

1. The competition law context of the pharmaceutical industry

This section seeks to determine whether the treatment of pharmaceutical products is differentiated under the competition law of your jurisdiction.

1.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 Italian antitrust legal framework applicable to a potential competition law infringement in the pharmaceutical sector is mainly represented by articles 2 and 3 of Law 287/90 (“Italian Antitrust Law” or “IAL”) that contain the same principles of article 101 and 102 TFEU.

Indeed, article 2 prevents “*all agreements and/or concerted practices between undertakings, as well as decisions, even if adopted pursuant to their regulations or bylaws, by consortia, associations of undertakings and similar entities*”, which have as their object or effect an appreciable prevention, restriction or distortion of competition in the national market or in a substantial part thereof, including those that

- a) “*directly or indirectly fix purchase or selling prices or other contractual conditions;*
- b) *limit or restrict production, market outlets or market access, investment, technical development or technological progress;*
- c) *share markets or sources of supply;*
- d) *apply to other trading partners objectively dissimilar conditions for equivalent transactions, thereby placing them at an unjustifiable competitive disadvantage;*
- e) *make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts*”.

Prohibited agreements are null and void.

Article 3 sets forth that “*The abuse by one or more undertakings of a dominant position within the domestic market or in a substantial part of it is prohibited. It is also prohibited:*

- a) *directly or indirectly to impose unfair purchase or selling prices or other unfair contractual conditions;*
- b) *to limit or restrict production, market outlets or market access, investment, technical development or technological progress;*
- c) *to apply to other trading partners objectively dissimilar conditions for equivalent transactions, thereby placing them at an unjustifiable competitive disadvantage;*
- d) *to make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.*”.

With reference to the relation between European and Italian *antitrust* rules, it has to be noted that when an agreement is able to affect the competition between Member States, at the national level articles 101 and 102 TFEU only apply, pursuant to the so-called “single-barrier” principle, according to which the application of national *antitrust* provisions is excluded whenever EU rules are applicable (article 1.1 of IAL).

Nevertheless, should national *antitrust* law (*i.e.* articles 2 and 3 of IAL) apply (agreement and conduct that are not able to affect trade between Member States), pursuant to article 1.4 of IAL the national *antitrust* law shall be interpreted in accordance with the principles of the EU competition law (article 1.4 of IAL: “*the provisions of this Title shall be interpreted in accordance with the principles of the EU competition law*”).

This means, for instance, that the Italian Antitrust Authority (“IAA”) - as well as national Courts - when it applies the Italian competition law to vertical agreements, applies also EU *antitrust* principles, among which those contained in the EU Regulation no. 330/2010 that, as known, amends the EC Regulation no. 2790/99 (*Block Exemption Regulation on vertical restraints* – “new BER”), in the *Guidelines on Vertical Restraints* (as modified following the amendment of the BER) as well as in the *Commission Notice on agreements of minor importance (de minimis Commission Notice)* that, therefore, represent the referential rules for the assessment of the applicability of article 2 of IAL to vertical agreements.

In this respect, it has to be considered that, following to the “modernization package” introduced by EC Regulation no. 1/2003 (EC Regulation no. 1/2003 entrusted the national antitrust authorities, as well as national Courts, with the power to directly apply EU antitrust provisions), article 2 of IAL has now a residual scope of application compared to the correspondent European antitrust provision (art. 101 TFEU), since agreements able to affect the whole national market or a substantial part thereof are frequently deemed to affect the trade between Member States. Indeed, the *Commission Notice concerning the effect on trade concept contained in Articles 81 and 82 of the EC Treaty* (now Articles 101 and 102 TFEU), states that the effect on trade between Member States is independent from the definition of relevant geographic market. As a consequence, trade between Member States may be affected also in cases where the relevant market is national or sub-national (par. 22 of the *Commission Notice*).

1.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.

To give a definition of the market, the IAA generally adopts as parameter the therapeutic classes, that is the chemical action and the therapeutic scope of the commercialized drug.

Those classes are chosen following the Anatomical Therapeutic Classification (ATC), that divides drugs in an alpha-numeric classification with five levels. This classification, developed by the WHO, is the most used by the IAA even if in a few cases also the EphMRA classification has been used. Anyway, there are no big differences between these two categorizations.

The third level of this classification, ATC3, identifies a therapeutic pharmacologic subgroup to which drugs that are supposed for the same diseases and that, most of the time, are replaceable belong, but not drugs that belong to other categories. Actually, the Commission and the IAA start from this third level to evaluate the possibility to replace products and to identify the relevant market.

In its past decisions concerning the pharmaceutical sector, the Authority generally made reference to the third level of the ATC for the purpose of the product market definition (e.g., in case C11910 – *DMWSL 723/Doc Generici* of 18 June 2013, the Authority identified 61 separate product markets on the basis of the third level of the ATC). However, the Authority also found that it may be necessary to carry out analyses at other levels of the ATC, where it is appropriate to group specific third level categories together (e.g., in case C11073 – *ACRAF/Ramo di azienda del Gruppo Novartis* of 8 June 2011, the Authority took into account the ATC4 levels for the purpose of market definition).

In the cosmetic and nutrition segments, the Authority has defined the product market more generically, without using the ATC (e.g., in case C11488 of 22 February 2012 – *Lauro Quarantotto/Prime European Therapeutics (Euticals)*).

According to the Authority, the geographic dimension of the relevant markets in the pharmaceutical sector is the entire national territory, given that the production and commercialization of the products have homogeneous features throughout the national territory, and peculiarities in relation to the other European countries.

The most significant factors in this regard are the sector-specific legislation, the safety standards to comply with in the production phase, the marketing authorizations, the price differences for similar products and the distribution systems (e.g., case C11910 of 18 June 2013 – *DMWSL 723/Doc Generici*). With specific regard to the distribution market, the Authority has defined it as sub-national, corresponding to regional areas. According to the Authority, the production and commercialization of active ingredients may instead be considered as a European market, due to the reduced incidence of transport costs and the potential absence of technical or administrative barriers (as stated in case C11876 of 16 January 2013 – *Société d'exploitation de produits pour les industries chimiques – SEPPIC/ Biotechmarine*).

The market for research and development in the pharmaceutical sector may be considered to have, instead, worldwide scope (e.g., case C10665 of 21 July 2010 – *APTUIT/Ramo di azienda di GlaxoSmithKline*).

In some recent cases, the IAA, starting from ATC classification, has used the third level as a basis for the definition of the market in the pharmaceutical sector, to reach then the fourth level using some kind of analysis of the specific replaceability between drugs, based for example on characteristics, therapeutic indications and the fact that they are essential for some groups of patients (14388/05 *Merck-Principi Attivi*; A431 - *Ratiopharm/Pfizer*).

To carry out this analysis, the IAA evaluates several factors, such as:

- different quality characteristics of the drugs

The Authority considers differences in terms of efficiency and security of drugs, compared in terms of effects, doses and administration. For this purpose, physician's preferences and scientific opinions are considered the answers to the requests of information by the competitors in the market (A431 - *Ratiopharm/Pfizer*);

- differences in terms of drugs' price and refunds' methods.

However, we should underline that, in a very recent case (A480 - *Incremento prezzo farmaci Aspen*), in the opening measure, the IAA supposed that market's definition could be found also in the fifth level of the ATC (ATC5), so referring to the drug itself and its active element. The Authority then evaluated many markets as many are the active elements of the drug, assessing the crucial importance of the therapeutic continuity, the price difference with different drugs and active elements that could be used in the same therapies.

Already in *Glaxo* case (IAA measure A363 - *Glaxo-Principi Attivi*), the IAA hypothesized that the particular characteristics of the product and its suitability to treat a specific disease make “*the administration of the drug (injected) essential and irreplaceable with other products (for ex. pills) and could lead to another limitation of the competition context (the drug the case was talking about) in which Glaxo would be the only operator*”. Therefore, the IAA gave an even more limited definition of the market, taking into account the active element in the specific injected form, then stopping at the level 4, ATC4, because, even in that category, Glaxo was already dominant, so there were no differences in the evaluation of the particular case.

In another very recent case, the IAA proceeded to identify the relevant market with wide and disputable criteria, without making any reference to the ATC classes or to the marketing authorization. Indeed, the IAA defined the relevant market without any

evaluation of the ATC classes but taking into account the average demand from physicians for the unauthorized drugs.

Given the importance of the case, that launched several discussions in the antitrust community, we would like to give a brief summary of it.

On 27 February 2014, the IAA closed an investigation launched in February 2013 into the Italian market for ophthalmic drugs used to treat certain serious vascular eyesight conditions, following the complaints filed by the Italian Ophthalmologic Association and by an association of private hospitals.

The IAA found that the pharmaceutical companies F.Hoffmann-La Roche Ltd., Novartis AG, Novartis Farma S.p.A. and Roche S.p.A. had established a cartel aimed at preventing the off-label promotion of Avastin – a drug manufactured and distributed by Roche – within the Italian market, in order to foster the promotion of Lucentis, a more expensive drug produced by Novartis and licensed by Genentech, a Roche Group company.

In particular, the IAA found that since 2011 the companies had set up a complex collusive strategy in the eye treatments market with the intention of causing an artificial product differentiation between Avastin and Lucentis, by asserting that the off-label use of Avastin to treat common eyesight conditions was dangerous (the approved use of Avastin is limited to the treatment of some forms of cancer).

The IAA's decision stated that the off-label use of Avastin was in accordance with the Italian regulatory framework and that the companies' claims were clearly aimed at influencing the physicians and the health services, in order to increase the sales of Lucentis, i.e. the drug that had received specific regulatory approval for some eyesight conditions. According to the IAA, the companies had earned profits to the detriment of market efficiency, and this had impaired competition on the market of macular degeneration treatments. In this respect, the IAA found that the increased sales of Lucentis, on the one hand, had given to Roche significant royalties through its subsidiary Genentech, the licensee of the drug, and, on the other hand, had enabled Novartis to benefit both directly from Lucentis' sales, and indirectly from Roche's extra profits, since Novartis holds more than 30% of Roche.

