

OECD-GVH RCC Newsletter

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Foreword

Dear Readers,

In this issue, you will find three signatures below this foreword rather than the usual two. May 2019 marked a turning point in Sabine Zigelski's professional life and in the journey of the OECD-GVH Regional Centre for Competition. Sabine has moved on to other challenges at the OECD, and a new official has taken over her responsibilities at the Regional Centre. This new official is Renato Ferrandi, former Senior Competition Official for the Italian Competition Authority. Renato has extensive experience in international affairs and capacity building. Many of you may already know him, as he has participated as an enthusiastic speaker at several seminars of the Centre over the last few years. We are confident that Renato will continue to deliver the same outstanding quality and inspiration as Sabine has done. We would also like to take this opportunity to thank Sabine for the exceptional contribution she has made over the last 6 years. Thank you, Sabine: we will certainly all miss you!

The articles in this Newsletter focus on the pharmaceutical sector. The contributing authors deal with a range of competition issues in this industry, such as market definition and market power, the role of generics and IP rights, merger control and enforcement, and market studies and advocacy. We would like to thank our authors from Georgia, Italy, Russia, Serbia, Turkey and Ukraine for their valuable articles. This Newsletter also includes a new article concerning the work of the Eurasian Economic Commission. Finally, the "Literature Digest" at the end of this Newsletter introduces three inspiring articles on competition enforcement in the pharmaceutical sector.

For the next Newsletter, please send us articles on **competition enforcement and advocacy in the banking and insurance sectors**. We are interested in learning about which competition issues you have addressed in your jurisdiction with regard to the financial industry and whether the digital economy is bringing about new challenges. The deadline for handing in contributions will be 15 October 2019.

As usual, you will also find summaries of the OECD Competition Committee meetings in June 2019, with links to all the documents you might find interesting. Please use them to benefit from the work and experiences of peer competition authorities and from the work products of the OECD.

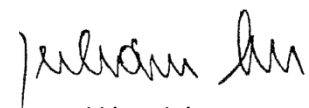
Please do not hesitate to send us your comments and contributions! If you wish to publish an article about your agency's work, please contact Renato Ferrandi (OECD – renato.ferrandi@oecd.org) and Andrea Dalmay (RCC - dalmay.andrea@gvh.hu).



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OECD-GVH RCC Events January – May 2019

February 13

Meeting of the Heads of Beneficiary Agencies

A total of fifteen Heads and Deputy Heads discussed the relationship between agencies and the judiciary and how to make cases fit for court, as well as the future training needs of the RCC. The identified training needs include trainings for dedicated groups of staff, e.g., young staff, lawyers and economists, sector specific seminars, training on soft and practical skills and exchange of experiences on cases and EU case law. The Request for Information instrument was also discussed. On average, one RFI per month is received, to which an average of six replies are given. Those agencies making active use of the RFI confirmed its usefulness and their desire to continue using the instrument.



March 11-13

Seminar on Vertical Sales Restrictions and E-Commerce

This seminar provided an opportunity to gain a better understanding of the analysis of the pro- and anti-competitive effects of vertical agreements, including selective and exclusive distribution systems, resale price maintenance, across platform parity agreements and various limitations on online sales. The speakers illustrated the relevant case law with an emphasis on the EU experience and on e-commerce related questions. Experts from competition authorities also introduced their case experience and practised

the analysis of vertical sales restrictions with the participants in hypothetical case exercises.



April 16-17

GVH Staff Training

The seminar provided an overview of recent developments in European competition law. Furthermore, it addressed the relationship between agencies and the judiciary, the implications of the ECN+ Directive, and other highly topical issues, including gun jumping in merger control and individualised pricing and the zero price economy. On day 1 these issues were dealt with in the form of presentations for the whole GVH staff, while on day 2 different groups of the GVH staff were involved in targeted training activities.



May 10-11

Seminar on European Competition Law for National Judges: Competition Economics

The event provided national judges with specific knowledge and practice related to competition economics in order to make them more at ease with economic notions and economics-based arguments. Judges were also provided with guidance on how to handle economic questions in court proceedings. The seminar addressed fundamental economic notions (e.g., supply and demand, elasticity, substitutability, the Hypothetical Monopoly Test and Critical Loss Analysis), explored the assessment of market power and devoted a specific session to the use of economic evidence in the context of damage claims.



May 28-30

RCC-FAS Seminar in Russia – Merger Control Investigation and Innovation, Kazan

The seminar focused on non-price considerations (e.g., regarding quality, innovation, data collection), which may play a significant role in the review of certain key mergers. Speakers and participants engaged in an open and hands-on discussion on the theories of harm for merger cases involving non-price considerations, basic economic methods, investigative steps and measures, and effective merger remedies. Merger control experts from OECD countries and FAS Russia presented case studies and the participants practised their merger skills in hypothetical exercises.



Future OECD-GVH RCC Events September-December 2019

- 10-12 September** **Outside Seminar in Ukraine – Competition Enforcement and Advocacy in the Pharmaceutical Sector**
- This seminar will cover a variety of topics in the pharmaceutical sector. We will look at market definition and market power, the role of generics and IP rights, merger control and abuse cases. In addition, the seminar will provide an overview of regulatory frameworks, and an introduction to competition assessment in the pharmaceutical sector. What kind of advocacy action is likely to be successful and how can competition authorities co-operate effectively with regulators? Experts from OECD member countries will present and discuss their experiences with the participants.
-
- 22-24 October** **Remedies and Commitments in Competition Cases**
- Remedies and commitments will often be the proportionate solution to competition problems in merger and abuse of dominance cases. We will explore the use of structural and behavioural remedies and commitments. What are adequate solutions if a structural remedy is not possible, and how can we avoid price caps or behavioural measures that are hard to monitor and enforce? The seminar will encourage an exchange of experiences between the participants and aims to enrich agencies' remedy toolboxes with the help of expert practitioners and the use of practical exercises.
-
- 22-23 November** **Seminar on European Competition Law for National Judges: New challenges in the application of Articles 101 and 102 TFEU - 16 – 17**
-
- 10-12 December** **Competition Rules and the Energy Sector**
- In this seminar the energy sector will be discussed and investigated from different angles. Numerous topics will be covered, including the interaction between regulation and competition law in energy markets, the role of innovation in energy market competition, issues of market definition, and merger control and abuse of dominance cases. Experienced practitioners will present case studies and will explain the main competition problems and recent developments.
-

