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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 the 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)?"

Background

The International League of Competition Law is gathering information relating to pharmaceutical antitrust questions ahead of its October 2016 Congress in Geneva. The Congress will analyse the following question with a view to making recommendations:

In the case of pharmaceuticals, in what way should the application of the 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)?

The interaction of the pharmaceutical sector and competition law is potentially very wide-ranging, encompassing issues such as (i) anticompetitive agreements, such as market sharing and "pay for delay" restrictions on entry; (ii) monopolisation allegations, including price discrimination, excessive pricing, "evergreening" and product hopping; (iii) merger clearances; and (iv) competition law issues in licensing agreements. The special protection of drug originators under intellectual property law has the potential to pose unusually pronounced competition law issues. With a view to determining whether Recommendations on shared practices can be made, the questions focus on: (i) whether pharmaceutical products receive differentiated legal treatment under competition law; (ii) whether any differentiated enforcement mechanisms exist, with particular reference to consumer protection; (iii) the interaction of pharmaceutical intellectual property protection and competition law; and (iv) whether there is shared practice on budgetary and other public interest considerations. Your answers to these questions will form the basis of the Report for the Congress, and will be very greatly appreciated. Please do not hesitate to direct any queries to the International Rapporteur, Stephen Dnes, via e-mail at s.m.dnes@dundee.ac.uk.

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.

In the Czech Republic the main legal provisions regarding protection of competition are specifically contained in the ACT No. 143/2001 Coll. of 4 April 2001 on the Protection of Competition and on Amendment to Certain Acts (Act on the Protection of Competition) as amended (hereinafter also „**Competition Act**“). It is necessary to mention that relevant competition law legislation on the European level, foremost Articles 101 and 102 of the Treaty on the functioning of the European Union and regulations 1/2003 and 139/2004 but also other relevant competition law regulations, that are directly applicable in the Czech Republic play also key role with regard to protection of

¹ Disclaimer – all ideas and thoughts in this report are solely authors and do not necessary correspond nor might by in any way considered as official opinion of the Office for the Protection of Competition.

competition in the Czech Republic. Nevertheless within this report I focus on the national competition law not to the competition law on the European level.

The key provisions of the Competition Act regarding potential competition law infringements are:

- 1) **Article 3 (1) that prohibits anticompetitive agreements between undertakings.** This article states that: *„All agreements between undertakings, decisions by associations of undertakings and concerted practices (hereinafter referred to as “agreements”) which have as their object or effect the distortion of competition shall be prohibited and null and void⁴), unless this Act or a special act provides otherwise, or unless the Office for the Protection of Competition (hereinafter referred to as “the Office”) grants an exemption from this prohibition by its implementing regulation. Agreements with insignificant impact on competition shall not be prohibited.“*
- 2) **Article 11 (1) that prohibits abuses of dominant position.** This article states that: *„Abuse of dominant position to the detriment of other undertakings or consumers shall be prohibited. Abuse of dominant position shall consist particularly of: a) direct or indirect enforcement of unfair conditions in agreements with other participants in the market, especially enforcement of performance, which is at the time of conclusion of contract conspicuously inadequate to the counter-performance provided, b) making the conclusion of contracts subject to acceptance by the other party of supplementary performance, which by its nature or according to commercial usage has no connection with the object of such contracts, c) application of dissimilar conditions to identical or equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage, d) termination or limitation of production, sales or research and development to the prejudice of consumers, e) consistent offer and sale of goods for unfairly low prices, which results or may result in distortion of competition, f) refusal to grant other undertakings access for a reasonable reimbursement, to own transmission grids or similar distribution networks or other infrastructure facilities, which are owned or used on other legal grounds by the undertaking in dominant position, provided other undertakings are unable for legal or other reasons to operate in the same market as the dominant undertakings without being able to jointly use such facilities, and such dominant undertakings fail to prove, that such joint use is unfeasible for operational or other reasons or that they cannot be reasonably requested to enable such use. The same also applies in due proportion to the refusal of access for a reasonable reimbursement, of other undertakings to the use of intellectual property or access to networks owned or used on other legal grounds by the undertaking in a dominant position, provided such use is necessary for participating in competition in the same market as the dominant undertakings or in any other market.“*
- 3) **Article 18 (1) that prohibits merging without notification and approval by the Czech Competition Authority** (hereinafter also „the Office“ or „the Czech NCA“)). This article states that: *„The undertakings must not implement the concentration before the day of filing concentration notification pursuant to Article 15(1) and before the day the Office’s decision on the concentration approval enters into force.“*
- 4) **Article 19a (1) that prohibits anticompetitive measures adopted by public authorities.** This Article states that: *“Distortion of competition by providing aid favoring particular undertaking, or by other means, shall be prohibited to public authorities.“*