Notwithstanding the specific objections of the parties in regard also the lack of restriction by object (peculiarity of the case; lack of precedent; the two undertakings involved are not competitors since they are linked by a license agreement; healthy implication due to the fact that the lower efficacy or safety of Avastin off-label, although not supported by certain scientific findings, cannot be incontrovertibly excluded at the stadium of the scientific knowledge available at the time of the facts, etc.), the IAA considered the agreement between Roche and Novartis restrictive by object (market sharing).

After the Authority's measure, on 2nd December 2014, the TAR of Lazio (the Regional Administrative Court of Latium) dismissed the actions brought by Roche and Novartis, two leading pharmaceutical companies, seeking the annulment of an IAA decision which had imposed fines on the two companies for a total amount of over €180 million, with reference to the marketing of the medical products Avastin and Lucentis.

The TAR of Lazio confirmed the IAA decision, establishing the existence of an anti-competitive agreement in violation of Article 101 TFEU, implemented by Roche and Novartis, artificially differentiating their respective products in order to affect their sales. According to the decision of the TAR of Lazio, the medical and scientific considerations submitted by the applicants, as well as the performance of their "pharma-vigilance" duties, fall outside the scope of the judgment, which concerns the alleged existence of an agreement restricting competition. In this respect, after having affirmed the substitutability between Avastin and Lucentis to treat the same pathologies affecting sight, and consequently the competitive relationship between the two products, the TAR of Lazio considered the complaints made by Roche and Novartis, namely violation of law and misuse of power, as unfounded. The decision of the IAA was therefore declared unchallengeable by the TAR of Lazio, which also rejected the claims relating to the quantification of fines.

The Italian Council of State (the Administrative Supreme Court), finally appealed, issued - at the parties' request - a request for a preliminary ruling to the EU Court of Justice on five points:

- (a) whether two parties to a license agreement can be considered competitors in a market where the licensee is active only by virtue of that agreement and, in any case, whether possible restrictions of competition between the licensor and the licensee are caught by Article 101 of the TFEU;
- (b) whether, in the pharmaceutical sector, a competition authority can define the relevant market independently of the limits imposed by the marketing authorizations granted by the competent authority;
- (c) whether off-label use of a medicinal product to treat a certain disease can be considered to be in the same relevant market as medicinal products specifically authorized for that use;
- (d) whether the supply of a medicinal product compliant with the relevant sectorial regulation must be assessed to define the relevant market; and

(e) whether an agreement aimed at emphasizing that a medicinal product is less safe or effective than another can be considered a restriction of competition when, although not scientifically proved, it cannot be excluded.

Therefore, in the case at issue, three queries are specifically related to the definition of the market in the context of the widely discussed conflict between antitrust rules and sector regulation.

The proceedings before the European Court of Justice is pending. It is likely to have a final judgment in two years. The Court of Justice's decision will undoubtedly be very interesting as it will help identify the correct balance between antitrust rules and the regulation in the pharmaceutical sector. Furthermore, it will serve to improve the level of legal certainty and help undertakings to define the parameters of the legitimacy of their behavior.

1.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.

As we said, Article 2 of IAL, that recalls Article 101.1 of the TFEU, prohibits agreements between undertakings which have as their object or effect the prevention, restriction or distortion of competition within the domestic market. The distinction between "restrictions by object" and "restrictions by effect" arises from the fact that certain forms of collusion between undertakings can be regarded, by their very nature, as being injurious to the proper functioning of normal competition.

Restrictions of competition "by object" are those that by their very nature have the potential to restrict competition. These are restrictions which, in the light of the objectives pursued by the Union competition rules, have such a high potential for negative effects on competition that it is unnecessary - for the purposes of applying Article 101.1 TFEU - to demonstrate any actual or likely anti-competitive effects on the market. This is due to the serious nature of the restriction and experience showing that such restrictions are likely to produce negative effects on the market and to jeopardize the objectives pursued by competition rules.

The fact that an agreement contains a restriction "by object", and thus falls under Article 2 IAL / Article 101.1 TFEU, does not preclude the parties from demonstrating that the conditions set out in Article 4 IAL / Article 101.3 TFEU are satisfied. However, practice shows that restrictions by object are unlikely to fulfill the four conditions set out in these Articles.

The three classical "by object" restrictions in agreements between competitors are price fixing, output limitation and market sharing (sharing of geographical or product markets or customers). However, restrictions of that kind may not constitute restrictions "by object" where they are part of a wider cooperation agreement between two competitors in the context of which the parties combine complementary skills or assets.

In order to determine with certainty whether an agreement involves a restriction of competition "by object", the IAA applies the EU principles and in particular the case law of the Court of Justice of the European Union, according to which a number of factors must be taken into account, such as the content of its provisions, its objectives and the economic and legal context of which it forms a part (See the judgments of the Court of Justice in Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline* [2009] ECR I-9291, paragraph 58, Joined Cases 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82 *IAZ International Belgium and Others* [1983] ECR 3369, paragraph 25, Case C-209/07 *Beef Industry Development Society (BIDS)* [2008] ECR I-8637, paragraph 16 and Case C-32/11 *Allianz Hungária Biztosító Zrt and Others* (judgment of 14 May 2013), paragraph 36).

Among the various cases, it is of peculiar importance the *Cartes Bancaire* case. The European Court of Justice has provided much awaited clarification of the notion of "by object" restrictions of competition under EU competition law in granting an appeal by the *Groupement des Cartes Bancaires* "CB". In a landmark and welcome ruling, the Court confirmed that the European Commission (the Commission) needs to abandon its simplistic use of the "by object" restriction notion in cases that are not obviously harmful to competition and focus on the actual effects of the conduct. The Court also emphasized the obligation of the General Court to ensure a full judicial review, including a detailed and thorough analysis of the arguments of the parties and of the evidence on which the decision relies.

On 11 September 2014, the European Court of Justice quashed the judgment of the General Court that had previously upheld the European Commission's decision finding that certain pricing measures adopted by the *Groupement des Cartes Bancaires* "CB" (CB Group) were "by object" restrictions of competition. The CB measures in question were aimed at balancing the issuing and acquiring activities within the CB payment system in France. The Court of Justice declared that an agreement must be, by its very nature, sufficiently harmful to the proper functioning of normal competition in order to restrict competition by object. The Court of Justice stated that the elements relied on by the General Court did not support that conclusion. The judgment marks a significant turning point in EU competition law. While in recent years the Commission expanded the category of "by object" restrictions, the judgment at issue signals a welcome return to normality, where agreements involving integration of economic activity are caught by Article 101.1 TFEU only when they have potential restrictive effects on competition.

A recent case in Italy, in which the parties recalled the principles of *Cartes Bancaire* is the above-mentioned *Avastin/Lucentis* case (24823/2014).

In this case, notwithstanding the specific objections of the parties that regarded also the lack of restriction by object (peculiarity of the case; lack of precedent; the two undertakings involved are not competitors since they are linked by a license agreement; healthy implication due to the fact that the lower efficacy or safety of Avastin off-label, although not supported by certain scientific findings, cannot be incontrovertibly excluded at the stadium of the scientific knowledge available at the time of the facts, etc.), the IAA considered the agreement between Roche and Novartis restrictive by object (market sharing). Also said ascertainment has been confirmed by the TAR of Lazio.

As mentioned above, the Italian Council of State (the Administrative Supreme Court), finally appealed, issued a request for a preliminary ruling to the EU Court of Justice; the questions referred to the Court are five and the fifth regards specifically the possible restriction by object. In particular the Judges asked the Court to clarify “*Whether the alleged behavior, aimed at emphasizing the less safety or efficacy of a drug, can be considered as a restriction of competition by object, when the said lower efficacy or safety, although not supported by certain scientific findings, cannot be incontrovertibly excluded at the stadium of the scientific knowledge available at the time of the facts*”.

As said, the proceedings before the European Court of Justice is pending. It is likely to have a final judgment in two years.

1.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 "hardcore" rule?

In our jurisdiction, there is not specific legislation or guidance establishing justification of restrictions of competition in pharmaceutical competition law cases.

In any case, we deem that the important principles shall rise from the judgment of the European Court of Justice in the case *Avastin/Lucentis* that, as we mentioned in point (c), has to clarify whether the alleged behavior, aimed at emphasizing the less safety or efficacy of a drug, can be considered as a restriction of competition by object, when the said lower efficacy or safety, although not supported by certain scientific findings, cannot be incontrovertibly excluded at the stadium of the scientific knowledge available at the time of the facts. Therefore, also the relevant judgment of the Italian Council of State (the Administrative Supreme Court), following the one of the European Court of Justice will give importance criteria on the issue of the restriction *per se* in the pharmaceutical market.

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

There is not a specific legislation defining excessive or discriminatory pharmaceutical pricing in our jurisdiction.

Please note that the prices of pharmaceuticals reimbursement by the National Healthcare Service (NHS)

is set through negotiation between the Italian Medicines Agency (AIFA) and the Pharmaceutical Companies, in accordance with Law no. 326 of 24 November 2003, and Interministerial Committee for Economic Planning (*Comitato Interministeriale per la Programmazione Economia – CIPE*) Resolution of 1 February 2001. The aim of these legislative measures is to regulate the temporary redefinition of the industry margin and the new positive reimbursement list based on cost and efficacy, in order to ensure the full respect of Pharmaceutical Price Regulation criteria.

Within this specific competence, the whole preliminary activity - an economic evaluation of the different products - is carried out by the Price Reimbursement and Marketing Department, also supported by the consumption and pharmaceutical expenditure databases carried out by the Medicines Utilization Monitoring Centre (OSMED), for the AIFA's Committee Prices and Reimbursement (CPR), composed of expert members using state-of-the-art knowledge and expertise in different fields to evaluate applications which are submitted by contractors in order to get the reimbursement of their pharmaceutical products.