OECD Competition Committee Meetings, 3-7 June 2019

Working Party No. 2 on Competition and Regulation

Roundtable on Publicly Funded Education Markets¹

Competition agencies face serious challenges when advocating (and enforcing) competition rules in education markets, as numerous features of these markets can prevent, restrict or distort competition. For example, competitive incentives can be smothered by capacity constraints, uninformed passive consumers and a lack of exit risk, or distorted by competitive neutrality issues. Moreover, other policy goals are important to governments, e.g., providing equal opportunity for all, providing the skills required to fulfil an industrial strategy or prioritising the needs of the highest or lowest achievers. Competition authorities must ensure that their activities complement and do not contradict those goals. The roundtable allowed delegates and experts to share their experiences and views on how competition can best be used to help policymakers achieve their goals.

Presentations on Tools for Addressing Competitive Neutrality

Participants from a number of delegations gave presentations on the tools that they use to address competitive neutrality issues in their markets. Through their presentations the delegates were able to demonstrate how they have effectively and comprehensively addressed different types of competitive neutrality problems. The discussion that

followed the presentations considered the possibility of a revised set of principles on competitive neutrality and the steps that could be taken to develop them.

Working Party No. 3 on Co-operation and Enforcement

Roundtable on the Standard of Review by Courts in Competition Cases²

Parties involved in competition cases should be able to seek judicial review of the decisions made in their cases. The availability of judicial review ensures that limits are placed on a competition authority's exercise of its powers; furthermore, it influences competition law enforcement in terms of the conduct of investigations and the collection of evidence, how economic concepts are interpreted and applied, and how decisions are substantiated. The roundtable looked at the standard of review applied by courts in antitrust cases and the ensuing implications for competition authorities.

The Secretariat also presented a proposal for a Recommendation on transparency and procedural fairness to consolidate the extensive work already conducted by the OECD and the International Competition Network on this topic.

Fighting Bid Rigging in Argentina

In 2018, Argentina's competition authority (Comisión Nacional de Defensa de la Competencia) requested the Secretariat to review Argentina's federal rules for the

¹ <http://www.oecd.org/daf/competition/publicly-funded-education-markets.htm>

² <http://www.oecd.org/daf/competition/standard-of-review-by-courts-in-competition-cases.htm>

procurement of public works and to provide recommendations for better competition, based on the OECD Recommendation for Fighting Bid Rigging in Public Procurement.

The Secretariat analysed Argentina's legal and institutional set up for the procurement of public works, identified good practices and challenges, and made recommendations for improvement. This was the first time that the OECD undertook a competition review of procurement for public works in a country. Throughout the project, the Secretariat and some delegations provided capacity building and presented good practices followed by competition authorities to prevent and detect bid rigging.

Competition Committee

Roundtable on Competition Issues in Labour Markets³

The session explored the relationship between competition law and employment issues. It explored to what extent the existing competition law framework may be used to prevent the creation and abuse of monopsony power in labour markets, for example through mergers, no-poaching agreements or other anticompetitive practices. It analysed the factors contributing to the market power of employers, the question of why cases involving monopsony power have been so rare, its effects on workers and consumers, and the tools that might be used to counteract it. The impact of the digital economy on labour markets was also considered, in particular in light of the distinction between employees and self-employed contractors and

³<http://www.oecd.org/daf/competition/competition-concerns-in-labour-markets.htm>

the emergence of new intermediary forms of employment.

Roundtable on Digital Disruption in Financial Markets (FinTech)⁴

The Competition Committee has addressed the topic of Financial Markets and Competition several times and from different angles in the last 10 years. This session discussed issues related to financial stability, prudential regulation, systemic effects, too-big-to-fail, regulation and competition. The main focus of the discussion was the digital disruption resulting from the emergence of FinTech/BigTech operators in the provision of financial services, and their competitive relationship with traditional financial institutions. The session also discussed how financial regulation could be adapted to deal with the particular challenges arising from a multi-layered and multispeed financial services environment.

Roundtable on Licensing of IP Rights and Competition Law⁵

The treatment of IP rights and related business conduct by leading competition agencies has undergone far-reaching changes in recent decades, as knowledge-based capital has become increasingly prevalent in OECD economies and the interaction between competition and IP law has grown in prominence in tandem with increased digitalisation.

While the OECD Competition Committee has issued two Recommendations that specifically address the interaction between competition

⁴ <http://www.oecd.org/daf/competition/digital-disruption-in-financial-markets.htm>

⁵ <http://www.oecd.org/daf/competition/licensing-of-ip-rights-and-competition-law.htm>

and IP law, the most recent one was issued in 1989. This session looked at the developments that have taken place concerning the competition treatment of the licensing practices pertaining to Intellectual Property (IP) rights since these OECD IP Recommendations were adopted, with the ultimate goal of identifying points of international convergence and disagreement as regards to the competition treatment of all types of licensing practices.

Roundtable on Vertical Mergers in the Technology, Media and Telecom Sector⁶

The recent wave of high profile merger cases in the Technology, Media and Telecom (TMT) sector around the world provided the perfect setting for delegates to revisit, through the lens of these cases, the way in which competition authorities apply antitrust economics to vertical mergers and design remedies. The roundtable discussed how vertical integration and associated theories of harm can be an important concern in the particular context of the TMT sector. At the same time, both economic theory and empirical evidence suggest that vertical mergers have important efficiency effects and are often welfare enhancing. Remedies in problematic cases are often behavioural in nature as competition authorities try to eliminate anti-competitive effects while permitting the parties to reap substantial efficiencies. The roundtable thus revisited the assessment of vertical mergers in light of recent developments in economic theory and case law, illustrating the main challenges identified in some of the most important mergers in the TMT sector.

