine in order to ensure the necessary supply[58], but the amendment was rejected, considering that the article 151 was going already very far as regards the obligations imposed to laboratories[59].

j) Are there any decisions of competition authorities or court judgments that deal with the application of the competition rules to agreements or conduct in relation to the distribution of pharmaceutical products (e.g. agreements between manufacturers and distributors or retailers or conduct such as refusal to supply)? To what extent do those decisions of judgments suggest that the application of the competition rules to the distribution of pharmaceutical products is affected by the characteristics of pharmaceuticals?

The wholesale-distributors intervene within the distribution channel of medicines in France. Their margin is regulated as far as the distributions of refundable medicines is concerned, and are subject by law to obligations of public service[60]. Even if generally the French Competition Authorities have the tendency to look favourably at short commercialisation channels[61] (avoiding the catchment of a part of the profit by intermediaries at the expenses of others actors of the value chain), the role of the wholesalers-despatchers, appears in the opinion of the French Competition Authority, in the actuals conditions of the distribution of medicines, necessary to the regular and fast supplies of the dispensaries network[62], as whished for by public authorities.

Since, the analysis of the practices of quotas system by pharmaceutical companies towards wholesalers-exporters (that buy the medicines to laboratories to export them later in order to benefit from differences of price within the UE) takes into consideration this reality.

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56 Codifié à l'article L. 5121-29 du Code de la santé publique.

57 http://www.leem.org/sites/default/files/Dossier-de-presse-Atelier-presse-20-mai-2014_0.pdf ; la liste des médicaments en rupture de stock est disponible sur le site de l'ANSM : http://ansm.sante.fr/S-informer/Informations-de-securite-Ruptures-de-stock-des-medicaments.

58 L'amendement est ainsi rédigé : « Insérer deux alinéas ainsi rédigés : « *Si la rupture n'est liée à aucune raison technique ou de qualité le laboratoire doit avoir l'obligation de le produire et de le fournir. Si la rupture est liée à des problèmes techniques ou si le produit n'a plus la qualité requise, il y a obligation pour l'entreprise de corriger les problèmes dans un délai donné. En attendant le retour à la normale, la production de ce médicament, que ce soit le principe actif ou la formulation pharmaceutique qui soit défaillante, peut être confiée à un tiers pour assurer l'approvisionnement nécessaire* ». Cet amendement avait pour objectif de permettre à l'ANSM d'imposer à un laboratoire qui décide de suspendre la commercialisation d'un médicament de produire celui-ci.

59 http://www.senat.fr/seances/s201509/s20150929/s20150929008.html ; le corapporteur a indiqué que l' « *obligation de produire et de fournir, ainsi qu'une nouvelle possibilité de confier à un tiers la production de médicaments qui posent des problèmes en matière de droit de la propriété. Le risque, en effet, est que l'État se trouve obligé d'indemniser le laboratoire du fait des obligations qu'il lui impose, ce qui n'est certainement pas l'objectif recherché par les auteurs de l'amendement.* »

60 Livraison des officines dans les vingt-quatre heures et de détention d'un stock de deux semaines comprenant au moins neuf dixième des spécialités pharmaceutiques effectivement commercialisées en France.

61 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, point 618.

62 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, page 11.

If in normal times the practices of quotas system are rarely analysed positively by Competitions Authorities, the French Competition Authority considered that "*a pharmaceutical laboratory might organise the distribution of its productions with regard to a legitimate objective of optimal supply of the different nationals markets*[63]" specifying that if the quotas system can be justified, it would be only "*at the condition that the restrictions induced by this regulation would be limited to what is strictly necessary to a reliable and optimal supply of the national market"*[64].

Moreover, the Competition Council specified that systems of quotas could be justified only in a very specific context, particularly reminding the specifics obligations imposed to laboratories on the French market "*on the double context of security of supplies and the policy of the control of the health expenditures*" [65]. These principles are reminded in the opinion n° 12-A-28 of the 20th of July 2012 by the Authority[66].

k) Please comment on any other aspects that you consider being relevant of the interplay of consumer protection law and competition law in the context of the pharmaceutical sector in your jurisdiction.

It should be noticed that the "*DGCCRF*", attached to the Ministry of the Economy, ensures particularly the protection of consumers. The DGCCRF has among other the mission to protect their physical security and their health. In this regards, it is in charge of the information and the protection of consumers against abusive or illicit commercial practices.