Contractors reach an agreement on the various applications which have been recorded by an Italian marketing authorization, a Mutual recognition and an European marketing authorization - respectively called National, Mutual and Centralized procedures - by fixing the prices and the conditions of reimbursement during the AIFA's Committee Prices and Reimbursement (CPR) Meeting. This agreement will be firstly subordinated to the Management Board for the examination and, therefore, it will be ratified for the following and final deliberation.

On the contrary, pricing of non-reimbursed drugs is not subject to the negotiation with AIFA.

Please note that the pricing of reimbursable drugs, negotiated by the pharmaceutical company and the AIFA, does not prevent the IAA to intervene to ascertain any violation of the antitrust rules.

In this respect, the IAA has decided to initiate an investigation against the companies Aspen Pharma Trading Limited and Aspen Italia S.r.l., belonging to the South African group Aspen, so as to verify the thesis of a possible “abuse of dominant position” in the market of band A anticancer drugs, the costs of which are borne by the National Healthcare Service. One is dealing, in particular, with four products: Alkeran, Leukeran, Purinethol and Tioguanina. Aspen, according to the thesis put forward in the resolution to embark on the investigation, *“allegedly forced Aifa (the Italian drug agency) to accept extremely high price increases, thereby occasioning an increased expense for the National Healthcare Service”*.

The investigation began after a consistent price increase - from 250% up to 1,500% - applied to these drugs in the course of 2014. The news had been circulated even by the “Altroconsumo” association within the context of a newspaper investigation into the so-called “disappearance of the drugs”. Since April 2013, based on the reconstruction by the Antitrust which relied on the Financial Police’s investigations, Aspen has manifested to AIFA *“the need to urgently align the selling price in Italy to the considerably higher one in force in the main European Union countries”*. In that manner, it succeeded in *“altering the structure of competition within the significant markets so as to secure extra profits”*. A constituent element of the disputed abuse allegedly consisted in Aspen’s threat to AIFA to withdraw the authorization to the marketing of the drugs, in the event that no agreement was reached on the new prices.

Since one is dealing with therapeutic indications of an “essential” character, which the producing company itself acknowledges as being “unique” in treating certain specific pathologies, Aspen’s strategy was allegedly aimed – apart from the achievement of extra profits in the national market – even “at limiting the phenomenon of parallel trade on the part of the local distributors”. The investigation by the IAA tends to ascertain whether the right to request a price review or a review of the refundability class of its own drugs has “been exercised in an exploitative manner inconsistent with the purpose which the governing set of rules acknowledges to be legitimate”, by means of possible “undue pressures” and an abuse of its dominant position.

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.

N/A

2. Enforcement mechanisms, remedies and consumer protection

This section seeks to assess whether there are special patterns of enforcement, such as the use of consumer protection law, specialist bodies, specialized remedies, and whether the balance between public and private enforcement differs in the case of the pharmaceutical industry.

2.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?

N/A

2.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.

In the Italian legislative framework, there is not a proper interaction between competition law and consumer protection law in the two mentioned fields. In fact, on one hand, the goal of antitrust law is to remove the distortions in the competitive process, and, on the other, consumer protection law aims to prevent and punish the so called unfair commercial practices.

Nevertheless, in the Consumer Code (Legislative Decree no. 146 of 2 august 2007, which transposes the Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market), the purpose of prohibiting unfair commercial practices is not defined in general terms, but rather in specific terms, as practices that - through deception, coercion or otherwise in contrast with professional diligence - alter the commercial decisions of the average consumer. As a consequence, counteracting the conducts that may significantly distort the commercial behaviors of consumers, the rules on unfair commercial practices promote - in the second instance - a fair competitive process.

The same can be said from an antitrust point of view: pursuing its goals, competition law indirectly provides significant benefits to consumers. In fact, the importance of consumer interest in the application of competition rules is recognized by article 3 (b) of IAL, which prohibits - as mentioned above - abusive conduct aimed at *“limit or restrict production, market outlets or market access, investment, technical development or technological progress, to the prejudice of consumers”*, and also by article 4 of IAL, which finds, amongst the conditions for the exemption from the prohibition of agreements restricting competition, stated in article 2 of IAL, the fact that the agreement improves supply conditions in the market, *“leading to substantial benefits for consumers”*. Even though

competition rules recall the attention in favor of consumers, it does not mean that there is a real interaction between antitrust law and consumer protection rules.

In any case, a direct connection among the regulations here discussed is due to the fact that the expertise in the field of consumer protection law and competition law is held by the same authority, the Italian Antitrust Authority (IAA, as stated in IAL, Title II - Establishment and functions of the Competition Authority - and in Legislative Decree no. 146, article 27).

The IAA has expressly stated that it considered in a unified and complementary sense its expertise in antitrust and consumer protection fields. In the report on its activity in 2007, after observing that

the assignment to the Authority of "a central role in the application of consumer protection discipline complies with its mission to protect competition, [since] the behaviors that impact on the commercial choice of consumer alter the [correct] functioning of the market, incorrectly subtracting customers to competitors", the IAA added that "competition policy and consumer protection policy are integrated [...] and fulfill the system of protection" (cfr. ibidem, p. 6). Moreover, the Italian Court of Cassation (judgment no. 2207 dated 4/2/2005,) has acknowledged the importance of consumer interests in the field of antitrust, recognizing the legitimacy of consumers to bring legal action to assert claims for damages based on violations of the antitrust law: "antitrust law is not only the law of undertakings, but it is (also) the law of market players, meaning anyone with an interest, procedurally relevant, in preserve his competitive nature".

2.c. Are there any specialist bodies with responsibilities relating to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical regulator 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.

As said in paragraph above the pharmaceutical regulator in Italy is the Italian Medicines Agency (AIFA) which is responsible for drugs regulation in Italy.

It is a public body operating autonomously, transparently and according to cost-effectiveness criteria, under the direction of the Ministry of Health and under the vigilance of the Ministry of Health and the Ministry of Economy. It cooperates with the Regional Authorities, the National Institute of Health, Research Institutes, Patients' Associations, Health Professionals, Scientific Associations, the Pharmaceutical Industry and the Distributors.

Its mission is to promote good health through medicines, set fair pharmaceutical policies and assure their consistent application nationwide, manage the value and cost of medicines, promote pharmaceutical research and development, demonstrate independence and leadership both at national and international level.

More specifically, the Agency: guarantees access to medicines and their safe and appropriate use as means to protect public health; ensures unity of the national pharmaceutical system in agreement with the regional authorities; ensures innovation, efficiency and simplification of the marketing authorization procedures, in order to grant rapid access to innovative drugs and to drugs used for rare diseases; provides drug expenditure governance in the framework of economic and financial viability and competitiveness of the pharmaceutical industry; encourages investments in Research & Development (R&D) in Italy; enforces the relationship with the Agencies of other Member States, the European Medicines Agency (EMA) and other international bodies; interacts with the community of patients' associations, the scientific medical world, pharmaceutical companies and distributors; promotes pharmaceutical culture and knowledge.

The Agency does not have authority in competition law matters.

There is not a consumer protection body with specialist pharmaceutical competence. The only similar competence belongs to the Italian Ministry. A specific application for each advertisement (even if this advertisement is released through several different media) must be submitted to the Ministry of Health for authorization to market drugs to consumers.

If the Ministry of Health does not provide this authorization within 45 days from the date of the application, it is deemed to have been granted. The authorization lasts for 24 months.

Authorization is not required when: the promotional message is included in newspapers or periodical press and reproduces in full the information provided in the patient information leaflet; it consists of a picture of the package put on price tags.

According to Italian regulations, the promotional nature of the message shall be clear as well as the fact that the object of the same is a drug. Moreover, the promotional message shall include at least the following information: the name of the drug, as well as the name of the active ingredient (if the drug contains only one active ingredient); the information necessary for correct use of the drug; an express and legible invitation to read carefully the instructions on the package leaflet or on the outer packaging. For promotional messages included in newspapers or periodical press, this invitation must be in font size nine.

Promotion of drugs to consumers is only permitted if the drugs are non-prescription or do not need the intervention of a physician for diagnostic purposes.

The following categories of drugs must not be promoted to consumers at all: drugs available only on medical prescription; drugs which contain psychotropic or narcotic substances; drugs which are totally or partially reimbursed by the National Healthcare System.

2.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?

The IAA, launched an inquiry into the pharmaceutical sector in 1994, ending in 1998, in order to concretely analyze and verify the competitive structure of the pharmaceutical sector.

The survey was aimed at ascertaining the current competitive conditions of the sector and especially unjustified legal distortions and actions necessary to promote competition.

Considering that an hard public intervention to protect and promote public health is justified, in order to control pharmaceutical public expense, the Authority focused its examination on the spheres of the sector where the functioning of competition could have made possible by the absence of such needs. In particular, in relation to drugs to be totally charged to patients, price setting has been liberalized since November 1995.

The liberalization has completely changed the structure of pharmaceutical public expense. More precisely, the aggregate share of drugs to be paid, partially and totally, by the National Public Health out of the total of ethical medicinal products on prescription only has decreased, shifting from 80.8% in 1993 to 65.9% in 1996, whilst the share of drugs to be totally paid by patients has shown an increase, shifting from 10.5% to 27.8% over the same period.

This conduct was facilitated by the presence of unjustified legal obstacles to the proper functioning of competition.

The most significant obstacle was the provision on the fixed price sale of drugs non-reimbursed by the National Public Health all over the national territory. As a consequence, chemists were prevented from granting discounts on prices set by producers.

Such a law provision is likely to impede that consumers could derive benefit from competition between distributors. Indeed, if they try to obtain more convenient supply

conditions, they gain higher margins than the fixed ones, whereas consumers do not enjoy the benefit of lower selling prices.

Price liberalization at the sales points would lead to lower consumer prices, in virtue of competition between chemists on the same drugs. Consistently with this, advertising of these drugs should be allowed. The Authority therefore expressed the hope that such a fixed price system would be removed.