⁶ <http://www.oecd.org/daf/competition/vertical-mergers-in-the-technology-media-and-telecom-sector.htm>

The AMCU's Competition Enforcement and Advocacy Activities in the Ukrainian Pharmaceutical Markets

Pharmaceutical markets are constantly in the focus of the AMCU due to their social importance, specific structure and sophisticated regulation, as well as the ongoing reform of the medical system in Ukraine. Between 2016-2018 the AMCU presented the results of two comprehensive market studies and issued a number of recommendations and proposals to policy makers and the Government; furthermore, it delivered decisions in four cases relating to the anticompetitive conduct of pharmaceutical manufacturers and distributors, in one case relating to the abuse of a dominant position by a pharmaceutical manufacturer and in several cases relating to unfair competition.

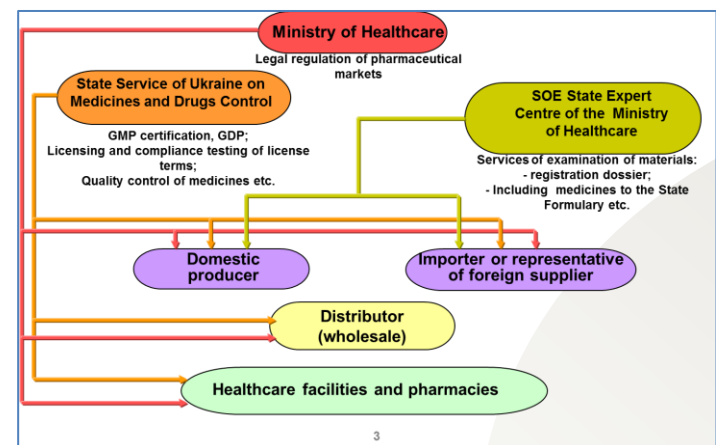
The AMCU actively advocates for the market entry and consumption of generic medicines. One of the AMCU's recent cases was related to softening competition between original and generic drugs.

Thus, the AMCU's competition advocacy and enforcement activities in the Ukrainian pharmaceutical markets are one of its top priorities.

▪ Pharmaceutical Market: to Regulate a Regulation

The actions of a competition authority on this specific market must stem from a thorough understanding of pharmaceutical regulation, which is usually country-specific.

Figure 1. Pharmaceutical market regulation in Ukraine



Over the last few years the AMCU has prompted a number of changes to the regulations governing pharmaceutical markets in order to ensure competition. To highlight a few examples, the AMCU has issued recommendations to the Ministry of Healthcare ("the MOH") and the Ministry of Economy and Trade ("the MEDT") about the definition of the subject matter of public procurement, to the MOH and the Ministry of Finance ("the MOF") about the reimbursement of drugs, and numerous recommendations to local authorities.

Screening: Market Studies

A comprehensive study of the pharmaceutical markets in Ukraine

The AMCU carried out a study that covered all the stages of a drug's development, from the state registration of a drug to its retail sale. An assessment of the impact on competition of external and internal factors, such as the economic and political behaviour of market

participants and market regulators, was undertaken during the analysis of each level. The market study report was approved by the AMCU in 2016 and sent to the Regulator and state authorities.

The proposals made to the government were aimed at strengthening the competitive environment in the pharmaceutical markets and were comprised of the following: a) introduction of reference pricing for medicines; b) gradual transition to a reimbursement system; c) introduction of electronic registers of patients by types of diseases treated using public funds; d) review of certain requirements of licensing conditions for conducting business activities; e) introduction of the term "medical service" into the applicable legislation and the approval of the method of its calculation; f) introduction of health insurance.

Hemodialysis equipment and spare parts market study

Another market study was conducted in relation to hemodialysis equipment and spare parts, which was approved by the AMCU in 2017.

A binding recommendation was issued to the MOH and the MEDT regarding the elimination of the gaps in legislation relating to technical regulation, standardisation, unification of substitutability of spare parts and equipment, as well as the definition of control procedures.

As a result of the AMCU's advocacy efforts, in 2018 the MOH set out a number of specific steps that could be taken to more efficiently treat kidney disease and develop a competitive environment on the hemodialysis market, which comprised of the following: a) introduction of an electronic register of patients; b) a new financing mechanism for treatment by hemodialysis; c) establishment of a single tariff for hemodialysis services for all health facilities regardless of their

ownership; d) creation of conditions for the development of competition in the hemodialysis market

The drafting of appropriate legislation is currently in progress.

Prevention of Competition Diseases: Advocacy Measures

Public procurement

One of the ways in which generic medicines can be promoted is through the removal of administrative barriers to entry. An important step forward is to define the subject matter of public contracts on the basis of the international non-proprietary names of the products, as this enables generics to compete with original drugs in public tenders. The AMCU actively promotes competition in the public procurement of medicines as a way to avoid excessive pricing.

In 2018 the AMCU issued recommendations to the MOH and the MEDT aimed at improving the procedure used for defining the subject matter of public tenders. These recommendations highlighted the possibility of, in particular, the development of a methodological framework or the introduction of amendments to the current procedure.

According to the current procedure, the purchases are based on lots containing a wide list of products (up to several hundred drugs) with different nosology, which can be only provided by wholesale suppliers that offer a broad scope of medicines. As a result, the number of possible competitors is reduced to only large distributors. Thus, sellers can stipulate discriminatory conditions in tender documents. This possibility has been confirmed by the substantial number of public procurement appeals that have taken place in this area. One of the possible ways to eliminate this could be a "one INN - one lot" principle (i.e., one lot for each pharmaceutical

substance or active pharmaceutical ingredient).

In pursuance of the recommendations of the Committee, the MOH and the MEDT drafted general recommendations and guidelines and sent them to all stakeholders. These documents comprised new requirements to: a) conduct analysis on the prices of similar medicines (specific sources of information were recommended); b) correctly define the subject matter of a public procurement and, if necessary, split the procurement into several lots; c) ensure maximum competition during the procedure; d) avoid discriminatory conditions via setting the dosage form for the drugs.