The DGCCRF conduces regular controls in order to verify compliance with the "*Anti-Gift Act*" that forbids pharmaceutical companies to grant advantages to doctors and pharmacists in order to influence/affect their prescription of medicines[67].

Part 3 – Innovation questions / Questions sur l'innovation

a) Is there legislation promoting generic entry in your jurisdiction? If so, please provide details of instances in which competition law has been applied in the context of the legislation.

In France, the entry of generics is promoted by a set of legislatives or statutory measures concerning particularly the substitution, prescription and refund by health insurance, along with the simplification of the administrative procedure to grant the marketing authorisation of generics.

First of all, in 1998, a "*Répertoire des groupes génériques*" that lists all authorized substitutable medicines in France by speciality groups was created. The Health Authority registers the groups in a folder that are "*classified by active ingredients identified by their common denomination preceded by the indication "common name" and by administrative way*"[68].

The Law n°98-1194 of the 23 December 1998 on social security financing for 1999 (LFSS), introduced a pharmacist's substitution right allowing them to replace prescribed reference medicines or generic version with other generic medicines belonging to a same group. To encourage the substitution, the law-maker also created a single officinal margin for generic medicines belonging to the same group. Since then, pharmacists have the insurance to obtain the same margin for both generic and princeps medicines, being usually the price of princeps higher than the one of generics.

Afterwards, the LFSS for 2002 introduced the prescriptions with a Non-proprietary Name (NN) according to which "*when a pharmacist delivers a speciality under the presentation of a NN prescription, the delivery of this speciality shall not lead to an additional expense for the health*

63 Conseil de la concurrence, décision n° 07-D-22 du 5 juillet 2007 relative à des pratiques mises en œuvre dans le secteur de la distribution des produits pharmaceutiques, pt. 99.

64 Conseil de la concurrence, décision n° 07-D-22 du 5 juillet 2007, précitée, point 100.

65 Conseil de la concurrence, décision n° 07-D-22 du 5 juillet 2007, précitée, point 99.

66 Autorité de la concurrence, avis n°12-A-18 du 20 juillet 2012, précité, point130.

67 Voir : http://www.economie.gouv.fr/dgccrf/lapplication-loi-anti-cadeaux-dans-secteur-sante.

68 Article R. 5121-8 du Code de la santé publique

insurance which would be higher than the expense at what it would have led the delivery of the speciality of the most expensive generic of the same group"[69]

According to the LFSS for 2009, prescribing by INN is mandatory for all specialty medicines belonging to the same group of generics[70]. Since then, if the prescription is issued by INN, the pharmacist may dispense any generic medicine belonging to the same group of generics[71].

However, the prescribing physician can specifically prohibit substitution, considering the patient's particular status, by a handwritten comment on the prescription ("*do not substitute*" mention). At the end of 2011, the law on the increase of sanitary supervision and sanitary control of products for use by humans made prescription by INN became mandatory also for branded pharmaceutical products, to enter into force on 1 January 2015.

The LFSS for 2003 completed the pre-exiting regime by introducing the "*reference price reimbursement system*" (TFR) that establishes the possibility of reimbursement limited to a reference price for medicines belonging to the same generic group.

Finally, the "third-party payment in exchange for generics system" was established. The LFSS for 2007 amended the Social Security Code by reserving the benefit of the third party payment system only to patients accepting substitution medicines (generics), except where generics are subjected to the TFR system or where it exists a generic of the considered group of generics for which price is higher or equal to the price of the princep medicine.

These different provisions are considered by the French Competition Authority in its decisions as indicators of anti-competitive practices. Thus, in the abovementioned decisions *Plavix* and *Subutex*, the French Competition Authority, in assessing the behaviour of the laboratory, examined the evolution originator medicine substitution rates and concluded that this change was "unusual", thus suggesting that the advertising of the laboratory had the effect to limit substitution.

b) A major aim of the report is to identify whether there is consistency across jurisdictions in the factors taken into account to assess the interplay of competition law and intellectual property law claims. Please comment on whether the following factors tend to be taken into account when a court or regulator decides whether intellectual property has been exercised in an anti-competitive way in pharmaceutical markets.

i. Do courts and regulators in your jurisdiction provide a shield for potentially anti-competitive conduct on the basis that it falls within the scope of intellectual property (sometimes referred to as a "scope of the patent" approach)?

