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Questionnaire A for National Reporters of LIDC Geneva 2016

"In the case of pharmaceuticals, in what way should the application of he competition rules be affected by the specific characteristics of those products and markets (including consumer protection rules, the need to promote innovation, the need to protect public budgets, and other public interest considerations)?" ?

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.

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.All the provisions of competition law may be applied to the pharmaceutical sector, including those that prohibit the abuse of dominant position, anticompetitive concerted actions, as well as unfair competition. You may find the main provisions of competition law as follows:

Article 6 of the Law of Ukraine "On Protection of Economic Competition" "Anticompetitive Concerted practices of Economic Entities"
1. Concerted practices which resulted or can result in the prevention, elimination or restriction of competition shall be anticompetitive con- certed practices.
2. Concerted practices shall be considered as anticompetitive ones if they, in particular, concern:
1) setting of prices or other conditions with respect to the purchase or sale of products;
2) restriction of production, product markets, technical and technologi- cal development, investments or the establishment of control over them;
3) the distribution of markets or sources of supply in accordance with the territorial principle, the assortment of products, the volume of their sale or purchase, in accordance with the circle of sellers, buyers or consumers or in accordance with other signs;
4) distortion of the results of auctions, contests, tenders;
5) removal of other economic entities, buyers, sellers from the market or the limitation of their entry into (exit from) the market;
6) application of different conditions to equivalent agreements con- cluded with

economic entities in terms of competition;
7) conclusion of agreements provided that other economic entities as- sume additional obligations whose content or which in terms of customs in trade and other fair customs in entrepreneurial activities have nothing in common with the subject of these agreements;
8) substantial limitation of the competitiveness of economic entities on the market without objectively justified causes.
3. Anti-competition concerted practices shall also include perform- ing by economic entities of similar acts (omissions) in product markets, which have led or may lead to prevention, elimination or restriction of competition if the analysis of situation in product markets shows that there are no objective reasons to perform such acts (omissions).
4. Anticompetitive concerted practices shall be prohibited and shall entail responsibility according to laws.
5. A person who had committed anticompetitive concerted practices, but earlier than the remaining participants in the actions voluntarily in- formed the Antimonopoly Committee of Ukraine **(hereinafter – the AMCU)** or its territorial office on the fact and submitted information of essential importance to taking a decision on the case must be relieved from the responsibility for committing anticompetitive concerted practices which are provided for by Article 52 of the present Law.

The bodies of the Antimonopoly Committee of Ukraine shall keep all information about such individual confidential following a substantiated request and in order to protect the interests of investigation into the case regarding violation of the legislation on protection of economic competition.

The person defined in the present part may not be relieved from the responsibility if the person:
- having informed the Antimonopoly Committee of Ukraine on anti- competitive concerted practices, did not take efficient measures to terminate the actions;
- was the initiator of the anticompetitive concerted practices or ma- naged them;
- did not submit all such evidence or information on the relevant violation committed by the person that was known to and that could be freely got by the person.

Article 8. of the Law of Ukraine “On Protection of Economic Competition” “Concerted Practices Relating to the Supply and Use of Products”

1. The provisions of Article 6 of the present Law shall not be applied to concerted practices relating to the supply and use of products if a par- ticipant in the concerted practices imposes, with respect to another par- ticipant in the concerted practices, restrictions on:
- use of products supplied by the participant or on the use of products of other suppliers;
- purchase of other products from other economic entities or on the sale of other products to other economic entities or consumers;
- purchase of such products that due to their nature or in terms of cus- toms in trade and other fair customs in entrepreneurial activities have nothing in common with the subject of the relevant agreement;

other economic entities or consumers.

2. The provisions of Article 6 of the present Law shall be applied to the concerted practices provided for by Part 1 of the present Article if actions of that sort:

- result in the substantial restriction of competition on the whole mar- ket or in its significant part, including the monopolisation of the re- levant markets;
- limit the entry of other economic entities into the market;
- result in the economically unjustified raise in prices or the growth in product deficit.

Article 13 of the Law of Ukraine “On Protection of Economic Competition”
“Abuse of a Monopoly (Dominant) Position on the Market”

1. Such actions or inactivity of an economic entity occupying a monopoly (dominant) position on the market that resulted or can result in the prevention, elimination or restriction of competition, in particular restriction of the competitiveness or in the infringement of the interests of other economic entities or consumers, which would be impossible in case of the existence of substantial competition on the market, shall be considered as abuses of a monopoly (dominant) position on the market.