The above-mentioned requirements will contribute to the establishment of transparent and equitable conditions for the public procurement of medicines and will improve the compliance of procurement entities.

Drugs given on preferential terms or free of charge

The rules approved by the MOH state that doctors should indicate the brand names of medicines when prescribing medicines provided by pharmacies on preferential terms or free of charge. However, medicines containing the same active substances in the same dosage forms and amounts under international non-proprietary names are interchangeable and, therefore, the manufacturers of branded medicines and generic medicines are competitors. Consequently, prescriptions specifying branded medicines may distort competition by excluding the manufacturers of generic medicines.

In order to address this issue, the Committee provided the MOH with binding recommendations to amend the Rules relating to prescriptions in such a way that they

encourage doctors to indicate international non-proprietary names when they issue prescriptions for medical products provided on preferential terms or free of charge.

The Committee supported the MOH in its intention to address this issue together with the approval of the updated National List of Essential Medicines, the introduction of a reference pricing mechanism for medical products that are subject to reimbursement, and the introduction of an electronic prescription system.

As a result, in October of 2018 the MOH adopted amendments⁷ to its order on the Rules regarding prescriptions, according to which "Prescriptions shall indicate the international non-proprietary name of the medical product. The brand name may be indicated only if the medical product in question does not have an international non-proprietary name and/or is a medical product of biological origin or biosimilar". As a result, transparent and effective competition was established in the markets of medical products with one active substance, which are provided on preferential terms or free of charge.

Introduction of reference pricing

Based on its 2016 pharmaceutical market study the AMCU recommended that the Government should introduce a reference pricing as the most effective tool for reducing prices.

Reference pricing and the reimbursement mechanism have already been introduced in Ukraine:

- for insulins as a pilot project of state price regulation. This enables patients with type 1 diabetes to receive insulin in pharmacies for free or for a small charge;

⁷ <https://zakon.rada.gov.ua/laws/show/z1300-18>

- for the list of INN medicines included in the "Available medicines" programme of the Government. This enables patients with cardiovascular diseases, bronchial asthma and type 2 diabetes to receive medicines in pharmacies for free or for a small charge. The list currently includes 23 INNs, but the possibility of adding further drugs under this programme to the list is presently being discussed.

As a result of these measures, prices have decreased.

Removal of administrative barriers for participation in state programmes

In 2015 the MOH added a drug containing the active substance Docetaxel, exclusively in doses of 80 and 140 mg, to the National Programme for the control of cancer. Other versions of the drug available in different doses were not added to the programme.

Given that in Ukraine Docetaxel is sold under various brand names and doses the number of possible competitors that could participate in this programme was artificially reduced.

In April 2016, the AMCU urged the MOH to remove such administrative barriers to participation in procurements. Already in June 2016 a new Nomenclature of Drugs for Procurement was introduced, which included additional doses of Docetaxel and led to a significant decrease in the price of Docetaxel. The ex-post evaluation estimated an annual economic impact of 145 000 EUR.

Recommendations to establish transparent and fair promotion practices

Marketing and promotional practices are widely used by producers and distributors of pharmaceutical products. The AMCU's enforcement shows that under certain conditions such practices are not transparent and may lead to anticompetitive exclusionary and/or exploitative conduct. Therefore, in

September 2018 the AMCU issued recommendations to the MOH suggesting that it should develop and approve a regulatory act encouraging transparent and non-discriminatory promotion of pharmaceutical products for all market players in order to: a) avoid the distortion of competition due to non-transparent promotional practices; b) ensure independent consumer choice in pharmacies; c) eliminate the possibility of excessive pricing as a result of promotion schemes, which, in particular, may overrule the state price regulation.

Based on the AMCU's letter, the Prime Minister issued a mandate to the MOH, MOF and MEDT to fix this issue in close cooperation with the AMCU.

Prescriptions: Enforcement Examples

Market sharing agreements

Defendants: Servier Ukraine LLC, BaDM LLC, Optima-Farm, Ltd, A'STA LLC, Lyudmyla-Farm LLC.

According to an agreement between Servier Ukraine LLC and local distributor Lyudmyla-Farm LLC, individual discounts were given to a specific distributor relating to 27 healthcare facilities. As a result, prices for Lyudmyla-Farm LLC were between 30-50% lower than for other distributors.

Furthermore, according to the agreement between Servier Ukraine LLC and local distributor A'STA LLC, the latter was selected as the exclusive distributor for healthcare facilities in the Donetsk region.

Thus, competition between distributors for certain healthcare facilities and pharmacies was distorted, and in the Donetsk region completely eliminated.

In its decision the AMCU held that the agreements, among other infringing

behaviours, amounted to anticompetitive market sharing agreements.

The High Court upheld the AMCU's decision in the appeals brought by Servier Ukraine LLC and BaDM LLC.

Refusal to supply

Decision of the AMCU dated August 16 2018 № 404-P.

Defendant: Farmchim LLC.

Farmchim LLC was the only Ukrainian producer of the pharmaceutical substance mebhydrolyne, which is used to produce certain drugs. Technological and administrative barriers to entry to this product market exist (requirement to be registered as a substance producer). Farmchim LLC refused to supply the substance to the main customer without objective grounds, aiming to insist on a higher purchase volume.

Farmchim LLC agreed with the definition of its monopoly position and infringement. The company voluntarily paid a fine for its infringement.

Other vertical agreements restricting competition

Defendants: Roche Ukraine LLC, BaDM LLC, JSC Alba Ukraine, Venta LLC, A'STA LLC, Lyudmyla-Farm LLC, Business Centre Pharmacia LLC.

According to an agreement between Hoffman la Roche Ltd and Roche Ukraine LLC on the import of medicines on one hand, and the agreement between Roche Ukraine LLC and local distributors on the other hand, the concerned pricing mechanism was designed in such a manner that it caused excessive prices in public procurements and harmed competition. In particular, Hoffman la Roche Ltd granted *de-facto* rebates, in the form of irrecoverable financial aid calculated as a percentage of sales provided on a regular

basis. This scheme enabled local distributors to avoid the front margin cap set by local regulators. The investigation by AMCU found that the alleged intent of the financial aids to foster affordable prices for drugs and lower state expenditures was not confirmed by reality.