In France, Competition authority and jurisdictions consider that intellectual property rights on pharmaceuticals such as patents and supplementary protection certificates (SPC) do not exonerate the laboratories from their obligations under competition law. In other words, a laboratory can be convicted of a conduct on a medicinal product protected by a patent.

ii. If so, how expansive is the protection? Does the mere presence of intellectual property trigger an absolute bar to competition law enforcement (e.g. allowing even a large reverse payment provided it is made within the patent term), or is a balance struck between the intellectual property right and competition law?

A medical product can be protected by a patent, for which the objective is to grant the inventor an exclusive right for a limited period of 20years[72]. In practice, the protection period is frequently much

69 Article L. 162-16 du Code de la sécurité sociale

70 Article 50 de la loi n°2008-1330 du 17 décembre 2008 de financement de la sécurité sociale pour 2009 et article L. 5125-23 du Code de la santé publique

71 Article L. 5125-23 du Code de la santé publique

72 L'article 33 de l'Accord sur les aspects des droits de la propriété intellectuelle (accord « TRIPS ») dispose que « *la durée de la protection offerte ne doit pas prendre fin avant l'expiration d'une période de 20 ans à compter de la date de dépôt* ».

shorter, since the 20 years of the patent cover also the timing of studies performed on animals and humans as well as the time required in order to obtain the marketing authorisation.

For those reasons, at the expiration of the patent and under the regulation n° 469/2009 EC, the laboratory can apply for a supplementary protection certificate, allowing it to provide a supplementary protection of 5 years, not exceeding however a total term (patent + SPC) of 15 years from the date of the first marketing authorisation issued in the EU. In practice, the marketing of originator brand medicines is secured for about ten to fifteen years.

It also exists an administrative-data protection: the results of the studies carried out on originator brand medicines, filed in its dossier MA, are data that benefit of an administrative protection of 8 years. An application for MA for a generic medicine can thus be filed at the French Health Products Safety Agency within 8 years from the granting of the first European MA for the reference medicinal product.

French Competition Authority does not have the competence to decide on the validity of an IPR or on scientific debates.

The speech of the Competition Authority invites to strike a balance between IP and competition law. Therefore, the Competition Authority stated that "*the imperative to put competition policy at the service of innovation and value creation*[73]" and considers that "*the animation of competition is likely to boost innovation and competitiveness of pharmaceutical companies*[74]". It endorses the legitimacy of originator companies to defend their IPR on their medicinal products before jurisdictions in order to ensure keeping innovation.

Mainly, two practices relating to IPR have been identified as likely to be anticompetitive/potentially anticompetitive.

The first practice is the right to bring proceedings for infringement of IPR (counterfeiting). Indeed, the competition Authority considers that the use of IPR will be abusive in cases where, proceedings aiming to protect a patent, would have served rather as a signal to deter generic entrants. It should be pointed out that with regard to patent litigation, claims for abusive proceedings, brought by defendants against proceedings for infringement of patent, are manly rejected. French courts often consider that "*the holder of a patent could have been legitimately under any misapprehension as to the scope of his rights*". Thus far and to our knowledge, no abusive practice for actions for infringement has been characterised by the competition authority.

The French Competition Authority and the Court of Appeal also stated that originator companies' right to protect the quality of their medicines should not have been implemented through a commercial denigration of the generic companies. In the judgement Plavix mentioned above, the Court of Appeal recalled that companies have "*the right to promote their originator products, since the promotion remains objective and does not introduce an element of suspicion with regard to competing products*". Thus, in the cases *Plavix* and *Subutex*, the Competition Authority sanctioned the pharmaceutical laboratories Sanofi and Plough for have denigrated their generics.

iii. Must an agreement exclude rivals to trigger competition law enforcement, or does it suffice for an agreement (e.g. pay for delay) to exclude only the party to the agreement?

To our knowledge, the French Competition Authority has never sanctioned a practice of "*pay-for-delay*" (or "postponing agreements") in the pharmaceutical sector. If the Authority would come to characterise or to sanction such a practice, it is likely that it will adopt the same approach as the one adopted by the European Commission on the cases *Lundbeck*[75] and *Johnson & Johnson*[76], considering that it suffices to exclude solely the party from the agreement to characterise an anticompetitive one.

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73 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité

74 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité.