Moreover, price liberalization would strengthen competition among outlets, as the Authority advocated in the conclusions of its fact-finding investigation into professional orders. That survey highlighted the opportunity to expand the sale of drugs out of prescription to outlets different than chemistries.

According to the IAA, another serious obstacle to competition is constituted by the obligation of wholesalers to hold at least 90% of commercial drugs. As such, they are obliged to purchase nearly all of the medicinal products existing in a particular market, and the establishment of a comparison between manufacturers of drugs having similar therapeutic characteristics is discouraged. Drugs manufacturers are not incentivized to compete in prices.

Finally, according to the IAA, generic prescription drugs are scarcely diffused. Even if the law connected to the so-called 1996 Financial Law had incorporated provisions aimed at developing generic medicinal products, their enforcement met difficulties. Indeed, there is a lack of legal instruments, as the following ones, necessary to spread such drugs: certainty and knowledge of patent expiration dates, terms of patent validity in line with European standards, the possibility to register a generic drug before the expiration of the patent covering its active principle, an incentive system to spread generic prescription drugs and to sell them instead of speciality medicinal products. With regard to this aspect, the European countries which have marketed generic drugs to a great extent have adopted different solutions. In the United Kingdom, for instance, medical prescriptions have to indicate not only the prescribed product trademark but also the corresponding ingredient.

The objective of these rules is to require physicians, before a generic drug is marketed, to make prescriptions by taking into account not only the existing commercial product but also the active principle involving generic drug substitution. In addition, if a generic drug is available, physicians are required to indicate if the prescribed speciality medicine can be substituted by a corresponding generic drug.

Generic prescription drugs development, holding that their average price is lower than that of speciality products, would promote price competition and increase the number of drugs manufacturers.

- In May 2002 the IAA reported on the potential competition-distorting effects of a bill that extended the duration of the supplementary patent coverage for several hundred pharmaceuticals. In the report, the Authority pointed out that the proposed extension of the supplementary patent coverage would distort competition in three main ways: *i*) by preventing the development of the market for generic drugs in Italy, that was already much smaller than in the other European countries; *ii*) by keeping prices higher because of the lack of competition caused by the existence, in Italy alone, of a system of patent coverage for a large number of products; *iii*) by restricting the growth of the basic chemical industry since the patent extension would not allow firms to manufacture patented molecules even for export to countries where the patent had expired.

- In June 2005 the IAA sent a report to the Parliament and the Government under Article 21 of Law 287/1990 regarding the possible anticompetitive effects of a decree law introducing: *i*) a maximum price for non-prescription and self-medication pharmaceutical products, to be fixed by the undertaking that introduces the products onto the market and indicated on the package; and *ii*) the possibility for pharmacists to apply price discounts of up to a maximum of 20%. In its report, the Authority criticized the introduction of restrictions on the prices of pharmaceutical products which had previously been liberalized.

Such limits, it argued, would result in elements of rigidity in business practices. Moreover, the maximum price could become a benchmark for undertakings to establish collusive practices. As regards pharmacists applying price discounts of up to a maximum of 20%, the Authority observed that imposing limits on the discounted price introduced *de facto* minimum prices for pharmaceuticals that had no economic justification whatsoever. On the contrary, this would only hinder the achievement of fully competitive conditions with negative effects for the general public. The Authority therefore called for the removal of this limit and for pharmacies to be left entirely free to set prices.

- In October 2007 the IAA sent a report to the Parliament and the Government under Article 21 of Law 287/1990 concerning measures on health spending introduced with the budget decree. The Authority pointed out that these measures risked holding back the competitive dynamic amongst innovative pharmaceuticals manufacturers and not encouraging the development of manufacturers of generic pharmaceuticals. In its report, the Authority argued that regulation throughout the pharmaceutical supply chain must motivate companies to carry out adequate research and development, offer an incentive for parallel imports of lower-cost pharmaceuticals and at the same time promote competition amongst pharmaceuticals that are not covered by patents so as to encourage the entry of manufacturers of generic drugs.

Article 5 of the Decree accompanying the 2008 budget, by modifying the mechanisms for reimbursement of pharmaceuticals by the National Healthcare System, fostered instead a market structure that in large measure preserved the relative positions of suppliers causing a slowing down of the market dynamic amongst competitors. The Authority advocated the adoption of criteria that create incentives for companies that invest in research and development, while the percentage of incremental resources the Decree set aside for reimbursing the expenditure of the most innovative companies was too small for this purpose.

The IAA therefore suggested increasing it, reducing instead the percentage of resources assigned to the generality of companies on the basis of 'historical quotas'. In its report, the Authority also suggested to include mechanisms that, by modifying the rules for prescribing medicines and attributing margins to pharmacies, would promote price competition from generics companies and parallel importers whose positive effects for consumers and the National Healthcare System were still extremely limited in Italy compared with most other European countries.

- In January 2008 the IAA sent a report to the Parliament and the Government under Article 21 of Law 287/1990 concerning the design of public tenders for pharmaceuticals. In its report, the Authority pointed out that the tenders' design, allowing pharmaceutical firms to make offers grouping different products (both patented and off patent) and offering discounts not only for the single products but also for the bundle, might result in a barrier to entry for generics.

- In May 2009 the IAA sent a report to the Parliament and the Government under Article 21 of Law 287/1990 concerning the remuneration mechanism set for distribution of reimbursable pharmaceuticals. The Authority pointed out that the application of fixed margins, in percentage of the product's final price, has no correlation to the costs actually faced by distributors for selling the drugs and that this mechanism creates an incentive for the pharmacists to dispense higher price drugs. The Authority proposed a new remuneration system based on a lump-sum *fee for service*.

- In September 2010 the IAA highlighted that DDL 2079 on para-pharmacy restrictions being debated in senate are anti-competitive because of their negative influence on prices and consumer freedom of choice.

DDL (draft law) 2079 limits the opening of new para-pharmacies, restricting competition and promising negative consequences for consumers. This is the message submitted to the Government and the Parliament by the Antitrust Authority in a report that appeals for rejection of the rules under discussion.

These rules suspend the opening of new businesses until the regulations on pharmaceutical sales have been redefined and introduce limits on the number of para-pharmacies. According to the Antitrust Authority, this type of structural limitation would restrict competition in recently-liberalized markets, and these rules, if approved, would have a negative impact on price levels and quality of service. Capping of the number of para-pharmacies in each Municipality on the basis of demographic criteria would be added to restrictions on the "authorized personnel strength" of pharmacies, a subject of previous Antitrust Authority reports. This would bias competitive dynamics in a sector where actual numbers of pharmacies are often too low to meet demand.

The IAA reasserts that setting quantitative limitations on pharmaceutical businesses does not stimulate the satisfactory geographical distribution of businesses that sell pharmaceuticals to the public, and instead can translate into a form of income-level protection for existing pharmacies. Ensuring universality of service clearly requires the establishment of a minimum number of pharmacies, not a maximum number.

- In 2011 the IAA report submitted to the Government and the Parliament in response to proposed amendment no. 1,206 to decree no. 225 (aka *mille proroghe* - the annual decree extending the life of various measures). According to the Antitrust Authority, if this proposal is passed, then no new sales points could be opened. With permission from the administration of competence, existing pharmacies could either transfer to another zone within the same municipality or to a different municipality that had no pharmacy.

The Antitrust report reasserts the fact that quota restrictions on the number of pharmacies practicing in Italy translates into a form of income protection for existing pharmacies, which are too few in number to meet the needs of inhabitants in most Italian municipalities. According to the IAA, the said restriction would exert a negative impact on price levels and quality of service by seriously diluting the competitive effects that free development has had on this new distribution channel. On the contrary, the liberalization of pharmaceuticals distribution should be continued by increasing the number of sales points and permitting class C (prescription only) pharmaceuticals to be sold outside of pharmacies, although still in the presence of a pharmacist.

- In 2012 the IAA presented to the Government and the Parliament possible measures for restarting economic growth as soon as possible - among which those of pharmaceuticals - liberalizing category C, increasing the number of pharmacies.

In regard to pharmacies, the sale of medically-prescribed pharmaceuticals at the patient's full expense (also known as category C drugs) is in need of liberalization and the barriers to opening new pharmacies need to be lifted while increasing authorized staff strengths. The possibility for individual owners to own multiple pharmacies should be augmented by raising the maximum number from 4 to 8.

2.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?

N/A

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

Enforcement in pharmaceutical cases is primarily public.

Following the outcome of the Commission sector inquiry in the pharmaceutical industry, the IAA carried out investigations into a number of leading players in the sector, some of which have already concluded with significant fines being imposed.

Recently, in the *Pfizer* case, the IAA found that the company had abused its dominant position in delaying the entry onto the market of glaucoma treatments based on Latanoprost (marketed by Pfizer as Xalatan). Pfizer was found by the IAA to have implemented a complex strategy of fraudulently seeking to extend the patent coverage for Latanoprost by making a divisional patent application and requesting a supplementary protection certificate (SPC) to extend patent protection until 2011, and to have started a number of legal and administrative actions against generics producers. The company, however, argued that it had lodged its application in full compliance with intellectual property law in order to protect its investments in research and development, and was merely defending itself in litigation brought by generics.

The €10.6m fine imposed by the IAA was at first instance annulled by the Court, which fully accepted the Pfizer's defiance based on compliance with IP law. However, the Italian Council of State (the Administrative Supreme Court), overturned the first instance judgment in January 2014 and reaffirmed the IAA's decision (see €10m fine for Pfizer for abuse of dominance upheld).

Said case is of peculiar importance considering that the Council of State applied for the first case the concept of the "abuse of law" to the antitrust field.

In the *Avastin/Lucentis* decision dated 27 February 2014, the IAA found that the two companies had infringed Article 101 TFEU by taking part in an anti-competitive agreement in the market for ophthalmic drugs used to treat some serious vascular eyesight

conditions, including age-related macular degeneration (AMD), the main cause of blindness in developed countries.