2. The following actions, in particular, shall be considered as abuses of a monopoly (dominant) position on the market:

1) setting of such prices or other conditions for the purchase or sale of a product that would be impossible in case of the existence of sub- stantial competition on the market;

2) application of different prices or other different conditions to equiva- lent agreements with economic entities, sellers or buyers without objectively justified causes;

3) conclusion of agreements on condition that the relevant economic entity assumes additional obligations which due to their nature or in terms of customs in trade and other fair customs in entrepreneurial activities have nothing in common with the subject of the contract;

4) limitation of production, markets or technical development, which caused or can cause damage to other economic entities, buyers, sellers;

5) partial or complete refusal to purchase or sell a product if there are no alternative sources of sale or purchase;

6) substantial restriction of the competitiveness of other economic enti- ties on the market without objectively justified causes;

7) creation of entry (exit) market barriers or the removal of sellers, buy- ers, other economic entities from the market.

3. An abuse of a monopoly (dominant) position on the market shall be prohibited and shall entail responsibility according to laws.

The Law of Ukraine "On Protection from Unfair Competition"

Article 4 of the Law of Ukraine "On Protection from Unfair Competition" “Unlawful Use of Trademarks”

Using the name, commercial (firm) name, trade mark (mark for goods and services), advertising materials, design of product packaging and
periodicals, other designations without permission (consent) of the eco- nomic entity

or may result in confusing them with the activities of this enterprise shall be illegal.
Use of a natural person name in a company name shall not be qualified as unlawful if the person name is somehow made distinct, so as to rule out its confusion with the activities of other economic entity.

Article 15-1 of the Law of Ukraine "On Protection from Unfair Competition" "Dissemination of Misleading Information"
Dissemination of misleading information shall be dissemination by the economic entity, either directly or through another person, to one or se- veral persons or certain persons, including in advertising, of any incom- plete, inaccurate, false (in particular by misrepresentation) information, silencing certain facts or providing vague wording that has affected or may affect the intent of these persons with respect to acquisition (order) or sale (delivery, performance, provision) of goods, works and services by such economic entity.
The misleading information shall include, in particular, any information that:
contains incomplete, inaccurate or false data about the origin of pro- duct, manufacturer, seller, manufacture method, source and method of purchase, sale, quantity, consumer properties, quality, complete- ness, usability, standards, characteristics, particular features of selling products, works and services, information about price and discounts on such products, works and services, as well as data about essential terms and conditions of the contract;
contains incomplete, inaccurate or false data about financial position or economic activities of the economic entity;
alludes to powers and rights that do not exist or relationships that are not maintained;
includes references to volume of production, purchase, sale or supply of goods, works and services, which actually did not exist at the date such information was disseminated.

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.

The procedure of determining the product market is stipulated by the Methodology for determining the monopoly (dominant) position of undertakings in the market, which is applied to all sectors of the economy, so there are no peculiarities of defining goods markets in the pharmaceutical sector. According to clause 5.1 of the Methods, product boundaries of a market shall be determined by forming a group of substitute products (product groups), within which consumers, under normal conditions, can easily switch from one product to another. A group of substitute products (product groups) is formed from the list of products, which the sellers (suppliers, producers) or buyers (consumers, users) see as having signs of one (similar, alike) product (product group) in terms of interchangeability, which are particularly: similarity of purpose, consumer properties, conditions of use, etc.; similarity of physical, technical, operational properties and characteristics, quality indicators, etc.; availability of a common consumer goods

(product group) in terms of their production, i.e. the ability of manufacturers to offer new products to replace the existing ones.

The above provisions of the Methods are mandatory for the AMCU in its investigations into whether an undertaking enjoys a monopoly (dominant) position. As of June 2016, the AMCU has not published its official stance regarding its approaches to determining the market boundaries of the pharmaceutical markets. At the same time, such approaches are implied in the investigations on anticompetitive concerted actions of manufacturers, importers and distributors of medicines (more details about these investigations please see in 1 j below). In the relevant cases, the AMCU, in particular, investigates whether manufacturers/importers have the market power enabling them to set the terms for circulation of products in the market, in particular to influence the pricing.
According to the AMCU's approaches, the product boundaries of pharmaceutical markets are determined based on the active pharmaceutical ingredient. Thus, the AMCU does not consider therapeutic equivalence as a condition for determining whether a substitute medicine is available in the market. Due to this, the situation is that the manufacturer is qualified as having the market power in the market of own medicines in the case where there is no medicine with the same active ingredient in the market. This approach is widely used by the AMCU to justify the existence of anticompetitive concerted actions between manufacturers/importers and distributors of medicines. However, the AMCU has not made any decisions upon its investigations in the relevant cases. Therefore, the authority's ultimate approach has not been formed yet.