The AMCU held that these actions had restricted competition and increased the prices of Roche medicines sold through public procurement procedures.

It is worth mentioning that in the long-term such concerted actions may increase participants' market power, and soften and distort competition.

The AMCU's recent investigation highlighted a common practice of many international drugs producers, namely the provision of a two-digit retrospective discount for the import invoice price - both to their representative office and to all local importers. Though discounts have substantial procompetitive effects, a number of questions arise: a) What are the reasons for keeping the import invoice price at a higher level than the "real" or net price including the discount? b) What is the rationale for such extensive discounts? c) Are there any links to the international reference pricing system?

Given that the answers to these questions seem to be beyond the AMCU's jurisdiction, a discussion on this matter with other competition authorities at the OECD RCC event on pharmaceutical markets in September 2019 would be most welcome.

Competition Enforcement in the Pharmaceutical Sector: The Case for Turkey in Light of the Turkish Pharmaceutical Sector Report



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Introduction⁸

The pharmaceutical sector plays an important role in the wellbeing of society. Due to their must-have nature, pharmaceuticals are typically associated with low price elasticity of demand.⁹ One unique feature of this sector is that the decider does not pay or consume, the consumer does not decide or pay and the payer does not decide or consume; thereby raising possible conflicts of interest.¹⁰

Governments strictly regulate the pharmaceutical sector to maintain an efficient and sustainable health policy, with the objective of keeping public expenditures under control and ensuring support for innovation through the adequate protection of intellectual property (IP) rights. The spectrum of regulations is broad, ranging from issues such as the efficiency, safety and quality of medicines, to the determination of

prices, profit margins and the activities of undertakings at wholesale and retail levels.¹¹

Competition law enforcement in this area acts as a complementary regulatory system, and helps to ensure that there is access to affordable and innovative medicines. This is achieved either through interventions in individual cases against restrictive agreements or abuses of dominant position, or through competition advocacy activities aimed at preventing potential infringements.¹²

I. Competition Enforcement in the Pharmaceutical Sector in Turkey

The Turkish Competition Authority (TCA) is responsible for enforcing competition rules and engaging in competition advocacy activities to promote competition in Turkey. Act. No. 4054 on the Protection of Competition (Turkish Competition Act) is in line with EU competition law, resulting in case law that is similar to that of the EU.

In the pharmaceutical sector, the TCA adopted 5 decisions regarding Article 4¹³, 42 decisions regarding Article 5¹⁴, 15 decisions regarding

⁸ The views and opinions expressed in this article are those of the author and do not necessarily reflect those of the Turkish Competition Authority.

⁹ UNCTAD (2015), "The role of competition in the pharmaceutical sector and its benefits for consumers", para. 10.

¹⁰ FERRANDIZ (2001), "Essays on the Pharmaceutical Industry", p. 1.

¹¹ KARAKOC (2005), "Price Competition in the Pharmaceutical Sector", p. 7. Available only in Turkish.

¹² Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 7.

¹³ Article 4 of the Turkish Competition Act prohibits anticompetitive agreements between undertakings. This article is closely modelled on Article 101 of the Treaty of the Functioning of the European Union (TFEU).

¹⁴ Article 5 of the Turkish Competition Act provides that the prohibition contained in Article 4 may be declared inapplicable if the four conditions are met cumulatively. It is closely modelled on Article 101(3) of the TFEU.

Article 6¹⁵ and 11 decisions regarding Article 7¹⁶ of the Turkish Competition Act between 2012-2019. Additionally, the TCA completed a sector inquiry in the pharmaceutical sector and published a report on its findings entitled “Pharmaceutical Sector Report” in 2013, as part of its advocacy tasks¹⁷. Below the main findings and evaluations of the Report will be summarised with a special emphasis on generics competition, and a case related to pay-for-delay agreements will be presented.

II. Turkish Pharmaceutical Sector Report (the Report)

The Report starts with an overview of the structure of the Turkish pharmaceutical sector, the structure of supply and demand, the characteristics of the distribution channels and the importance of patent protection. It then sets out the framework for sector-specific regulations, such as licensing, pricing, refunding conditions of pharmaceuticals and the effects of each of these issues on competition in pharmaceutical markets. The Report then focuses on the possible restrictive effects of patents on competition. Lastly, the Report explains under what conditions competition may be affected by R&D activities, marketing operations, horizontal agreements between suppliers, trade relations between suppliers and wholesalers, and market entry by originators and generics.

The main findings of the Report can be summarised as follows:

- The pharmaceutical sector is one of the most investigated sectors by the TCA. The investigations initiated between 2001 and 2011 concerned mergers and acquisitions at the supply level; vertical agreements between suppliers and wholesalers affecting the conditions of participation in tenders; and the decisions and practices of pharmacist associations.

- In the Turkish pharmaceutical sector, the government is the biggest buyer of pharmaceuticals and receives a discount of approximately 40% on its purchases. Thanks to a reference pricing system applied by the government¹⁸, the prices for pharmaceuticals in Turkey are lower than in most EU countries.

- The most important element of price competition is generics entry. Undertakings might seek to delay the market entry of rivals by means of strategic practices such as misuse of the legislative and regulatory framework, patent negotiations or reverse patent settlements.

- The most important element of price competition is generics entry. Undertakings might seek to delay the market entry of rivals by means of strategic practices such as misuse of the legislative and regulatory framework, patent negotiations or reverse patent settlements.

- There are more than 300 types of agreements between competitors in the Turkish pharmaceutical sector, which are related to supply, production, distribution, licensing and marketing. While recognising that in most instances these agreements help undertakings serve their customers better, safer, faster and at a lower price, the Report

¹⁵ Article 6 of the Turkish Competition Act prohibits abuse of dominance. It is modelled on Article 102 of the TFEU.

¹⁶ Article 7 of the Turkish Competition Act governs mergers and acquisitions. It is modelled on Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings.