75 Commission européenne, *Lundbeck*, 19 juin 2013, aff. COMP/AT.39226.

76 Commission européenne, Johnson & Johnson, 10 décembre 2013, aff. COMP/AT.39685.

iv. Are there examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in your jurisdiction?

The French Competition Authority has never been called on to rule on an agreement between originator and generic companies in the pharmaceutical sector. Instead in the *Subutex* case, the Authority ruled on an agreement between a pharmaceutical laboratory and its retailer. In this case, Schering Plought and this retailer Reckitt Benckiser were accused to have entered into an agreement aiming from one side to "*delay/ discourage the entry of generic medicines*" and on the other side "*to minimise the penetration of generic*" through the "sale to pharmacists" and through "costumers' loyalty programs". Thus, it considered that the agreement was anticompetitive by object.

v. Is the date of the settlement in the context of the patent term a relevant consideration?

The French Competition Authority has never been called on to rule on "*pay for delay*" practices.

c) Please comment on any other relevant factors other than those already raised in question 3(b), if any, that tend to be looked at in pharmaceutical cases in your jurisdiction to adjudicate conflicts between competition law and intellectual property law claims.

As mentioned above, the Competition Authority has never sanctioned « *pay for delay* » practices. On the other hand, it has developed a decision-making practice relating to commercial denigration by originator companies of generic companies. In carrying out the analysis, the French Competition Authority takes into account many contextual factors, extraneous from the behaviours of the parties. Therefore, the Authority considers the following factors: the mistrusts of patients and health professionals towards generics, the level of knowledge and information of health professional on medecines and on the applicable legal framework.

d) Please briefly comment on the barriers to entry typically faced by a generic drug maker looking to enter the market. Are there examples of these barriers being in any way artificially raised?

The barriers to entry of generic medecines result of the use made by the originator companies of their patents.

Firstly, originator companies may submit supplementary protection certificates applications in order to extend the length of patent protection. The French Competition Authority recognised that " *certain (certificates) have sometimes a questionable nature as their only objective seems to be to hamper entry of generic medicines onto the market.*"[77]

Secondly, generic companies may face a plurality of patents registered by an originator company on a medicine. Indeed, a medicine can be protected by patents on the active ingredient and its different synthesis process, but also by patents protecting the pharmaceutical formulation and the galenic formulation. At the expiration of the patent protecting the active ingredient, the pharmaceutical forms are frequently protected by their patent. Consequently, the originator companies can place the molecule onto the market but they cannot use the appropriate galenic formulation.

Thirdly, an originator company may decide to launch a "second-generation medicine". This strategy was condemned in the case *UCB Pharma*[78]. The company withdrew from the market its reference medicine few months before the expiration of the patent before launching a second version of it, protected by a new patent.

77 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, point 343.

78 Autorité de la concurrence, décision n° 10-D-37 du 17 décembre 2010, précitée.

Fourthly, generic companies face the risk of infringement actions (counterfeiting), particularly in the case of patents portfolios that create an uncertainty on the extent of the protected rights.

Fifthly, pharmaceutical companies often resort to "divisional patent applications" that lengthen the deadline for examining applications, since the exam of divisional patents applications continues even if the initial application is withdrawn.

Finally, there are natural barriers such as administrative barriers. They include delays in the processing of applications for MA for generics and the overrun of time-limits set in national texts.

Part 4 – Public finance considerations / Problématiques liées aux financements publics

a) Some jurisdictions exempt certain bodies in the healthcare industry from competition law, such as by granting insurers or bodies exercising a public competence blanket exemptions or by not including them as relevant "undertakings". Is competition law applied consistently to healthcare purchasers and providers in your jurisdiction? If it is not, what is the basis for differential treatment?

In accordance with European law, French law considers that a body is subject to competition law, regardless of its legal status and the way in which it is financed, if it constitutes an undertaking. The definition of undertaking under Competition Law is stated at article L.410-1 of the Commercial Code as "*all production, distribution and service activities*". According to case law, applying the European decision-making practice, a body to be qualified as an undertaking shall be "*a provider on the market*", *i.e.* offering goods or services[79] on a given market, regardless of the lucrative or not character of the activity[80]. Therefore, a demand for care services or health products on a given market suffices in order to apply competition law.

The case law and the decision-making practice made a distinction, in the health care sector between health services and products marketing activities and entities conducting social protection activities.