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.

For the time being there are no such tendencies as well as no one decision has been taken by the Ukrainian antitrust authority yet.

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?

No, there is not.

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 no special legislation in this regard. The Ukrainian legislation contains

a number of regulations which establish general pricing principles as well as regulate pricing issues, in particular, for medicinal products. Though control over compliance with the pricing requirements is carried out by state authorities other than the AMCU, the rules stipulated by pricing legislation have a direct impact on the course of antitrust investigations related to pricing issues or actions of undertakings that result in unjustified overpricing, in particular, for end consumers.

Violations under the Law of Ukraine "On Protection of Economic Competition", which include the price fixing element, are monopoly (dominance) abuse and anticompetitive concerted actions, in particular:

- monopoly (dominance) abuse which consist in price fixing or imposing other conditions for purchase or sale of products, which would be otherwise impossible under significant competition in the market (paragraph 1 of part 2 of Article 13 of the Law of Ukraine "On Protection of Economic Competition");
- anticompetitive concerted actions of undertakings, which consist in price fixing or imposing other conditions for purchase and sale of products (paragraph 1 of part 2 of Article 6 of the Law of Ukraine "On Protection of Economic Competition").

Besides, economically unjustified prices resulting from permitted vertical concerted actions are regarded as a ground for applying the provisions of Article 6 of the Law of Ukraine "On Protection of Economic Competition" prohibiting anticompetitive concerted actions[1] of undertakings that are parties to a vertical agreement.

Under the Law of Ukraine "On Prices and Pricing", breach of requirements for forming, establishing and using of state regulated prices shall lead to: confiscation of unreasonable received revenues, which is a positive difference between: i) the actual proceeds from the sale of goods, and ii) the proceeds which would be received if prices were set out according to the method stipulated by regulations, and an additional penalty of 100 percent of unreasonably received revenues by the State Inspection of Ukraine on Price Control.[2]

Moreover, under clause 7 of the Resolution of the Cabinet of Ministers of Ukraine dated October 17, 2008 No. 955 "On Measures to Stabilize Prices for Medicinal Products and Medical Devices", the State Inspection on Price Control takes measures prescribed by the legislation to make business entities align prices with the provisions of the abovementioned Resolution. As defined in subparagraph 4) of paragraph 4 of the Regulation on the State Inspection on Price Control, the Inspection shall provide the bodies of the AMCU with information that may be an evidence of breach of legislation on protection of

[1] Part two of Article 8 of the Law of Ukraine "On Protection of Economic Competition" dated 11.01.2001 № 2210-III

[2] **Comment:** the State Inspection on Price Control is undergoing reorganization under the Resolution of the Cabinet of Ministers of Ukraine No. 442 dd. 10.09.2014, with transferring its powers in sphere of the state control

economic competition. Even though the incorrect calculation of wholesale prices is not a breach of legislation on protection of economic competition *per se*, it might become a ground for the AMCU to investigate the entity's activities[3].

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.

There are no additional comments.

1. Enforcement mechanisms, remedies and consumer protection

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?

No, there is not.

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

The key area of interaction of consumer protection law and competition law is the sphere of advertising. Unfair advertising of products, including medicinal products and medical devices, is prohibited by legislation. In particular, the Law of Ukraine "On Protection from Unfair Competition" prohibits dissemination of misleading information as was described in 1a above.

The AMCU has formed its systemic approach to imposing fines for unfair advertising of medicines. For instance, the AMCU imposed a fine of UAH 1 million on a manufacturer which disseminated an advertising of a medicinal product with the following slogan "Cough will be cured, the throat will be cleared", although the product had no relevant pharmacological properties. The AMCU considered that the medicinal product does not cure a cough, and

[3]**Comment:** It should be additionally noted that pursuant to the Resolution of the Cabinet of Ministers of Ukraine No. 442 dated 10.09.2014 "On Optimization of the System of Central Executive Authorities" the State Inspection on Price Control shall be liquidated. Instead, the state control over the compliance with the requirements as to calculation, establishment and application of state regulated prices shall be carried out by the State Service of Ukraine on Food Safety and Consumers' Protection.