¹⁷ The Pharmaceutical Sector Report was published on the TCA’s webpage on 27.03.2013. It provides sector-specific statistics, regulations, case law and, among others, details the relationship between competition enforcement and the exercise of intellectual property rights. Available only in Turkish.

¹⁸ In this system, the lowest ex-factory prices in France, Greece, Italy, Portugal and Spain serve as a benchmark for the ex-factory prices of original and generic pharmaceuticals.

sets out the possible risks to competition posed by strategies aimed at delaying the market entry of generics.¹⁹

- Since the structure of the pharmaceutical sector is conducive to multi-market conducts, the risk of coordination between undertakings should not be underestimated. An agreement - such as a patent settlement preventing generics entry - made in one market might affect another market in which one of the parties operates. Therefore, especially agreements between generics producers and originators should be investigated more cautiously in order to capture these effects.

- According to the survey conducted by the TCA, following the entry of the original product, on average, the first generic product enters the market after 73 months, the second after 89 months and the third after 105 months. It is reasonable to suggest that the most serious delay relates to the entry of the first generic product. Consequently, it is important for government to eliminate any obstacles to the entry of the first generic product.

III. A Case Related to Pay-for-delay Agreements:

GlaxoSmithKline/Bilim Ilac²⁰

With regard to IP rights and generics, so far the TCA has mainly dealt with requests for negative clearance and exemption, including for horizontal agreements between competitors that had potential to restrict competition, such as pay for delay agreements.

An important case in which the TCA discussed the anticompetitive effects of reverse patent

¹⁹ The TCA's Pharmaceutical Sector Report, p. 263-264. Available only in Turkish.

²⁰ The TCA's decision dated 13.03.2017 and numbered 17-10/119-54. Available only in Turkish.

settlements was GlaxoSmithKline/Bilim Ilac. GlaxoSmithKline (GSK) and Bilim Ilac signed a cooperation agreement in 2017. The purpose of the agreement was to provide Bilim Ilac with exclusive marketing rights over GSK's Seretide product. The parties applied to the TCA for individual exemption. Seretide was a medicine that was produced and distributed by GSK at the time of the agreement and used in the treatment of asthma and chronic obstructive pulmonary disease. Bilim Ilac was a local generics manufacturer. It produced a drug named Ventofor Kombi, which although containing different active ingredients to GSK's Seretide product, treated similar diseases as Seretide. Therefore, it was Seretide's rival based on level-3 of the ATC classification system.

It is important to touch upon some specific clauses of the agreement. According to an exclusivity clause agreement, Bilim Ilac made a commitment not to sell, distribute, advertise or market any rival product that contained the same active ingredients as Seretide. Furthermore, Bilim Ilac was remunerated by GSK based on its sales performance.

The TCA began by establishing that the exclusivity and non-compete clauses contained in the agreement were restrictive within the meaning of the competition rules and thus decided not to issue a negative clearance. It then determined that the block exemption could not be granted in relation to the agreement because Seretide and Ventofor Kombi were rivals²¹.

When evaluating whether the first condition of the individual exemption was satisfied,, the TCA concluded that due to the cooperation of the parties, Seretide would be marketed more efficiently and at a lower cost.

With regard to the second condition related to consumer benefit, the TCA concluded that the

²¹ Vertical restraints are regulated under Article 4 of the Turkish Competition Act. The Block Exemption Communiqué No. 2002/2.

savings obtained in marketing would be reflected in the price of the products, thereby possibly affecting price competition positively.

As for the third condition, the TCA highlighted that some agreements in the pharmaceutical sector, such as pay-for-delay agreements, might be aimed at enabling the anticompetitive gains achieved to be shared among the concerned parties. Parties, instead of establishing a direct pay-for-delay agreement that is easy to detect, might establish a different type of agreement and hide the pay-for-delay relationship behind it. Thus, Bilim Ilac was asked whether it was planning to develop or whether it was already developing a generic version of Seretide. Bilim Ilac stated that it had no such plan or product, thereby satisfying the concerns of the TCA concerning the existence of a hidden pay-for-delay agreement.

With regard to the fourth and last condition, the TCA stated that since the exclusivity clause only applied to rival medicines containing the same active ingredients, the agreement did not limit competition more than what is necessary.

In the light of the above, the TCA reached the conclusion that all of the conditions required to grant an individual exemption existed in the specific case. The case is significant insofar as it was the first case in which reverse patent settlements were discussed in detail.

Conclusion

The TCA enforces competition rules and engages in competition advocacy activities to promote competition in pharmaceutical markets, paying utmost attention to the sector specific characteristics of pharmaceuticals. While prioritising patients' access to innovative and affordable medicines, the TCA keeps a close eye on anticompetitive conducts and looks for ways to increase the

efficiency and effectiveness of its investigations.

Taking into account the fact that the pharmaceutical market is characterised by several types of agreements between potential competitors, the core concern of the TCA is that some of these agreements might hide anticompetitive relationships. Most of the time the parties subject to these agreements apply to the TCA for negative clearance or group/individual exemption. When this occurs it is crucial that the TCA carefully analyses the restrictive clauses contained in these agreements and, if necessary, questions the parties and conducts dawn raids in order to identify the main purposes behind the agreements.

Pharma Antitrust Enforcement in Italy



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Introduction

This short article ²² focuses on the enforcement record of the Italian Competition Authority (hereafter: the Authority or the AGCM) in the pharmaceutical sector and provides an overview of how the Authority attempts to ensure a level playing field by preventing anticompetitive restrictions, while allowing innovators to enforce intellectual property rights²³.

A report by the European Commission published in January 2019 shows that active competition law enforcement, at EU and national level, in the pharmaceutical sector contributes to delivering more affordable medicines and more choice to patients and healthcare systems, and promotes further innovation ²⁴. Infringement decisions taken by the AGCM led to the imposition of fines amounting to a total of €198.5 million between 2009 and 2017, the second largest amount after the European Commission.

²² The views expressed here are the author's and do not necessarily reflect those of the Italian Competition Authority.