These provisions are applied within the administrative law to undertakings. Nevertheless according to the Act No. 40/2009 Coll. of 8 January 2009 Criminal Code, as amended by subsequent acts (hereinafter also “**Criminal Code**”) also natural person might according to the Article 248 (2) commit a crime by conclusion of a prohibited price-fixing

agreement, division of a market or another agreement distorting competition with its competitor in violation of the law and by such act cause damage of greater extent to other undertakings or consumers.

- 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.

There are no specific provisions regarding market definition in pharmaceutical sector compared to other sectors. Of course specificities of this sector (price regulation especially, public health insurance regulation, legal provisions etc.) have been always taken into account in practice when markets within it were defined.

Most important decisions of the Czech Competition Authority (hereinafter "the Czech NCA") in this sector where the relevant market has been defined are

- The Czech NCA decision S284/2007/KD-13557/2008/850 - relevant market has been defined as pharmaceutical care.
- The Czech NCA decision S075/2007/KD-14287/2007/720 – relevant markets have been defined as wholesale distribution of drugs and wholesale distribution of complementary goods designed to be sold in pharmacies.
- The Czech NCA decision S60/06-22 189/06-300 - relevant market has been defined as drugs wholesale distribution to pharmacies.
- The Czech NCA decision S162/04-489/05-OHS - relevant market has been defined as wholesale distribution of drugs and medical tools.

In all above mentioned cases geographical relevant market was defined as whole territory of the Czech Republic.

- 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.

With regard to the specific per se or object infringement rule there is no such rule designed specifically for cases concerning pharmaceutical sector. Generally if there is an object infringement (typically cartels – price fixing, market sharing, output limitation and bid rigging) of the Article 3 (1) of the Competition Act there is no need to prove any harmful effect to punish such behavior.

- 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?

There is general rule in the Competition Act in Article 3(4) that enables if the agreement of undertakings fulfills relevant criteria it does not breach competition law and also there is according to the case law possibility to objectively justify conduct of dominant undertaking that would otherwise constitute abuse of dominant position. But the criteria and scope that must be fulfilled to comply with competition law are same for all cases and no specific rules for cases regarding pharmaceutical sector exist. Any relevant legislation in force that is specific to the pharmaceutical sector which restricts some aspects of competition is considered as regulation and its following by undertakings might not be sanctioned as competition law breach. Nevertheless if there is only some limitation of competition given by existing laws and within it there is possibility to

compete any agreements or abusive practices of dominant undertakings besides these given by valid laws would be considered anticompetitive and would be prohibited and punished by the Czech NCA.

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

In case of drugs paid, at least partially, from public health insurance there is maximum price set by State Institute for drug control (hereinafter "SUKL") and therefore there is no scope for excessive pricing in competition sense. SUKL controls following of the set maximum prices by pharmacist and in case of breach it has the right to impose sanction. The price of drugs in pharmacy is generally set by three components – price of the developer (price for which the drug is distributed to the pharmacy by producer or distributor, the maximum price for producer is, with regard to the drugs paid at least partially from public health system, set by SUKL) sales margin (divided between distributor and pharmacy, comprises by percentage and fixed value and its ceiling is set according to the price regulation issued by the Ministry of Health, actually 37%) and value added tax (set by the Ministry of Finance, actually 15%). The price of drugs that are not paid from public health insurance is not regulated.

- 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.

Markets in pharmaceutical sector work to some extent specifically compared to "general" markets. This fact and particular specificities are necessary to take into account within the competition law assessment. Nevertheless generally any aspects that are not regulated by specific laws and where competition might work general competition rules are applied also for pharmaceutical sector. For example the variety of drugs available in pharmacies is not regulated and depends on commercial strategy of each pharmacy.