(i) Health services and products marketing activities

Within health services and products marketing activities, two types of activities can be distinguished: the activities taking place on a so called "open" market, in which prices are established by free competition, and the activities taking place on a "regulated" market in which mechanisms of price control have been implemented. (Cf. réponse à la question 4 c).

On the "open" market, the principle that economic operators shall be free to fix prices remains fully applicable as the rest of competition rules.

In the case of a "regulated" market, the Competition Council considered that the existence of a regulation restricting free competition did not preclude the application of competition rules[81]. (cf. question 1. d)

The activities of many players in the health sector have been more specifically analysed according to articles L. 410-1 and seq. of the Commercial Code. For example, are considered as economic activities on a given market and to fall within the scope of competition law, the activities implemented by specialised doctors[82], liberal radiologists[83], companies responsible for emergency medical

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79 Cour de cassation, Chambre commerciale, 12 décembre 1995, Direction météorologique.

80 Par exemple, Cour de cassation, Chambre commerciale, 21 octobre 1997, chambre syndicale des pharmaciens du Maine-et-Loire dans laquelle la Cour de cassation a considéré, s'agissant de mutuelles que *« le régime juridique des mutuelles, comme le caractère non lucratif de leur activité, n'est pas de nature à les exclure du champ d'application de l'ordonnance du 1er décembre 1986, dès lors qu'elles procèdent, comme en l'espèce, par la commercialisation de médicaments, à une activité de production, de distribution et de services* ».

81 Conseil de la concurrence, décision n° 01-D-07 du 11 avril 2001 relative à des pratiques mises en oeuvre sur le marché de la répartition pharmaceutique.

82 Cour de Justice des Communautés Européennes, Pavel Pavlov e.a. contre Stichting Pensioenfonds Medische Specialisten, 12 septembre 2000, aff. jointes C-180/98 à C-184/98.

transportation[84], biologist[85], dental surgeons[86], pharmaceutical laboratories[87], medical device manufactures[88], pharmacists[89] or the Order of pharmacists[90] and this even if they are practising the in a mutualistic scheme[91].

(ii) Entities conducting social protection activities

Social security bodies can manage both activities falling within the scope of a mission of public service and competitive activities.

A distinction is made by the decision-making practice between the social activity based on solidarity, and the competitive activity of social security bodies. According to this latter, the social activities of social security bodies are exempted from competition rules while the activities performed outside those missions of public service enter within the scope of competition law. Thus, the criterion of distinction for the application of competition law to these bodies is a material one.

The decision-making practice and case law qualified as social activity based on the principle of solidarity supplementary old-age insurance schemes, even optional[92], regulatory bodies for which the membership is compulsory and of which the contribution rate as the benefits that they issue are fixed by law and statues[93], the electronic data capture systems of health insurance[94], the national family allowance fund (CNAF) when it proposed a free website in competition with other similar websites run by private operators[95].

On the opposite, the activity of social security bodies that doesn't concern the managing of social security schemes, may be qualified as a service activity falling within the competition scope, when these bodies sell goods or services[96]. For example, were considered as falling within the scope of competition law bodies in charge of the supplementary old-age and health insurance schemes[97] or the supplementary benefits (offered) by mutual[98].

b) Does enforcement on behalf of third party payers such as insurers or public funding bodies tend primarily to be public or private in character? Please comment on any relevant differences, if any, in the enforcement pattern on the basis that such bodies are involved.

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83 Conseil de la concurrence, n° 06-D-36 du 6 décembre 2006 relative à des pratiques mises en œuvre par la société civile de moyens Imagerie Médicale du Nivolet.

84 Conseil de la concurrence, n° 06-D-05 du 15 mars 2006 relative à des pratiques mises en œuvre dans le secteur des transports sanitaires d'urgence dans le Doubs et le Jura.

85 Conseil de la concurrence, n° 99-D-01 du 5 janvier 1999 relative à des pratiques mises en œuvre par la société Distri club médical.

86 Conseil de la concurrence, n° 05-D-43 du 20 juillet 2005 relative à des pratiques mises en œuvre par le Conseil départemental de l'Ordre national des chirurgiens-dentistes du Puy de-Dôme et le Conseil national de l'Ordre national des chirurgiens-dentistes.