²³ For more information, see the Italian contribution to the OECD Workshop on "Recent Challenges in Competition and IP in Pharmaceutical Markets", 26 February 2019.

²⁴ The report is available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html>

Abuses and agreements to prevent generics competition

The majority of cases investigated by the AGCM have mainly dealt with exclusionary conducts by pharmaceutical companies holding licences for active substances aimed at delaying entry of generic firms.

In two cases, concluded in 2006 and 2007 respectively, the Authority assessed Merck's and Glaxo's refusal to grant licences to chemical companies for the production of two active ingredients (Imipenem Cilastatin and Sumatriptan Succinate) to be supplied to generics companies in European countries, where all patents on those products had already expired²⁵.

Both cases must be considered in the context of the peculiar regulatory framework governing supplementary protection certificates (SPC). An SPC can extend a patent right, and is aimed at offsetting the loss of patent protection that occurs due to the compulsory lengthy testing that a pharmaceutical product requires prior to obtaining regulatory marketing approval. The Italian regulation of SPCs provided pharmaceutical companies with a longer extension period compared to the European legislation. Furthermore, it did not impose an obligation on SPC holders to provide a licence (for export) to requesting parties and merely established a procedure for the granting of a voluntary licence. According to the regulation, in the event of disagreement between the SPC holders and the generics companies, the

²⁵ AGCM case A363 – *Glaxo-Principi Attivi*, decision No. 15175 of 8 February 2006, published in Bulletin No. 6/2006. Italian Competition Authority, case A364 – *Merck-Principi Attivi*, decision No. 16597 of 21 March 2007, published in Bulletin No. 11/2007.

competent Minister may inform the AGCM. Indeed, in both cases, the AGCM received all the documentation related to the negotiation process from the competent Minister. Thus, this provision envisaging a potential intervention of the AGCM meant, according to the Authority, that the freedom to refuse to grant a voluntary license is not absolute but shall be balanced against the objective of preserving competition.

In this context, the Authority considered that such refusal resulted in an abuse of dominance as it hindered the production of an essential input for generics producers, which could become potential competitors of pharma companies in those markets not involving IPRs. Therefore, in these two cases there was no trade-off between favouring entry and recouping investments in R&D and the investigations were closed with commitments obliging the concerned companies to grant licences. In the case of Merck, the Authority had also adopted an interim measure obliging the company to issue – without delay – a licence in relation to one active ingredient. This measure was justified due to a failure in the negotiation process to grant a voluntary licence, thus preventing the development of generics competition and causing serious harm to consumers. Merck also undertook, as a commitment, to grant another licence in relation to a further active ingredient²⁶.

In 2012, the **Pfizer case** highlighted the tension between competition and IP rights²⁷.

²⁶ In relation to the Merck case: see the AGCM's press releases of June 21, 2005, available at <http://en.agcm.it/en/media/press-releases/2005/6/alias-1200> and of March 26, 2007, available at: <http://en.agcm.it/en/media/press-releases/2007/3/alias-1096>; for the Glaxo case: see the press release of February 21, 2006, available at: <http://en.agcm.it/en/media/press-releases/2006/2/alias-1267>

²⁷ AGCM case A431 – *Ratiopharm/Pfizer*, decision No. 23194 of 11 January 2012, published in Bulletin No. 2/2012. See the press release of January 17, 2012, available at: <http://en.agcm.it/en/media/press-releases/2012/1/alias-1986>

The AGCM questioned Pfizer's strategy of artificially extending patent protection from September 2009 to July 2011 by means of requiring a divisional patent²⁸ and additional SPC rights. While the Authority did not question Pfizer's application for a divisional patent as such, it questioned the timing of the request and the fact that its only purpose was not linked to innovation, the latter of which is a key element in assessing these cases. Indeed, Pfizer had not released any new product and attempted to discourage new entrants, by issuing warnings or threatening to bring claims for damages in case of the commercialisation of generic drugs before the new patent protection deadline. As a result of this complex strategy, the entry of generic drugs was delayed resulting in an increase in expenditure for the Italian NHS estimated at approximately €14 million.

The decision was confirmed by the higher administrative Court, which acknowledged that the patent had been obtained lawfully, but emphasised that the question was how such a legitimate right under IP law had been exercised in the specific circumstances of the case. Indeed, it should be stressed that the circumstances of this abuse were very specific and any enforcement action based on a similar assessment should be confined to those instances in which the misuse of the patent system clearly does not legitimately promote innovation to the benefit of consumers but is solely intended to illegitimately restrict competition.

In the **Roche-Novartis** case of 2014²⁹, the AGCM dealt with collusion, which although not involving generic medicines, mirrored

²⁸ A divisional patent application is a patent application that has been divided out of an earlier filed patent application (known as the parent application).

²⁹ See AGCM Case I760 – *Roche-Novartis/Farmaci Avastin e Lucentis*, decision No. 24823 of 27 February 2014, published in Bulletin No. 11/2014

conducts typically aimed at stifling generic competition. The Authority established that Roche and Novartis had put in place an arrangement designed to artificially differentiate between two drugs, namely Avastin and Lucentis, which in the Authority's assessment were equivalent in all respects for the treatment of eye diseases, although the off-label Avastin was much cheaper than the on-label Lucentis. According to the AGCM, Novartis and Roche raised and spread concerns about the safety of the off-label uses of Avastin among the medical community and the drug's end-users in order to favour the commercial performance of Lucentis, from which both Roche and Novartis took advantage. In fact, Roche collected significant royalties from the sales of Lucentis, which had been developed by its subsidiary Genentech, while Novartis directly gained from the sales of Lucentis. The Authority imposed fines on Roche and Novartis totaling €90.5 million and €92 million respectively. According to the Authority's estimates, the conduct caused the Italian healthcare system additional expenses estimated at €45 million in 2012 alone³⁰.