In light of the seriousness of the infringement, the IAA imposed on Roche and Novartis fines amounting respectively to €90.5m and €92m. The subsequent appeal by both companies failed on 02 December when the Regional Administrative Appeal Court (TAR of Lazio) upheld the fines imposed, confirming the IAA's finding that the drugs were interchangeable and holding that there was sufficient evidence to support the finding of collusion. Both companies appealed the judgment to the Council of State that in March 2016 referred the case to the European Court of Justice.

According to the IAA, starting in 2011, Roche and Novartis set up a complex collusive strategy, in order to avoid the commercial success of Lucentis being hindered by ophthalmic applications of Avastin. The companies are said to have colluded to create an artificial product differentiation between Avastin and Lucentis, and to have claimed that Avastin was more dangerous than Lucentis, in order to influence which product was prescribed for eye conditions by physicians and health services.

Originally, the use of Avastin was approved for the treatment of some forms of cancer and subsequently was used off-label to treat common eyesight conditions, in accordance with the Italian regulatory framework on off-label use of drugs. While an injection of Lucentis in Italy costs €900 (down from an earlier price of €1700), the price of an off-label injection of Avastin is at most €81.

The IAA concluded that the economic rationale for the companies' conduct stems from the relationship between the Roche and Novartis groups: while Roche collects significant royalties from the sales of Lucentis, which was developed by its subsidiary Genentech, Novartis benefits directly from Lucentis' sales and also holds more than a 30% share in Roche.

However, the IAA's decision does not appear to take into full consideration that, in 2012, the Italian Medicines Agency, AIFA, prohibited the off-label use of Avastin due to safety issues pointed out by the European Medicines Agency, EMA. The two regulatory agencies confirmed their view on safety concerns on off-label use of Avastin also after the publication of the IAA's decision.

Moreover, Roche's decision not to file a request to extend the scope of the marketing authorization for Avastin in order to cover also its use for treatment of eye diseases is fully in line with the EU and national legislative framework.

It is no accident that, a few days after the publication of the IAA's decision, the Italian Government changed the rules on the off-label use of drugs by means of a Law Decree. This entrusted AIFA with the power to order the extension of a marketing authorization for a given drug in order to include treatments already being applied off-label. The Law decree, which was expressly intended to solve the problem highlighted by the Avastin case, was transposed with significant amendments in Law No. 36/2014, in force from 21 May 2014 and is apparently not fully in line with EU principles (see ECJ judgment of 29 March 2012, C-185/10, European Commission v Republic of Poland).

Apart from the merits of the recent legislative amendments, the fact that a new piece of legislation has been introduced to dispel concerns on off-label registration itself confirms that the regulatory framework in which Roche and Novartis operated was unclear. A decision of the administrative court should clarify doubt on this point.

It has to be noted that on 28 May 2014, the Italian Ministry of Health announced that it will claim damages against Pfizer, Roche and Novartis (for the above mentioned cases) for a global amount of €1.2bn, equivalent to the harm suffered by the Italian National Healthcare System as a result of the antitrust infringements ascertained by the IAA.

The announcement potentially marks the first example of an antitrust damages action brought by a public institution in Italy. Separately, a number of major consumer associations and some regions anticipated the Government's decision by filing damages actions against the three pharmaceutical companies.

While the IAA's decision against Pfizer has now become final, as a result of the judgment of the Council of State, the case against Roche and Novartis is not final.

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

If the investigation launched by the IAA reveals infringements of articles 2 or 3 of IAL, the IAA shall set a deadline within which the undertakings and entities concerned are to remedy the infringements. In the most serious cases it may decide, depending on the gravity and the duration of the infringement, to impose a fine up to 10% of the turnover of each undertaking or entity during the prior financial year; time limits for the undertakings to pay the penalty shall be laid down.

In the case of non-compliance with the notice referred above, the IAA shall impose a fine of up to 10% of the turnover or, in cases where the above-mentioned fine has already been imposed, a fine of no less than double the penalty already imposed with a ceiling of 10% of the turnover as defined in subsection. It shall also set a time limit for the payment

of the fine. In cases of repeated non-compliance, the IAA may decide to order the undertaking to suspend activities for up to 30 days.

The Authority, in accordance with EU law, will use a general provision of its own to define the cases in which, based on assistance by companies under investigation in ascertaining infringements of competition rules, the fine may either not be levied or may be reduced in cases foreseen by EU law.

To increase transparency and deterrence of its enforcement activity, in October 2014 the IAA published Guidelines for the calculation of fines, which are consistent with the EC Guidelines.

The Guidelines are an important step towards ensuring more transparency and coherency in competition enforcement, thus contributing to more consistent application of competition rules. Prior to the Guidelines, fines for antitrust infringements in Italy were set on the basis of a general law on criminal sanctions (Law no. 689/1981), as well as the European Commission's 2006 fining Guidelines.

Similar to the Commission's methodology, the Guidelines use a two-step process when setting the amount of the fine: (i) determining the basic amount (up to 30% of the sale of services or goods of the infringement), and (ii) making upwards or downwards adjustments to take into account multiple aggravating or mitigating circumstances. In any event, the final amount of the fine may not exceed 10% of the undertaking's total turnover in the previous business year, as provided for by Article 15 of the national competition law (law no. 287/1990).

Some highlights of the Guidelines:

- for the most serious infringements (i.e. price fixing, market sharing and output limitation), the proportion of the value of sales taken into account as the basic amount will not be lower than 15%.
- the fine can be increased up to 50% if the undertaking achieved significant worldwide revenues or belongs to a group of significant economic strength.
- there is also a possibility of further increasing the fine to guarantee the proportionality and deterrence of the sanction when the illicit gains improperly made by the undertaking can be reasonably estimated.
- an "Amnesty plus" program is introduced, according to which the amount of the fine can be reduced up to 50% if, during the investigation, the undertaking provides information and documents that may be decisive for ascertaining a separate antitrust infringement and the contribution falls within the scope of the leniency program.
- the adoption and effective implementation of a specific compliance program can be recognized as a mitigating factor. However, in order for this to apply, the mere adoption of a competition compliance program is not sufficient; the compliance program must be specific and suitable, as well as in line with the international best practices. More

importantly, the firm must show a concrete and effective commitment to applying the program. The IAA will take into account the experience developed in other NCAs and considers providing ad hoc guidance in the future.

Finally, the Guidelines provide specific guidance on calculation of the value of sales in relation to collusive agreements for participation in public tenders.

As a whole, the Guidelines indicate that IAA intends to impose heavy fines on the most serious infringements but is willing to consider and reward investments in competition compliance intended to prevent violations of competition law. The new guidelines, which benefitted from the public consultation with the various stakeholders, have been welcomed by the legal community.

Furthermore, it has to be noted that under article 14-bis of Law 287/90, the IAA may adopt *ex officio* interim measures, prior to the finding of an infringement, when a serious and irreparable harm to competition is likely to occur. The Authority may impose fines up to the 3% of turnover to companies not complying with the decision setting out the interim measures.

Finally, under article 14-ter of Law 287/90 (introduced by Law-Decree No. 223 of 4 July 2006), the IAA can accept and make the commitments offered by the parties binding, in order to avoid the negative effects of potentially infringing conducts under investigation, and close the proceedings without ascertaining the alleged breach of articles 2 or 3 of Law 287/90 (or articles 101 or 102 TFEU).

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

The Italian Patent and Trademark Office (U.I.B.M., *Ufficio Italiano Brevetti e Marchi*) makes available to the public its database, which contains information related to patents, their variations and the status of patent applications. However, from that database it is not possible to access the settlements reached by the parties in relation to patent disputes. This means that it is not possible to monitor patent settlements in the pharmaceutical sector.

2.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?

Pharmaceutical suppliers obliged in your jurisdiction to make available pharmaceutical products that they are licensed to sell, safe for the case in which they are in dominant position.

In order to assess whether a party may be considered to be solely or jointly in a dominant position, the Authority takes into account the criteria set out in the Communication of the Commission on the enforcement of article 102 TFEU (Guidance on the Commission's enforcement priorities in applying article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings).

According to the Commission, dominance is not likely to occur if the company's market share is below 40 per cent. However, in the assessment of dominance, the Authority and the Commission take into account the overall competitive structure of the market, and in particular the market position of the companies allegedly in a dominant position and their competitors, the existence of barriers to entry or expansion of the market, and the countervailing buying power of customers.

In the *Pfizer* case, the Authority took into account the market share of the company (above 50 per cent), but also considered the latter in light of its power to exercise an appreciable influence on the functioning of the market and to behave, to an appreciable extent, independently of its competitors, customers and ultimately of its consumers. Therefore, the Authority assessed the structure of the market and the degree of actual and potential competition as well as the levels of technological developments.

Collective (or joint) dominance implies that a dominant position may be held by two or more economic entities legally independent of each other provided that from an economic point of view they present themselves or act together on a particular market as a collective entity (European Court of Justice, case C-396/96 P of 16 March 2000, *Compagnie Maritime Belge v Commission*).

In case T-342/09 of 6 June 2002, *Airtours v Commission*, the General Court emphasized that the three key elements of collective dominance are transparency (i.e., '*each member of the dominant oligopoly must have the ability to know how the other members are behaving in order to monitor whether or not they are adopting the common policy*'), deterrence (i.e., '*the situation of tacit coordination must be sustainable over time, that is to say, there must be an incentive not to depart from the common policy on the market*'), and the reaction of customers and competitors (i.e., '*the foreseeable reaction of current and future competitors, as well as of consumers, would not jeopardize the results expected from the common policy*').

In case C10955 of 16 March 2011 – *Ardagh Glass/FI.PAR. Finanziaria di partecipazione industriali*, the Authority looked *inter alia* at the following market factors for ruling out that the transaction could lead to the establishment of a potential joint dominance: high concentration levels on the demand side; buyer's power; several possibilities of reaction of customers; low levels of technological change; and negligible barriers to entry.