87 Conseil de la concurrence, n° 07-D-09 du 14 mars 2007, précitée.

88 Conseil de la concurrence, n° 99-D-01 du 5 janvier 1999, précitée.

89 Conseil de la concurrence, n° 97-D-18 du 18 mars 1997 relative à des pratiques relevées dans le secteur du portage de médicaments à domicile.

90 Autorité de la concurrence, décision n° 09-D-17 du 22 avril 2009, précitée.

91 Cour de cassation, Chambre commerciale, octobre 1997, Chambre syndicale des pharmaciens du Maine-et-Loire.

92 Cour de cassation, Chambre criminelle, 25 novembre 1992, n° 91-83.512.

93 Conseil de la concurrence, n° 93-D-20 du 8 juin 1993 relative à la saisine présentée par la Confédération européenne de défense des travailleurs Indépendants.

94 Autorité de la concurrence, n° 14-D-12 du 10 octobre 2014 relative à des pratiques mises en œuvre dans le secteur de la fourniture de données de santé par la Caisse Nationale d'Assurance Maladie des Travailleurs Salariés et le GIE SESAM-Vitale.

95 Autorité de la concurrence, n° 10-D-24 du 28 juillet 2010 relative à des pratiques mises en œuvre par la Caisse Nationale des Allocations Familiales.

96 Conseil de la concurrence, n° 01-D-62, relative à la mise à disposition d'appareils médicaux par certaines CPAM.

97 Conseil de la concurrence, n° 01-D-55 du 21 septembre 2001 relative à des pratiques mises en œuvre sur le marché du remboursement complémentaire à l'assurance maladie.

98 Cour de cassation, Chambre criminelle,, 21 octobre 1997, n° 95-14.457 ; Cour de cassation, chambre commerciale, 12 mars 2002, n° 00-11.638.

As stated before, the enforcement of competition law is essentially public and there is no noticeable difference concerning actions initiated by insurers or public funding bodies.

Public bodies can initiate litigation before authorities or jurisdictions in order to recover the overpayments from laboratories, as a result of practices aiming to postpone or prevent the entry onto the market of generic medicines.

Public bodies can file a complaint before the Competition Authority if they consider that they have been harmed by certain anticompetitive practices. The Competition Authority will therefore assess these practices in the light of articles L. 420-1 and L.420-2 of the Commercial Code.

However, the French Competition Authority has no jurisdiction over damages actions resulting from anti-competitive practices. Therefore, the public body must have recourse to ordinary courts, and particularly the commercial judge, to seek compensation for the damage suffered. It would then be up to the third-party payer to prove the misconduct[99] of the parties involved in the anticompetitive practice, the prejudice and the causal link.

c) Please provide brief details of pricing controls of pharmaceuticals in your country. Do these differ if a public healthcare provider is purchasing medecines?

On French law, prices of pharmaceuticals are regulated. A distinction is made between the distribution of health product in the city and in the hospital market (private and public).

(i) Distribution of health products in the city

In France, the prices for medicines non-reimbursed by the social security are not regulated. The remuneration for the delivery is also not regulated. If manufacturers and brokers are free to set the price of those medicines, they are still subject to the same competition principles as any other consumer product. It is also noted that in accordance with the ethical principles of pharmacists, they must set prices with *"tact and moderation"*. [100] As derogation to the general rule of free pricing stated at the article L. 410-2 of the Commercial Code, prices and margins of reimbursable pharmaceuticals are regulated.

The price of reimbursable pharmaceuticals, originators or generics, is fixed by an agreement between the laboratories and the Economic Committee for Medicinal Products. Concerning generic medecines, the CEPS uses a method of calculating that consists in doing a discount of 60% from the price of the princeps, fixed before the entry onto the market of generic medecines. The maximal amount of margin realised by the wholesaler-distributor and/or by retail pharmacies is fixed by a decision of the 4 August 1987 concerning prices and margins of reimbursable medicines, vaccines and allergens products specifically prepared for an individual.

(ii) Distribution of health products in the hospital market

In France, the prices of health products purchased by public or private health bodies are not regulated. Concerning public health bodies, the purchase of health products is governed by the French Code of public procurement. Moreover, if on one side, health products distribution to health bodies is characterised by the deregulation of prices, one the other, competition law rules set the conditions under which pharmaceutical laboratories are able to set their prices and to grant discounts, rebates or reimbursement to their clients.

d) If so, are there restrictions on parallel trade or resales of those medecines subject to price control? Are any such restrictions specific to pharmaceutical products, e.g. special legislative provision, or do they merely reflect the application of ordinary competition law doctrine?