Comment: Though the State Service of Ukraine on Food Safety and Consumers' Rights Protection has been

only removes its symptoms. Thus, the abovementioned slogan could mislead consumers.
However, current legislation of Ukraine does not stipulate clear requirements for the scope of information on the medicines' pharmacological properties which shall be included into the advertising. Thus, lack of legal clarity may entail risks related to the AMCU's own interpretation of the term "necessary information". For instance, there is a risk that the AMCU may impose a fine in case a company does not include into its advertising the information specified in the product label (patient information leaflet) regarding the product's pharmacological properties and contraindications.

The other issue, which is significant for the purposes of defining interaction between the competition and consumers' protection law, is the issue of comparative advertising. The Law of Ukraine "On Protection from Unfair Competition" defines comparative advertising as advertisement, which contains comparison with products, work and services or activities of another business entity. According to a general rule, comparison in the advertisement is not considered to be unlawful, if information about products, work and services contained in the advertisement is: proved by the actual data; reliable, objective and useful for informing consumers.

However, due to specific characteristics of medicinal products and medical devices, the Law of Ukraine "On Advertising" establishes special restrictions. In particular, advertising of medicinal products and medical devices shall not contain comparison with other medicinal products and medical devices to strengthen the advertising effect.

It also worth mentioning that according to the Law of Ukraine "On Advertising" manufacturers and/or sellers of medicinal products and medical equipment are permitted to act as sponsors of TV and radio programs. Besides, such sponsorship is permitted only by means of provision of information of advertising nature about the name or the trademark without any reference to prescription medicinal products, as well as about medical equipment, use of which requires special knowledge or training. Therefore, the law permits the sponsorship for manufacturers and/or sellers of medicinal products, including prescription medicines, if the conditions above are met.

Thus, current legislation of Ukraine limits a number of promotion channels for pharmaceutical companies. Taking into account the aforesaid restrictions imposed on promotion, dissemination of misleading information on medicines and/or medical devices may have even worse impact on competition in pharmaceutical industry than in other spheres.

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***

so, please provide a brief description of the body and its powers.

There are no special bodies with responsibilities related solely to pharmaceutical competition law cases in Ukraine, and there are no consumer protection bodies with specialized competence in pharmaceutical area. Nevertheless, both the AMCU and the State Service of Ukraine on Food Safety and Consumer Protection (hereinafter – "the Service") pay close attention to the issue of dissemination of misleading information, in particular – in pharmaceutical area.

Both the abovementioned bodies have an authority to impose fines on business entities for dissemination of misleading information, though there are certain distinctions between their competences: while the AMCU is focused on competition issues (breach of economic competition between business entities by means of affecting the consumers' intentions towards purchasing the products), the Service pays its particular attention to protection of the consumers' rights (lack of necessary, accessible and reliable information about the product, as prescribed by the Law, placing misleading information on labelling) and compliance with legislation on advertising.

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?***

There have not been any sector-specific reviews of competition law in the pharmaceutical sector.

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?***

No, there is not.

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

Law enforcement in pharmaceutical cases has a public character.

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 of the AMCU reveals violation of legislation on protection of economic competition, the fines which may be imposed on the business entity may amount up to 10% of the undertaking's income (revenue) from the sale of products (works, services) for the last fiscal year preceding

the year in which the fine is imposed.

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

Mechanism for the monitoring is as follows:

Monitoring of database of SE "Ukrainian intellectual property institute" for the presence of application for the protection of an invention;
Monitoring of medicines database, which are registered;
Monitoring of database of marks submitted for the registration;
Monitoring of database of registered trademarks.

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?***

There is no such an obligation for the pharmaceutical suppliers in Ukraine.