For Italian cases of abuse of dominant position see point (f) above.

2.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 or judgments suggest that the application of the competition rules to the distribution of pharmaceutical products is affected by the characteristics of pharmaceuticals?

The main application in case law relating to distribution agreements in pharmaceutical market are linked to the so-called co-marketing.

A “co-marketing agreement” is a complex relationship through which a pharmaceutical patent holder of an active principle, in exchange for the payment of a fee (royalties on sales; a sum *una tantum*), licenses marketing and distribution rights of the active ingredient, or finished or semi-finished specialty, that it has supplied to one or more undertakings. These companies, having obtained the access to the registration dossier, will have to get their trademarks on the AIC of the marketed drug.

Through such a “production-distribution system” the promotion and sale of medicinal products based on the same active ingredients are carried out simultaneously by two or more pharmaceutical companies, with different trade names and trademarks, which independently engage in promotional activities for the brand in order to differentiate their products on the market.

In this way, it is possible to obtain an effective promotion of the active ingredient, thus being able to exploit the experience, the effectiveness, marketing and promotion strategies of the product to several sales networks, and the originator is not obliged to carry out significant investments required to establish a good network. Furthermore, undertakings participating in the co-promotional relationship will adopt policies aimed to promote a greater competition with different active ingredients having the same therapeutic effect, produced by other pharmaceutical companies and included in the same market.

Through co-marketing agreements, originator companies may: (i) promote the active ingredient with regard to a greater number of physician (ii) achieve specific targets of physicians thanks to the peculiarities of the product range, the specialization in promotional messages and sponsorship deriving from congresses or conferences of each distributor; (iii) reiterate the same message in case informers of different companies visit

the same physician with a consequent increase in the probability of prescription of the molecule, independently of the trademark that the physician may memorize.

Thus “co-marketing” is characterized by: (a) a supply relationship between the patent holder of the active ingredient and/or producer of the same, who holds the know-how and the scientific-industrial knowledge for the production of the medicinal product containing the active ingredient, and marketing companies; (b) the existence of several companies (among which the licensor that manufactures and markets the drug based on the same active ingredient), each of which markets and promotes the active ingredient with different trademarks and with their proper marketing authorization.

The possible problems arising from co-marketing agreements have been examined at the Italian level. In particular, in 1999 the IAA concluded three investigation proceedings related to restrictive agreements, concerning conducts of undertakings aimed at coordinating pricing policies of third companies by means of co-marketing agreements (*Istituto Gentili-Merck Sharp & Dohme-Neopharmed-SigmaTau Industrie Farmaceutiche Riunite-Mediolanum Farmaceutici*, published on the IAA bulletin No. 8/99, *Byk Gulden Italia-Istituto Gentili*, published on the IAA bulletin No. 8/99; *Servier Italia-Istituto Biologico Stroder*, published on the IAA bulletin No. 26/99).

According to the IAA (Sector Inquiry mentioned), the proliferation of co-marketing agreements may have positive effects in terms of promotion of active ingredients on the market; by using means and information resources of two or more companies, each with its own sales network, an effective interpenetration among physicians is achieved, without forcing the proprietor of the patent covering an active ingredient to make huge investments to establish an adequate network. Since this is the purpose of co-marketing, it proves particularly effective in the event of market launch of a new drug, making it well-known as soon as possible. On the other hand, as the co-marketers need to promote their product by differentiating it in commercial terms also from the product or products containing the same molecule, they strongly emphasize promotion as a competitive variable. However, this is done, in some cases, at the expense of price competition. As regards drugs not covered by the National Healthcare Service, which therefore must be totally paid by the patient under a free pricing regime, the IAA verified the existence, in relation to co-marketing agreements, of agreements restricting competition which had led to significant price increases to the detriment of consumers.

The Authority specified that a co-marketing system, though creating a certain linkage between the companies concerned, does not entail any need of coordination in terms of pricing.

In case *Servier Italia-Istituto Farmaco Biologico Stroder* (IAA, Decision No. 7337 (I331)), the companies involved had implemented a co-marketing agreement, which, according to the IAA, could lead to a substantial market-sharing. The investigation

revealed that price changes concerning both products resulted from an agreement restricting competition to the detriment of consumers, as well as from the high market share held by the companies concerned. The IAA also verified that the two companies had concluded an agreement to set tender prices in tenders for the supply of products to hospitals and public health structures. Eventually, a coordination of the respective activities came to light, aimed at avoiding direct comparison between their drugs for the benefit of physicians, which rendered more difficult and more expensive the access to the relevant market on the part of potential competitors, especially generics manufacturers.

Similarly, in cases *Byk Gulden Italia - Istituto Gentili* and *Istituto Gentili-Merck Sharp & Dohme -Neopharmed-Sigma-Tau Industrie Farmaceutiche Riunite-Mediolanum Farmaceutici* the companies had implemented a co-marketing agreement which was deemed to be aimed at a significant pricing coordination, with restrictive effects to the detriment of the consumer.

More recently, in *Arca / Novartis-Italfarmaco* (IAA, Decision No. 25508 (I770) *Arca / Novartis-Italfarmaco*) the IAA accepted the commitments submitted by the two companies, aimed at modifying the clauses of the existing contract which were considered by the IAA as producing anticompetitive effects. Originally, the IAA had launched the investigation in order to verify the correct performance of some public tenders organized by the purchasing groups of the Lombardia, Veneto and Emilia Romagna regions, for the supply of drugs containing the active ingredient *octreotide*. In the course of the inspections carried out at the premises of the two companies, the IAA then became aware of a license and supply agreement between the parties for the marketing of the abovementioned active ingredient. The IAA therefore decided to extend objectively the proceedings, since several clauses of the agreement seemed capable of restricting competition between the parties. It seems peculiar that the focus of the abovementioned proceeding was shifted from what had initially been highlighted in the decision to initiate the investigation. The discovery of the co-marketing agreement seems to have given rise to a transformation of the IAA's charge, from an alleged hard-core collusion (in relation to which, if confirmed, it would not have been possible to accept commitments) to an alleged cooperation with potential restrictive effects (by reference to which the aforementioned commitments have been submitted).

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

N/A

3. Innovation questions

This section gathers information relating to special treatment of pharmaceutical products to promote innovation, notably the treatment of originator patent protection by competition law in your jurisdiction.

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

The generic substitution of pharmaceutical drugs in Italy is governed by the Italian IP Code and the Health Law Regulations; in particular, the definition of an equivalent or generic substance as specified in EU Directive 2001/83/EC is included in Decree-Law 219/2006.

An important characteristic of the Italian off patent system is the contemporary presence of both generics and copies (copies are drugs of the same active substance marketed, with their own brand name, often by the originator itself). Two reasons explain this phenomenon: first, Italy lacked patent protection until 1978, when the Italian High Court included pharmaceutical among products on which patent rights could be applied. Copies (sometimes referred to as “equivalent” to generics) marketed before 1978 were allowed to stay in the market even after patent introduction. Moreover, in Italy co-promotion (the same brand sold by different companies) is forbidden. However, co-marketing, the practice of marketing the same active compound as different brands under the originator license has been a common practice, increasing the number of copies even after patent introduction.

In Italy the regulation of the National Healthcare System and of the pharmaceutical sector is complex.

The National Healthcare System, introduced in 1978, is a public system funded by general taxation which provides universal coverage and comprehensive health care. In the last decade, the National Healthcare System has been extensively reformed, increasing regional autonomy. The first important reform in the pharmaceutical sector was in 1993, and since then pricing schemes and reimbursement rules have continuously changed, and the pharmaceutical market has experienced several cost containment interventions in the health care sector.

Some of the features of the Italian regulatory regime have affected the diffusion of generic drugs.

In particular, three areas of the regulatory framework seem crucial in determining competitive conditions for generic drugs: legislation governing patents, marketing authorization procedures and pricing and reimbursement provisions.

In addition to patent coverage for a period of 20 years, the Italian Complementary Certificate of Protection was introduced in 1991 (just before approval of the European Supplementary Protection Certificate - SPC) extending patent protection for up to 18 years. The supplementary term of protection is calculated as the number of years that have elapsed from the date of filing the patent application to the date of the initial marketing authorization. This extension of patent coverage was granted to around 400 active substances. Despite all attempts to abolish it, the only compromise reached with Law 112/02 was a gradual reduction, starting in 2004, of six months every two years until Italy is aligned with the other European countries.

The term “generic drug” was first introduced in the Italian legislation in 1996 (Law no. 323/96). A generic drug has to be marketed under the International Non-Proprietary Name (INN) followed by the manufacturer’s name at a price at least 20% lower than the originator drug. The definition of generic was extended in 2003 to cover all off-patent drugs, including copies.

The regulatory authority in Italy is the Ministry of Health. Pharmaceutical products registration and marketing authorization are undertaken by the Ministry's pharmaceutical agency, the AIFA. The agency has the following responsibilities: marketing authorization procedures, including bio-equivalence assessment for generic drugs, vigilance on pharmaceutical usage, reimbursement, clinical trials and provisions for special use, monitoring pharmaceutical information and promotion.

Pharmaceuticals have been classified for pricing and reimbursement purposes as follows: essential or life-saving pharmaceuticals, that require a prescription and are fully reimbursable (Class A); pharmaceuticals which require a prescription but are not reimbursable (Class C); pharmaceuticals which do not require a prescription and over the counter drugs; hospital-use-only pharmaceuticals (Class H).

Innovative products are initially given non-reimbursed status (Class C) or hospital-use-only status (Class H), before their final classification is decided.

The prices of the reimbursed drugs (Class A) are set through negotiation between the government (through AIFA) and the industry, while prices of non-reimbursed drugs (Class C) have been liberalized since 1998. Even after liberalization, regulation required, until 2007, that the price of each drug was the same all over the country. Besides, in the last years, cost containment measures by the government often affected all categories of pharmaceutical.