The Competition authority was called upon to rule on practices implemented by pharmaceutical laboratories which seek to restrict parallel trade in medicines several times. On this behalf, the French Competition Authority "*analyses differently the practice depending on the status of the interested distributor: simple exporters or wholesalers-distributors subject to public service obligations*"[101].

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99 Seulement si l'Autorité de la concurrence ne s'est pas prononcée sur la pratique en question.

100 Article R. 4235-65 du Code de la santé publique.

101 Conseil de la concurrence, Rapport annuel pour 2008, Etude thématique « Droit de la concurrence et santé », p. 124.

In the case of restrictions on parallel trade by "simple exporters" [102], the Competition Council considered that pharmaceutical companies, that limited or denied deliveries of medecines to exporters, wishing to purchase medecines in France to at an administered price, in order to re-sold abroad at a higher price[103], didn't commit an abuse of dominant position According to the Competition Council, the discrimination against wholesaler-distributors is justified by the supply constraints to which wholesaler-distributors are subject under their public service obligations.

Next, regarding the quota system imposed by pharmaceutical companies to wholesaler-distributors, the Competition Council accepts the practice of pharmaceutical laboratories consisting in setting up a quota system for certain medecines "*provided that the restrictions in question are limited to what is strictly necessary to a reliable and optimal supply of national market*"[104].

Moreover, article L. 5123-1 of the Code of Public Health provides that the prohibition of sales in pharmacies of medecines at a higher price than the one provided by the regulation, doesn't apply "*to medecines and products not consumed in France and for export*". Thus, this provision authorises a "*dual pricing*" system. The Competition Authority has however not ruled on this system in the light of competition rules yet.

e) Please comment on any other points of current differentiation that you consider to be relevant in the competition law treatment of pharmaceutical products in your jurisdiction that are made on the basis that public funds are involved.

f) Please comment on any other public interest considerations you believe ought to be relevant to competition law analysis in the pharmaceutical sector, if any.

- **Online sale of medecines**

Since the « *DocMorris* » ruling of the ECJ[105], Member States cannot adopt or maintain measures preventing e-commerce of non-prescription medicinal products, at least when the offer comes from actors established in other Member States.

Furthermore, the Directive 2011/62/EU of the 8 June 2011[106] harmonised the national regimes related to online sale of non-prescription medicinal products. This directive has been implemented in France by the order of the 19 December 2012[107] which foresees the possibility for the Minister of Health and Social Affairs to adopt rules on good practice relating to the online sale of medecines[108]. However, the transposition has been limited to the online sale of non-prescription medicinal products, as it was expressly intended by the Directive.

The French Competition Authority had already ruled on online sales in general terms, in particular in the case *Pierre Fabre*[109], and it was moreover called upon to rule on online sale of medecines when examining by opinion several draft of ministerial decrees relating to good medecines dispensing practices by electronic means, under the article L. 5121-5 of the Code of public health[110]. In each opinion, the Authority strongly reminded that it is in favour of an extensive use by dispensatories'

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102 Un statut séparé de distributeur en gros à l'exportation est prévu par le Code de la santé publique (article R. 5124-2, 7°). Contrairement au grossiste-répartiteur, le distributeur en gros à l'exportation n'est pas soumis aux obligations de service public auxquelles sont soumis les grossistes-répartiteur.

103 Conseil de la concurrence, décision n° 05-D-72 du 20 décembre 2005, précité, point 270.

104 Conseil de la concurrence, décision n° 07-D-22 du 5 juillet 2007, point100.

105 Cour de Justice des Communautés européennes, *Deutscher Apothekerverband*, 11 décembre 2013, aff. (C-322/01).

106 Directive 2011/62/UE du 8 juin 2011 instituant un code communautaire relatif aux médicaments à usage humain, en ce qui concerne la prévention de l'introduction dans la chaîne d'approvisionnement légale de médicaments falsifiés.

107 Ordonnance n° 2012-1427 du 19 décembre 2012 relative au renforcement de la sécurité de la chaîne d'approvisionnement des médicaments, à l'encadrement de la vente de médicaments sur internet et à la lutte contre la falsification de médicaments.