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 AMCU pays a lot of attention to restrictive agreements in the pharmaceutical market. At the time being the AMCU is investigating restrictive agreements between drugs manufacturers and distributors operating in Ukraine. The AMCU has commenced the abovementioned proceedings due to the presence of one of the grounds under part two of Article 8 of the Law of Ukraine "On Protection of Economic Competition" (as stated above). One of the main charges brought by the AMCU is the application of retro discounts by participants of vertical agreements, which lead to unjustified overpricing. At the same time, the authority analyzes the current state regulation of pricing for medicines and amounts of retro-discounts and notes that the limiting trade markups are not the main income-generating factor for distributors. According to the AMCU, the major part of distributors' income is created exactly by retro discounts. In its investigations, the AMCU also uses the concepts "actual price" and "nominal price", which are not defined by the law. However, as seen from the publicly available information, these concepts are applied only in the AMCU investigations into anticompetitive concerted actions in the pharmaceutical markets. Thus, the AMCU understands a nominal price as a

price (on a price list) used by distributors/pharmacies to form their own prices. At the same time, the AMCU describes a price as an actual price, if it is paid by distributors/pharmacies due to obtained retro discounts. On average, according to the authority, such actual prices are 7-15% lower than nominal prices.
In simple words, the AMCU claims that due to the fact that discounts are provided retrospectively, distributors have possibility to sale products at prices exceeding maximum mark-ups, as they in fact receive 7 % - 15 % back after the products are sold, therefore overpricing is alleged by the AMCU.
The AMCU also pays special attention to the analysis of limiting trade markups for the purposes of participation in public procurement and in the practice of providing retro discount (and amounts of discounts), which exists between manufacturers/importers and distributors due to the latter's participation in public procurement. The allowed trading markup for participation in public procurement procedures regarding medicines amounts to 10 %. Such state regulation of prices is aimed at saving public funds and ensuring the necessary quantity of medicines available for end consumers. At the same time, in the AMCU's opinion, application of retro discounts for distributors participating in public procurement avows unjustified overpricing proposed by bidders and artificially increases the trading markup allowed by the State.

At the same time, as of the date hereof, the authority has not completed any such investigation, and the AMCU's official stance is not known.

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.***

Current legislation of Ukraine stipulates a number of special requirements for advertising of medicinal products and medical devices. For instance, according to the Law of Ukraine "On Advertising" advertising of medicinal products and medical devices shall include:

- objective information so that it is clear that the message is an advertisement and the advertised product is a medicinal product or medical device;
- a mandatory requirement to have a consultation with a doctor before using a medicinal product or a medical device;
- a mandatory recommendation to review the instructions for medicinal products;
- a following disclaimer: "Self-medication can be harmful to your health," which shall take at least 15% of the area (duration) of the whole advertisement.

Advertising of medicinal products and medical devices shall not contain, *inter alia*:

- information that the therapeutic effect from the use of a medicinal product or a medical device is guaranteed;
- statements that may trigger or develop people's fear of getting ill

products or medical devices;
- references to medicinal products and medical devices as to the most effective and safest or exceptional ones due to the absence of side effects;
- references to the therapeutic effects in relation to diseases that cannot be cured or are difficult to treat;
- references to specific cases of successful use of medicinal products and medical devices;
- recommendations or references to recommendations of medical professionals, scientists, medical institutions and organizations regarding the advertised products;
- special manifestations of gratitude, appreciation, letters, excerpts from them with recommendations or success stories and results of the advertised products from particular individuals;
- images and mentions of names of celebrities, film, television or animated film characters, or of authoritative organizations;
- images of physicians or other medical professionals as well as of individuals whose appearance imitates the look of doctors;
- other information that may mislead the consumer as to the composition, origin, efficiency or patent protection of the product etc.

Moreover, advertising of medicinal products shall not contain information which may suggest that:
- the product is a food, cosmetic or other consumer product;
- the safety or effectiveness of the product is due to its natural origin.

However the abovementioned special requirements and restrictions do not apply to advertising of medicinal products and medical devices placed in specialized publications intended for medical institutions and physicians or advertising disseminated at seminars, conferences and symposia on medical topics.

Besides, sometimes the AMCU interprets regulatory restrictions on advertising imposed by the Law of Ukraine "On Advertising" at its own discretion. For instance, the AMCU fined a company for:
placing the statements "dentists recommend toothpaste …" and "Ukrainian dentists recommend toothpaste …" on the consumer packages of toothpaste, as well as the use of such statements in advertising accompanied by a doctor's photo.

It was the AMCU's position that the company violated:
the Law of Ukraine "On Protection against Unfair Competition" having disseminated misleading information in terms of the actual consumption of toothpaste, though dentists' recommendations were supported by relevant documents;
the Law of Ukraine "On Advertising", because according to the AMCU

shall not be accompanied by a doctor's photo.

Though the appellate court supported the company's lawsuit and reasoning, the final judgment issued by the court of cassation upheld the AMCU's arguments concerning the violation of the Law of Ukraine "On Protection against Unfair Competition" and "On Advertising". Such law-enforcement practice, as well as interpretation of regulatory requirements for the advertising by the AMCU at its own discretion resulted in lack of legal clarity for the companies in Ukraine.