On the other hand the regulation in pharmaceutical sector might be found very specific as many drugs can be prescribed only by doctors which causes that demand and supply for them works differently compared to general goods markets as there is specific relation between patient who needs the drug, doctor who prescribes it, pharmacy that retails it and public health insurance system from which is the drug fully or partially paid – in fact the demand is represented and controlled mostly by doctors and is only limitedly influenced by final consumers – patients (in this sector there is moreover huge information asymmetry), there are restrictions for commercials regarding drugs (commercials for wide public are allowed only for drugs that are sold without doctors prescriptions), there is obligatory public health insurance subtracted obligatory from wage that creates solidarity system from which the most of costs are paid, there is the SUKL that regulates maximum prices for drugs paid at least partially from public health insurance and also there is a lot of intellectual property rights within pharmaceutical sector.

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, specialised remedies, and whether the balance between public and private enforcement differs in the case of the pharmaceutical industry.

- 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?

There is no such pattern that pharmaceutical competition law issues in the Czech Republic would be dealt primarily by some specific competition protection areas, e.g. restrictive agreements, mergers, abuses of dominant position, visible in decision making practice of the Czech NCA.

- 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.

Only in the way that as consumers need some special protection against undertakings especially because information asymmetry and vast difference in resources some of goods must fulfil standard criteria or there is given some special protection by law which might possibly lower competition. Nevertheless there are no special law provisions regarding interaction between consumer protection law and competition in pharmaceutical sector. Moreover as is mentioned above in this sector there is very specific interaction between demand and supply as mostly doctors who prescribe drugs create demand and not patients as final consumers.

- 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.

There is no specialized regulator dealing with consumer protection and general courts solve disputes regarding consumer protection. There are also some organizations for consumer support but these are not public nor act as regulators. Their role is mainly as advisors.

There is specialized SUKL that with regard to possibly competition issues sets maximum prices for drugs, deals with drugs registration in the Czech Republic, has the power to control drugs distribution by pharmacies and also regulates commercial regarding drugs. The Ministry of Health is responsible besides other tasks mainly for drafting legislation in the pharmaceutical sector.

- 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 are no specific reviews of competition law in the pharmaceutical sector in the Czech Republic.

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

There are no such specific guidelines particularly dealing with competition issues within pharmaceutical sector.

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

Competition law enforcement in the Czech Republic has been in pharmaceutical cases so far exclusively public in administrative proceedings led by the Czech NCA. The same situation is valid also in other industries as private competition law enforcement has not

developed so far in practice. Most cases in this sector led by the Czech NCA were mergers.

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

So far only fines and injunctions to continue in the anticompetitive behavior as remedies have been imposed within pharmaceutical sector by the decisions of the Czech NCA and eventually their appeals at courts.

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

There is no special monitoring mechanism of patent settlements in pharmaceutical sector within the Czech Republic.

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 are obliged to ensure for pharmacies supplies of humane drugs in amount and time intervals according to the necessity of patients within the Czech Republic. There is ongoing legislative proposal changing the rules according to which re-export of some drug might be banned because there is a view that current law is not sufficient to ensure that necessary drugs will be available for patients in the Czech Republic. Mostly criticized is that there are no specific and clear sanctions for the breach of current ban of export.

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?

There is the Czech NCA decision S60/06-22 189/06-300 fining four drug wholesalers and prohibiting their coordination the termination of supplying three hospitals in the Czech Republic by full range of drugs and start to supply them only with vital drugs with shorter time limits for payment as a concerted practice according to the Article 3 (1) of the Competition Act. Nevertheless nothing in this decision suggests that the competition rules should be applied differently to the distribution of pharmaceutical products.

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.

All specifics are given by valid legislation regarding pharmaceutical sector. There might be a question if at least some competition through commercials with regard to prescribed drugs should be allowed.

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.

- 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.

It does not regard directly generic entry but partially relevant might be that pharmacists has in the certain circumstances the possibility to substitute prescribed drug for its generic substitute according to the Article 83 paragraph 3 of the Act No. 378/2007 Coll. on medicine (hereinafter "**Medicine Act**") and also according to the Regulation no. 84/2008 on the correct pharmacist practices, conditions on dealing with drugs in pharmacies, medical facilities and other instances retailing drugs.

- 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. Have any such reviews led to increased enforcement activities? 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)?

So far there is no relevant decision regarding this matter. Generally it might be said that patents must not be abused in an anticompetitive way by undertaking which hold a dominant position. In this aspect a patent protection might be probably trumped.

- 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?

There is no relevant case law.

- 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 suffices when the agreement excludes only the party to agreement.

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

There is no relevant case law.