Regulation also affects distribution margins. For pharmaceutical products in Class A, Law 662/96 has established wholesalers and pharmacies margins over medicines’ fixed price, equal to 6,65% and 26,7%, respectively, of the industry price.

There is no correlation between the distribution prices and the costs actually faced by the distributors for selling the drugs, and the mechanism creates a clear incentive to sell higher price drugs. In order to partially correct this phenomenon and introduce some regression on distribution margins mandatory discounts to the National Healthcare System for reimbursable drugs were introduced in 1997, with higher discount rates applying to higher price ranges (discounts range from 3.75% for prices less than 25.82 euros to 19% for prices greater than 154.94% in 2003). This correction, however, had a marginal impact on the financial disincentive to dispense the cheaper generic drug.

Notwithstanding these measures, generics manufacturers have faced difficulties in placing their products since the regulation still provides an incentive for pharmacists to dispense higher price products.

Although not expressly allowed by the law, generic producers have offered high discounts to pharmacies (therefore reducing their margins from the level fixed by law) in order to promote the sale of generics by pharmacies. At the same time, generic producers were less willing to reduce the final prices in the negotiation with the regulator in order to use the discount leverage with the pharmacists.

In order to curb this industry practice, the legislator intervened, in April 2009, with a norm that reduced by 12% the price of generic drugs, at the same time allowing an increase of 8% to the margins of the distributors for the same products. The norm forbids any form of negotiation between pharmacies and generics producers (not originators) introducing sanctions in the case of non-observance of the margins established by law.

Starting from 2001 reimbursable off patent products have been subject to a reference pricing system: if a drug price is higher than the reference limit, the patient is expected to pay the difference (the reference limit is the lowest price among equivalent products available in the regional distribution network). The introduction of reference pricing was clearly aimed at containing demand for highly priced products by cutting down reimbursement pricing. Pharmacists are obliged to dispense the lowest price drug if the patient accepts the substitution and provided that the physician has not declared on the prescription that a higher price drug cannot be substituted.

In recent years the Italian Competition authority investigated conduct of pharmaceutical companies delaying entry of generic competitors.

In particular, the Authority assessed Merck's and Glaxo's refusal to grant licenses to chemical companies for the production of API's (Imipenem Cilastatin and Sumatriptan Succinate) to be supplied to generic companies in European countries where any patent on those products had already expired.

In February 2006 an investigation into the pharmaceutical group Glaxo concluded with the finding of abusive practices in violation of Article 82 of the EC Treaty. Glaxo refused to grant Fabbrica Sintetici Italiana (FIS), a chemical-pharmaceutical undertaking, a license to produce an active drug ingredient known as Sumatriptan Succinato, covered in Italy by a supplementary protection certificate, for use in other Member States (in which Glaxo no longer held any patent-rights) in the production of generic drugs known as triptans for the treatment of migraines. The Authority found that Glaxo, in addition to holding a quasi-monopoly on the production of Sumatriptan Succinato worldwide, occupied a dominant position in the Spanish and Italian markets for the production and marketing of triptans sold through hospitals.

In these markets Glaxo held a particularly high market-share, equal to about 96% in Italy and 58% in Spain.

As for the possibility of access for potential competitors, all the products sold in the markets concerned were found to be covered by industrial patent-rights, which were due to lapse between 2008 and 2012, with the exception of Sumatriptan Succinato which was not covered by any patent in the Spanish market. Based on the investigation's findings, the Authority deemed that Glaxo's refusal to grant the requested license constituted an abuse of dominant position in violation of Article 82 of the EC Treaty, since its refusal hindered the production of an active ingredient needed by producers of generic drugs, potential competitors of Glaxo, to access national markets where Glaxo did not have any exclusive rights.

According to the Authority, this conduct had no objective justification. Despite having ascertained the abusive nature of the conduct, the Authority did not impose any fine to the group because well before the end of the investigation, Glaxo had not only granted the licenses originally requested by FIS but had also set conditions allowing that company to save the time required to research and test an efficient production process for obtaining Sumatriptan Succinato. As a result, well before the conclusion of the proceedings, a producer of generic drugs based on this active ingredient had succeeded in entering the Spanish market.

In March 2007 the Authority concluded an investigation under Article 82 of the EC Treaty into the company Merck & CO. Inc. and its subsidiary Merck Sharp & Dohme (Italia) S.p.A., accepting the company's commitments under Article 14-ter, paragraph 1 of Law no. 287/1990, and closing the proceedings without establishing an infringement.

The investigation was launched to examine alleged abusive practices consisting in refusals to grant licenses requested by chemical-pharmaceutical firms for the manufacture

of two active ingredients, Imipenem Cilastatina and Finasteride, both covered by a Supplementary Protection Certificate (SPC) to be sold in other European countries in which Merck was no longer enjoying intellectual property rights. In order to ensure that, pending the outcome of the investigation, Merck's behavior would not continue to cause serious and irreparable harm in the markets concerned, in June 2005 the Authority adopted interim measures obliging the company to issue without delay – and at least for stockpiling purposes – licenses authorizing the production in Italy of Imipenem Cilastatina.

In accordance with this ruling, in August 2005 Merck issued a license to the chemical firm Dobfar to manufacture this active ingredient, whose Supplementary Protection Certificate expired in January 2006.

In November 2006 Merck presented a commitment under Article 14-ter of Law no. 287/1990, (later to be amended), offering free licenses to manufacture and sell the active ingredient Finasteride and related generic drugs, even though the Supplementary Protection Certificate would not expire until 2009.

The Authority deemed that this commitment was likely to result in the permanent removal of any anticompetitive effects flowing from Merck's former refusals to grant licenses. More specifically, the Authority considered that this commitment would remove an obstacle to the manufacturing of Finasteride in Italy and increase its sales and that of the related generic drug, both in Italy and in various European countries, generating a reduction in prices to the benefit of consumers and the National Healthcare Service.

As said in point (f), another recent case of peculiar importance is Pfizer case in which the IAA found that the company had abused its dominant position in delaying the entry onto the market of glaucoma treatments based on Latanoprost (marketed by Pfizer as Xalatan). Pfizer was found by the ICA to have implemented a complex strategy of fraudulently seeking to extend the patent coverage for Latanoprost by making a divisional patent application and requesting a supplementary protection certificate (SPC) to extend patent protection until 2011, and to have started a number of legal and administrative actions against generics producers. The decision of the IAA was confirmed by the Council of State that, as said, applied for the first case the concept of the "abuse of law" to the antitrust field.

3.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)?

N/A

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?

N/A

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?

Both in case of agreements excluding rivals and pay-for-delay agreements competition law enforcement applies. While in the latter option, there is no an Italian case to bring as an example (we refer the analysis of the issue to the point (d) discussed below), in relation to agreements excluding competitors category, for instance, case-law has recognized the boycott as an agreement according to the article 2 of IAL (Italian Court of Appeal, judgment 2009/98, *Tramaplast* case).

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

N/A

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

N/A

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.

N/A

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 existence of barriers to entry in the pharmaceutical market typically faced by a generic drug is basically constituted by the instruments of intellectual property and implies that their exercise (sometimes) contradicts the collective interest to an effective competitive structure of the market. This because of exclusionary power enjoyed by the holder of patent rights, of which the pharmaceutical sector is one of the main beneficiaries. As known, the generic drugs makers can enter in the market only when the time of patent exclusivity is expired, challenging the originators on the basis of lower prices. Over the years, originator pharmaceutical companies tried to prolong the commercial life of their medicines, through the so called ever-greening practice, extending the scope and duration of patent protection (follow-on patents), with the aim of postponing the entry into the market of generic drugs. These practices fostered a situation of legal uncertainty, driving the generic drugs industries to delay their entrance in the market.

Among said practices, it is relevant to recall: *(i)* numerous applications for only one drug (cluster of patents or patent thickets); *(ii)* the presentation of divisional applications patent; *(iii)* the reformulation of a drug and related patents; *(iv)* and the conclusion of agreements with companies that produce and sell generic drugs (patent settlement agreements).

This scenario confirms the trend concerning the strategic use of patent rights, not respecting the primary function of the right in question, which should *inter alia* promote innovation.

To clarify the issue under consideration, we would like to cite the already discussed Pfizer case, object of conducts involving the abusive use of patent procedures for anticompetitive purposes and judicial offensives acted against the generic drugs makers (*inter alia* Ratiopharm), capable of raising barriers to the entrance in the market.

In this case, the Pfizer conducts created a situation of deep uncertainty among generic drugs industries - which had relied on the deadline of the main patent protection provided, in Italy, in September 2009 - about the possibility or not to market the generic version of the original drug. Therefore, Ratiopharm (and several other competitors) decided to postpone the entry into the market, discouraged by the numerous warnings through which Pfizer threatened legal actions.

Additionally, settlement agreements between pharmaceutical companies have serious consequences, since they are capable of preventing a quick entry of generics in the

market. The debate around these instruments has progressively deepened also because of unlawful delays in competition between original medicines and generic ones. The said agreements can have both formal and informal nature and can aim at solving actual or potential disputes concerning patents. For instance, agreements that provide a value transfer (so called *pay for delay*, mentioned above) from the originator company to the generics makers are particularly risky from an antitrust point of view. Such a transaction can consist in a money transfer concerning licensing aspects or distribution aspects.

No cases relating to the payment for delay practice have involved our country so far, however - at the European level - the Commission, in the decision of 19/06/2013, concerning the *Lundbeck* case (*H. Lundbeck e Lundbeck/ Commission*, T-472/13), has stated that these practices violate the article 101.1 TFEU. The case is now pending before the Tribunal EU.

4. Public finance considerations

This section seeks to assess whether there is differential treatment of pharmaceutical competition law cases on the basis that public funds are involved, such as parallel trading bans to support price control.

4.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?

N/A

4.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.