Also, it should be noted that causing harm to consumers' interests is an independent qualifying sign of such violation as monopoly (dominance) abuse. Thus, according to part one of Article 13 of the Law of Ukraine "On Protection of Economic Competition" monopoly (dominance) abuse shall mean actions or omissions of an undertaking enjoying a monopoly (dominant) position in the market, which have led or may lead to prevention, elimination or restriction of competition, or infringement of interests of other undertakings or consumers, which would otherwise be impossible subject to significant competition in the market.[4] Therefore, the protection of consumers' interests, which is also the aim of the state regulation of prices for medicines, is an independent condition for the application of legislative provisions on protection of economic competition.

2. 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.

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.

No, there is not.

Moreover, as for generic entry, the Ukrainian courts have declared the start of any preparation for market entry by a generic manufacturer to be a patent infringement, in particular:
any actions taken to start the process to obtain a marketing authorization before the patent term expires are considered a patent infringement[5];
the applicant for a marketing authorization has to submit a sample of medicine to state regulatory bodies as part of the marketing authorization procedure. Production of such sample of medicine itself will be also considered as patent

[4] Law of Ukraine "On Protection of Economic Competition" dated 11.01.2001 № 2210-III

infringement without any difference whether it was just a non-commercial medicine production or not[6].

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)?

Provisions of article 9 of the Law of Ukraine "On protection of economic competition" regulate the issue of concerted practices relating to intellectual property rights. Namely, the provisions of Article 6 of the present Law shall not be applied to agreements on the transfer of intellectual property rights or on granting the right to use the intellectual property to the extent of the limitation, by the agreements, of economic activities of the agreement party to whom the right is transferred unless these limitations exceed the limits of the legitimate rights of the intellectual property entity.

It shall be considered that limitations relating to the volume of transferred rights, the period and territory of validity of the permission to use the intellectual property object, those relating to the type of activities, the sphere of use, the minimal volume of production do not exceed the limits of the rights mentioned in Part 1 of the present Article.

In general, the Law of Ukraine "On Protection of Economic Competition" stipulates the principle, under which restrictions on the rights arising from the content of intellectual property rights are not considered as restraint of economic competition. The mentioned Article 9 recognizes agreements that impose restrictions on the transfer or use of intellectual property within the relevant absolute right determined by special legislation on intellectual property rights as lawful. However, restrictions on competition, which go beyond the limits set by the law to protect such an absolute right, are prohibited.

Provisions of Article 6 of the Law of Ukraine "On Protection of Economic Competition" prohibiting anticompetitive concerted actions shall not be applied to agreements on the transfer of intellectual

property rights, except where the scope of restrictions on business operations of the party to the agreement the relevant rights are transferred to goes beyond the limits of protection of the intellectual property right. Accordingly, restrictive obligations can be established for the acquirer of intellectual property rights only to the extent that the law determines the monopoly of such intellectual property rights. All other obligations that go beyond the protection of intellectual property are considered by the AMCU as ordinary contractual obligations of the parties.

Part two of the mentioned Article 9 of the Law of Ukraine "On Protection of Economic Competition" fully corresponds with the provisions of the national legislation on intellectual property rights, which determine the standard restrictions to be applied by owners of intellectual property rights in relations with third parties: to limit the scope of the rights transferred to another person, to establish the term and territory for the use of intellectual property rights. At the same time, such standard restrictions may also be studied by the AMCU in terms of going beyond the permissible limits, e.g. the use of special restrictions on the territory (prohibition of sales to countries where there is no protection of intellectual property rights used, etc.).

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?***

Please see the explanation 3b (i) above.

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?***

It is sufficient to exclude only the party of the agreement.

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

Available practice does not contain such examples.

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

Please see the answer 3b (iv) above.

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.***

No additional comments.

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?***

Barriers that may be faced by a generic drug maker may be caused by the fact that generic manufacturers often understand "non-commercial use" too broadly. For example, they try to prove that preparation and obtaining market approval for generic before a patent expires is just non-commercial use of a patented invention, but not a patent infringement. As it was mentioned above, the start of any preparation for market entry by a generic manufacturer is considered as a patent infringement.

3. 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.

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?***

Competition law is applied consistently to healthcare purchasers and providers.