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

There is no relevant case law. Nevertheless it could be generally said that it should be important for competition assessment. For example it is highly probable that for a competition law analysis of settlement not to challenge a patent of original drug by potential generic entrant would be extremely important if a part of such settlement is agreement that potential generic entrant can enter the market before expiry of the patent, at the date of expiry of the patent or with some delay after the expiry of the patent.

- 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.

There is no relevant case law.

- 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 pharmaceutical undertaking which wants to sell a generic drug must have a registration from SUKL or on the European level from European Medicines Agency (hereinafter „**EMA**“).

According to the Czech Association of pharmaceutical firms the average delay for the generic entry to the Czech market is between 30 to 50 days after the patent expiry.²

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.

- 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?

According to the Act on public health insurance the insurance companies have a goal to provide health insurance in the Czech Republic. Providers of the healthcare (hospitals and other medical centers) conclude with insurance companies agreements regarding payments for healthcare based on the Act on public health insurance. Sole providing of public health insurance is not considered as a commercial undertaking as its main purpose is not gaining profit but providing healthcare to insured persons. Redistribution of the money collected from obligatory payments to the public insurance system based on solidarity system enables complex functioning of the public healthcare. According to the Czech NCA statement with regard to providing of the public health insurance the insurance companies are not undertakings in the meaning of the Article 2 subsection 1 of the Competition act. So far there is no relevant case law in the Czech Republic regarding this matter.³

- 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.

There is no such pattern as it can be said that within the Czech Republic there has not been any private competition law enforcement at all. Therefore all competition law enforcement in this sector has public character.

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

² Source: <http://www.cianews.cz/cs/w21463-caff-legislativni-zmeny-urychli-vstup-generik>.

³ <http://www.uohs.cz/cs/hospodarska-soutez/aktuality-z-hospodarske-souteze/1425-zdravotni-pojistovny-nejsou-souteziteli.html>.

SUKL is responsible for conducting of the price controls of pharmaceuticals in the Czech Republic according to the rules set in Medicine Act, Regulation No. 84/2008 Coll., Act No. 40/1995 Coll. on commercials regulation, Act No. 526/1990 Coll. on prices, Act No. 48/1997 Coll. on public health insurance (Hereinafter “**Act on public health insurance**”). SUKL also provides controls based on Act No. 372/2011 Coll. on healthcare services, Act No. 167/1998 Coll. on addictive substances, Regulation No. 123/2006 Coll. on evidence regarding addictive substances and Act No. 272/2013 on Drugs precursors. Since 2012 the results of controls are published in separate statements.

It might be said that most important controls regarding prices are if pharmacist comply with price regulation (maximum prices, maximum sales margins) and if patients are properly informed about price and setting of drugs supplementary payments. There is approximately 1300 controls annually.

Public healthcare providers have to buy drugs according to the Act No. 137/2006 Coll. on Procurement and are also controlled by the Supreme Audit Office.

- 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?

The Medicine Act in force according to its Article 11 letter h) enables the Ministry of Health to ban export of certain drug to provide its availability in the Czech Republic. But the rule is unclear and enforcement is weak as no clear sanctions are set. So far this Article has been applied very rarely.⁴ The Ministry of Health prepares an amendment of the Medicine Act that should prevent shortage of some drugs for patients in the Czech Republic caused by parallel trade (re-exports). According to this amendment if there is a drug that cannot be substituted and its shortage would have direct impact on public health SUKL will have the power with approval of the Ministry of Health to put such a drug on the list of drugs that are banned from export. Distributors will have to the obligation in case when they would like to distribute drugs listed on the mentioned list from the Czech Republic to announce such plan to the SUKL that will have the power to restrict such re-export. Such restriction will be immediately stopped when the reasons for its implementation cease to exist. For the breach of this rule there will be penalty up to 20 million CZK and eventually ban to undertake up to two years.

- 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 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 comments.

5) 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.

According to the Article 32 subsection 4 of Act on public health insurance the only acceptable form of benefit connected with dispensation of drug prescribed by a doctor

⁴ So far there has been only three cases - ban on export of Novomix 30 Flexpen, Actilyse and Antabus.

and paid form public health insurance is reduction of final price when such drug is dispensed in form of general discount, discount for specific item or discount for supplementary payment. Any other forms of benefits such as loyal cards, coupons, discounts for next purchases, volume discounts, discounts for other goods etc. are restricted. Such regulation seems to be unnecessary anticompetitive and makes no sense from competition point of view. Consumers would with high probability benefit if also other forms of benefits in above mentioned regard are allowed.