108 Article L. 5121-5 du Code de la santé publique.

109 Autorité de la concurrence, décision n° 08-D-25 du 29 octobre 2008 relative à des pratiques mises en œuvre dans le secteur de la distribution de produits cosmétiques et d'hygiène corporelle vendus sur conseils pharmaceutiques ; confirmée par la Cour de cassation, Chambre commerciale, 24 septembre 2013, CDS et autres c/ PIERRE FABRE Demo-comestique, n° 12-14.344).

110 Autorité de la concurrence, avis n° 13-A-12 du 10 avril 2013, précité ; et Avis n° 16-A-09 du 26 avril 2016, précité.

pharmacists of this new form of non-prescription medicinal products sale which allows to stimulate, modernise and make more visible their activities, enabling patients to benefit from the flexibility of online sales (such as extended hours of service, lower moving costs) lower fares and better information on products.

More specifically, on its last opinion[111], the Competition Authority concludes that the decrees assessed devoid of interest online sale of medecines for both patients and pharmacists, noting in passing the Government's will to restrict the already limited freedom for pharmacists to create an online dispensary according to the decree of 19 December 2012.

- **Entry of generic medecines onto the market**

In France, generic medicines still suffer a relative mistrust of both patients and certain health professionals (prescribing doctors, dispensary pharmacists) despite the different strategies launched by the Government to increase their market shares.

Such mistrust has been exploited for commercial denigration by pharmaceuticals laboratories against generic medecines in competition with their expiring princeps.

The Competition Authority, in its policy, encouraging the entry of generic medecines onto the market, decided to deal with these practices under competition law, as shown by the cases referred to in the report *Plavix*[112] and *Subutex*[113]. Reducing the standard of proof necessary in order to characterize commercial denigration under the article L. 420-2 of the Commercial Code on the pharmaceutical sector, the Authority has thus shown its willingness to punish any practice designed to use strategically this mistrust.

Likewise, the Competition Authority sanctions practices intending to delay or block market entry of generic medecines through rebates or discounts leading to saturation of displays.

This was the case in the *Subutex* decision[114] where the producer of originator medicines, even before the entry of generic medecines onto the market, offered some important discounts to pharmacists, without an objective counterparty, with the only aim to make pharmacist unable to source generic medecines. Some payment facilities (lengthening of payment periods, discounts) were also granted to them, in addition to the facilities usually proposed to pharmacists.

- **Distribution of medicines**

In France, the Public Health Code[115] reserves to pharmacists the preparation and the delivering of medicines to the public, in particular for medicinal products for human use, bandages, all products presented as complying with pharmacopeia, *etc.*

These French characteristic that is the medicinal monopoly, prevents therefore any sale of medicines on retails outlets others than retail pharmacies.

The French Competition Authority issued an opinion[116] in which it provided a number of observations and proposals too enhance the competition of the pharmaceutical sector, which is strongly regulated. If the latter, was relatively favourable to the opening of the medecines distribution channel of medecines in town its recommendations remain moderate[117].

Indeed, the French Competition Authority remains in favour of the sale of certain medicines in drugstores or in supermarkets but only for certain types of self-medecines and "*boundaries*" products (*i.e.* Pregnancy tests, contact lens solutions).

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111 Autorité de la concurrence, avis n° 16-A-09 du 26 avril 2016, précité.

112 Autorité de la concurrence, décision n° 13-D-11 du 14 mai 2013, précitée.

113 Autorité de la concurrence, décision n° 13-D-21 du 18 décembre 2013, précitée.

114 Autorité de la concurrence, décision n° 13-D-21 du 18 décembre 2013, précitée.

115 Article L. 4211-1 du Code de la santé publique.

116 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité.

117 Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, points 712 à 745.

Furthermore, the French Competition Authority established clear conditions to the opening-up of the market. Indeed, it specifies that the marketing of these products shall be circumscribed by strict rules that guarantee the quality and the security of medecines sale, and in particular the presence of a licensed pharmacist, the creation of dedicated retails space and the duty to deliver an advice.

These recommendations were taken into account by the Government since the "*Hamon*" Law of 2014[118] amended article L. 4211-1 of the Public Health Code which now authorises the sale of pregnancy and ovulation tests, as well as contact lens solutions outside pharmacies[119].

[118] Loi n° 2014-344 du 17 mars 2014 relative à la consommation, précitée.

[119] Autorité de la concurrence, avis n° 13-A-24 du 19 décembre 2013, précité, point 727.