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.***

So far, enforcement of third party payers is rather uncommon in Ukraine.

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

Article 10 of the Law of Ukraine "On Prices and Pricing" provides that business entities apply free prices or state-regulated prices in their business activities. Pricing for medicines is strongly regulated in Ukraine. State regulation of prices for medicines is implemented exclusively in the following forms and as regards certain categories of medicinal products: setting of mark-ups for medicinal products (both for commercial and public procurement market) and price declaration.

According to the Resolution of the Cabinet of Ministers of Ukraine "On Measures to Stabilize Prices for Medicinal Products and Medical Devices" No. 955 dated 17.10.2008:

medicinal products included into the National Essential Medicines List (except for narcotics, psychotropic drugs, precursors, and medical gases) are subject to a maximum supply mark-up not exceeding 10% of their wholesale price including taxes and fees, and a maximum retail mark-up not exceeding 25% of their purchase price including taxes;

medicinal products (except for narcotics, psychotropic substances, precursors, and medical gases) and medical devices, wholesale prices for which have been entered into the Register of wholesale prices for medicinal products and medical devices, which are in whole or in part procured for the costs of the state or a local budget are subject to a maximum supply mark-up not exceeding 10% of the declared change of their wholesale price, including taxes and fees, and a maximum retail mark-up not exceeding 10% of their purchase price, including taxes and fees. The actual wholesale price for each medical form, dosage, consumer packaging of a medicinal product, all types, kinds and brands of medical devices shall not exceed the amount of the price entered into the mentioned Register of wholesale prices in the national currency of Ukraine - hryvnia.

The procedure for establishment of prices for medicines and medical devices subject to the state regulation has been approved by the Resolution of the Cabinet of Ministers of Ukraine No. 333 dated 25.03.2009. The List of domestic or foreign medicinal products that may be purchased in whole or in part for the costs of the state or local budgets by healthcare institutions or establishments has been specified by the Resolution of the Cabinet of Ministers of Ukraine No. 1071 dated 05.09.1996. The Procedure for declaring changes in the wholesale prices for medicinal products and medical devices purchased for public or local funds has been approved by the Resolution of the Cabinet of Ministers of Ukraine No. 240 dated 02.07.2014 (hereinafter the Declaration Procedure).

from the state or local budgets shall purchase medicinal products and medical devices for prices, which do not exceed the level of declared wholesale prices including duties and value added tax as well as marginal supply and sale prices and trade (retail) mark-ups. Declaration Procedure does not apply to the medicinal products purchased within a procurement procedure by specialized organizations, as described below.

The Declaration Procedure also stipulates that wholesale prices for medicinal products and medical devices subject to declaration may change due to changes in terms of their manufacturing or sale not attributable to applicant's operation. The Declaration Procedure does not limit the frequency of changing the wholesale price. Moreover, if the average monthly USD to UAH exchange rate as set by the National Bank of Ukraine changes for more than 5%, the declared changes in the wholesale prices for medicinal products and medical devices shall be adjusted by the Ministry of Health itself and entered into the register of the wholesale prices for medicinal products and medical devices not later than on the 10th day of the following month.

The information above shows that there is a number of legal acts which set out special pricing rules for certain medicinal products and purchasing procedures. These rules inevitably influence the application of provisions of legislation on protection of economic competition.

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?***

There are no restrictions on parallel trade or resales of those drugs subject to price control. In case of parallel import of pharmaceutical clause 6 of article 16 of the Law of Ukraine “On protection of rights to marks and services” may be applied. According to article 16 the exclusive right of a certificate owner to prohibit the use of the registered mark by other persons without his permission does not extend to:

- exercising of any right acquired before the date of filing the application or, if the application priority was claimed, before the priority date;
- the use of the mark for the goods introduced into the commercial circuit with this mark by the certificate owner or by his permission, provided that the certificate owner has no essential reasons to prohibit such a use in connection with the following selling of the goods, in particular in case when the condition of goods changed or the quality of the goods lowered after its introducing into the commercial circuit;
- the use of the qualified indication of the origin of goods protected according to the Law of Ukraine "On the Protection of Rights to Indication of the Origin of Goods";

- the noncommercial use of the mark;
- all forms of broadcasting and commentaries on news;
- fair use of names or addresses of the said persons.

In other cases the owner has the right to prohibit the use of the registered mark.

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.***

No additional comments.

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.***

No additional comments.

4. **Any other considerations**

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.***

No additional comments.