N/A

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

As mentioned above, the definition of the reimbursement and supply system, as well as price fixing of drugs, involves complex procedures, which differ between the various

European countries. In the Italian context, these matters are in charge of AIFA and its advisory bodies.

Pursuant to law 326 of 24/11/2003, all the prices of medicines reimbursed by the National Healthcare Service (NHS) are determined by negotiation procedures between AIFA and pharmaceutical companies, according to the criteria set out in the CIPE Resolution no. 3 of 1/02/2001 (Identification of the criteria for the negotiation of the price of drugs). On the contrary, pharmaceutical companies can freely determine the price for medicines which are not reimbursed by the NHS; the said price can increase only in odd years.

As stated in article 8 (par. 9) of the law 537 of 24/12/1993, medicines are classified into different categories for the assignment of reimbursement class: drugs totally reimbursed to patients by the NHS belong to (i) CLASS A or (ii) H. In this latter case medicines are fully refunded by the NHS, but they are distributed by health facilities only; (iii) CLASS C identifies medicines which are not reimbursed by the NHS (with the exceptions of Law 203/2000 concerning "Deliverability of Class C drug from the NHS in favor of people with direct war pension").

The assignment of a repayment class has effects on the information relating to sales prices: while for drugs in classes A and H both the ex-factory price ("pef") and retail price ("pbw") are known, with respect to the class C the only reference data is the "pbw".

When a public healthcare provider is the purchaser, the supply of medicines is managed by tenders, usually awarded with the method of largest discount applicable on unit prices, corresponding to the price to the public. The minimum downside, imposed by the Ministry of Health through the AIFA, can range from 33,35% to 50% of retail price. On net sales price sellers may be required to give an additional discount.

However, in the Law Decree no. 264 of 8/07/1974, converted into Law no. 386 of 17/08/1974, entitled "*Provisions for the extinction of the debts of health insurers in respect of hospitals, financing of hospital expenditure and health care reform*", in article 9 (paragraphs 4 and 5), it is stated that institutions, hospitals and public health institutes can directly purchase drugs and pharmaceutical companies are obliged to practice on those products a discount of at least 50% off the retail price

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

Drugs, like any other good, can circulate within the common market (meaning in the Member States of the European Union-EU and the European Economic Area -EEA), according to the principle of free movement of goods, established in Article 28 TFEU. As a consequence of the aforementioned principle, as well as the so called regional exhaustion regime, which allows parallel imports between countries that are members of

a regional agreement, but not parallel trade coming from other States, it can be said that parallel trade has a strong foundation in the common market.

However, the pharmaceutical industry is among the most complex cases, since it is a sector that represents – undoubtedly - a striking example of a market where the price level is largely determined by exogenous factors, far beyond the control of producers. In fact, the price fixing of drugs is under the control of national healthcare systems and budget systems, meaning that in each country consumers may pay different prices for the same drug, according to different reimburse systems operating at national level. Even if there is such regulatory framework, no restrictions on parallel trade phenomenon are applied in Italy, also in the light of the above-mentioned principles.

The fact that a medicine, with marketing authorization (MA) in a Member State (EU-EEA), may have a different (lower or higher) price from an analog drug marketed in another Member State (EU-EAA), (over)stimulates parallel trade, which - for the sake of completeness - is about to transfer drugs having different prices within the EU or the EEA. Specifically, parallel trade emerges where international price differences exceed the costs of transporting and selling goods across borders, reason why this phenomenon of arbitrage allows parallel traders to obtain profits from the said price variations (in the case of medicines - as said above - resulting from different national price regulations) and act in competition with the patent holder or with the distributors from him authorized.

The legitimacy of wealth transfer from the producer to the intermediary (parallel trader) does not affect the principle of free movement; with no doubts, the rules on competition are more affected, since the parallel trade has consequences on the *intra*-brand competition as well as on the *inter*-brand competition and it may have a *pro*-competitive effect on the common market. In fact, parallel trade may foster lower costs because it increases the supply of drugs and, therefore, increases price competition, since it arises because of the said profitable opportunities for arbitrage between national markets.

In the light of this, the rules on competition do find ordinary application in relation to the issue here discussed.

Although parallel trade takes advantage (and genesis) from different price regulations and repayment systems between Member States, the said economic-commercial aspects (with no doubts of primary importance) cannot be separated from the regulatory approval aspects, which can be defined as the only (possible) restriction on parallel trade.

In fact, a parallel imported medicine is subject to a compulsory authorization granted by the Office of Evaluation and Authorization (AIFA) on the basis of a proportionally simplified procedure with respect to the marketing authorization (MA) process (necessary

to place a new drug in the market), provided that the imported product has obtained a marketing authorization in the exporter Member State and the imported product is essentially "similar" to a product that has already received the marketing authorization in the receiving Member State.

The parallel imports of medicines procedure is currently regulated by Ministerial Decree of 29 August 1997, according to whom the AIFA acquires from the export country all the technical details of the imported medicinal product in order to test the compatibility of the product marketed abroad with the one registered in Italy. Moreover, the parallel importer must repackage the product so the drug is labeled and contains instructions in the language of the receiving country. To ensure that no alteration of the drug occurred during the repackaging process, the importer must identify who repackaged and manufactured the product. The repackaging must not damage the reputation of the trademark or of its owner, and the trademark owner must receive notice before the repackaged product goes on sale. In fact, the MA holder has the right to protect the reputation of the brand, meaning that he can provide for further control the repackaging or re-labeling of the imported drug with specific comments or precise requirements, that - in certain cases - may affect the placing on the market of the parallel imported drug. The monitoring of the parallel imported drugs is operated by AIFA through the tracking system or through the request of a sample of the product as stated in the above-mentioned Ministerial Decree dated 29 August 1997.

However, for the sake of completeness, the AIFA has implemented a review process on the currently parallel imports procedure under the Ministerial Decree dated 29 August 1997, by submitting to the European Commission a new regulatory plan. The need for a review comes from the update of the general principles applied by the European Commission, conformed to the dictates of the case law of the European Court of Justice, contained in the Commission Communication, 30/12/2003 COM (2003) 839 and the entry into force of the legislative decree 24 April 2006 no. 219.

As regards the authorizations issued pursuant to Regulation 726/04/EC, it is necessary to underline that when a medicine has been authorized under the centralized procedure, the said authorization is valid throughout the EU/EAA. In this case, the parallel importer may directly market the product through the parallel system. The AIFA, once received the information by the EMEA according to art. 57, letter o) of the mentioned Regulation, releases the national identification number which allows the marketing of the parallel imported drug on the national territory.

It can be concluded that, simplified authorization system apart, competition law finds ordinary implementation in relation to parallel trade of medicines.

4.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.

N/A

4.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.

N/A

5. Any other considerations

5.a. Please comment on any other aspects of the interaction of competition law and the pharmaceutical sector in your jurisdiction that you consider likely to be relevant to the League's Report and Recommendations.

The particular and continuous attention to the pharmaceutical market on the part of antitrust authorities, including the Italian authority, in order to contain prices and to reduce pharmaceutical expenditure, seems to be confirmed.

In Italy in particular, as said above, this seems to be confirmed with the above-mentioned Roche/Novartis case, in which the IAA censured behaviors which were deemed lawful by sectorial pharmaceutical rules, given that Roche and Novartis were condemned for conduct that are in compliance with the Italian regulatory law (in terms of pharmacovigilance obligation, prohibition to promote a drug without the marketing authorization, etc.).

This trend, clearly spurred *inter alia* by the recent European public financial crisis, should nevertheless take into account the fair and equitable balance between the necessities of containing expenditure, which are considered increasingly important, and the right to health, which is - and must remain - a primary value to be protected. In this sense, the European Court of Justice (29 March 2012, case C-185/10, *Commission v. Poland*) held that, pursuant to Article 6 of Directive 2001/83/EC, the marketing of medicinal products on the EU market is conditional upon the achievement of the marketing authorization, thus inextricably relating the safety assessment with the relevant market. In interpreting the notion of "*special needs*" which, pursuant to Article 5 of Directive 2001/83/EC, allow derogation from the above-mentioned general principle, the Court stated that this notion shall be read as referred exclusively to individual cases justified by medical considerations, and therefore it assumes that the medical product is essential to satisfy the patients' need for health care. Similarly, the condition, laid down in the same Article 5,

that medical products have to be supplied in response to a “*bona fide unsolicited order*” shall mean that the medical product must have been prescribed by a physician on the outcome of an effective screening of his patients, on the basis of exclusively therapeutic evaluations. The Court consequently held that the derogation provided for in the Directive can be applied only when the physician considers that his patients’ state of health requires the administration of a medical product which does not have an equivalent product already authorized on the national market, or which is not available at national level.

In Italy, pharmaceutical regulation is more and more intrusive with respect to economic initiative in the industrial sector, which has resulted in a significant saving for the health system, but which has also dampened the possibility for undertakings to be able to exploit the competitive variable typical of non-regulated markets, where the competitive dynamics are more developed and, at the same time, there is a considerable impetus towards innovation (as it is, for instance, the case of the US pharmaceutical market, based on the free market, where the prices of medicinal products are set by operators and the purchasers are mainly private).

The particular features of the pharmaceutical sector, as well as the strict regulation provided in Europe, cannot be ignored by antitrust authorities. While it is correct to benefit from containing public expenditure, it also has to be considered that an excessively strict application of antitrust law could further undermine the competitiveness of the European pharmaceutical industry and hinder innovation, research and development.

The mentioned *Avastin/Lucenyis* case highlights the tendency of the IAA to intervene in regulated markets (i.e. the pharmaceutical sector), showing regulator characters that should be extraneous to its purposes. The consolidation of certain standards of application of competition law by the IAA could have serious consequences on the future development of key markets such as the ones involving pharmaceuticals. If the broader discretion of implementation of antitrust rules by the IAA was confirmed by the ECJ, antitrust sanctions could increasingly assume an unpredictable character, making *inter alia* almost impossible the antitrust self-assessment of conducts by undertakings.