The decision, upheld by the lower administrative court, is currently under appeal at the higher administrative court, which sent a preliminary reference to the Court of Justice of the European Union on several questions concerning the interpretation of Article 101 TFEU. In its answers the Court of Justice clarified, *inter alia*, that (i) in principle, a medicine used off-label for the same therapeutic indications as another product used on-label can be included in the same product market and that (ii) communication of misleading information regarding the safety of an off-label medicine to the authorities,

³⁰ For a more detailed description of the two cases, see the AGCM's contribution to the 2014 OECD Roundtable on Generic Pharmaceuticals available at [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD\(2014\)50&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD(2014)50&docLanguage=En)

medical professionals and general public may constitute a restriction of competition by object³¹.

Excessive prices in pharmaceuticals: the Aspen case

The recent Aspen case³² is very indicative of the exceptional circumstances in which antitrust intervention may be warranted to terminate an abuse based on excessive prices: in this case the market was unlikely to self-correct, the regulator's powers were insufficient and therefore weakened its bargaining position vis-à-vis the regulated company, there were no incentives to enter (due to the risk of not recovering the entry costs) and the need to remunerate R&D did not arise as no investments were made. This case also highlighted the role that competition authorities can play following an infringement decision to reduce the asymmetry in price negotiations between the regulator and the regulated company.

In September 2016 the Authority fined the Italian subsidiary of the South African pharmaceutical company Aspen €5.2 million for abusing its market power over four cancer drugs by increasing prices by between 300% and 1,500%. In order to achieve these price increases Aspen adopted a particularly aggressive negotiating strategy with the Italian medicines agency, AIFA, and threatened to discontinue the supply of the drugs on the Italian market if the increases were not approved by AIFA.

In the final decision, the Authority issued a cease and desist order with no indication on

³¹ Judgment of the Court of Justice of 23 January 2018, F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato, C-179/16

³² See AGCM Case A480 – *Incremento prezzo farmaci Aspen*, decision No. 26185, published in Bulletin No. 36/2016. For a detailed description and discussion of the case, see the AGCM's contribution to the 2018 OECD Roundtable on Excessive Pricing in Pharmaceutical Markets; available at: [https://one.oecd.org/document/DAF/COMP/WD\(2018\)106/en/pdf](https://one.oecd.org/document/DAF/COMP/WD(2018)106/en/pdf)

prices and required the party to inform the Authority, within 60 days from the decision's date, of the actions adopted to comply with the order. Aspen refused to comply with the decision and delayed the renegotiation with AIFA; therefore, in March 2017 the Authority initiated proceedings for non-compliance.

Negotiations between Aspen and AIFA continued in the subsequent months but turned out to be unsuccessful because AIFA rejected Aspen's requests to: include trademark acquisition costs among the production costs relevant to justify the price increases; use EU weighted average prices rather than 2013 prices as a starting point for the negotiation; use the prices of therapeutic alternatives as a benchmark.

In March 2018, the AGCM sent a Statement of Objections (SO) to Aspen, alleging a dilatory strategy by refusing to provide relevant information (i.e., contracts signed with the producers of the actual drugs). In April 2018, Aspen submitted all the relevant information (supplier contracts, costs related to quality & safety etc.) and reached an agreement with AIFA, according to which the new prices would be between 30% and 80% lower than the 2014 prices and the application of the new prices would be retroactive, to the date of the infringement decision (September 2016).

In June 2018, the AGCM closed the proceedings without imposing any sanctions and estimated that as a result of the new negotiations the public savings would amount to roughly €8 million per year.

Compliance With Antitrust Laws in the Pharmaceutical Sector



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In accordance with the recommendations of the OECD Council of July 17 2012 on combating anti-competitive behaviour in public procurement, *State governments should evaluate public procurement legislation and law enforcement practices in order to promote more efficient procurement and reduce the risk of anti-competitive actions.*

The Federal Antimonopoly Service of Russia determined that procurement officials, through the stipulation of requirements that could only be fulfilled by the manufacturers of brand-name drugs, were eliminating competition and discouraging generic manufacturers from bidding in the public procurement of drugs. At the same time, the Russian procurement law did not prevent this practice from occurring.

Following the recommendations of the OECD, in 2012 the Federal Antimonopoly Service of Russia sent opinions to public procurement agencies, concerning the use of International Nonproprietary Names (INNs) for medicines, in light of the indications of the World Health Organization (WHO) and of the global experience in this respect.

According to the World Health Organization (WHO) provisions, INNs identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. A nonproprietary name is also known as a generic name. Another important

feature of the INN system is that the names of pharmacologically-related substances indicate their relationship by using a common "stem". Through the use of common stems medical practitioners, pharmacists, or anyone dealing with pharmaceutical products can recognise that a particular substance belongs to a group of substances having similar pharmacological activity³³.

Following the initiative of the Federal Antimonopoly Service of Russia, in 2012 the Russian law on public procurement was amended, obliging public procurement agencies to buy medicines indicating their INNs. These changes should have made trading more transparent and opened up the market for generics. Unfortunately, this was not the case as many unresolved problems remained. For example, unscrupulous procurement officials stipulated strict requirements relating to characteristics such as the shape of the drugs, dosage and packaging, thereby limiting competition in public tenders.

To support competition advocacy and taking into consideration the recommendations of the OECD Council of July 17 2012, in 2017 the Federal Antimonopoly Service of Russia conducted an analysis on public procurement in light of the current legislation, law enforcement and judicial practice. For the purposes of the analysis, drugs that were being purchased by procurement officials of the Russian Federation between 2010-2017 were selected. On the basis of the analysis, the Federal Antimonopoly Service of Russia identified the most common restrictions to competition in tenders, which included the following:

³³ Guidance on INN. Source:
<http://www.who.int/medicines/services/inn/innguidance/en/index.html>

Antimonopoly Service of Russia identified the most common restrictions to competition in tenders, which included the following:

- procurement officials specifying only one description of the dosage form in the presence of a generic drug that had an equivalent dosage form, but a different name, for example, “powder” vs “lyophilised powder”, “concentrate” vs “solution”, “tablets” vs “coated tablets”, “prolonged - release tablets” vs “sustained release tablets” etc.;
- procurement officials specifying only one pattern of use of the drug in the presence of a generic drug that had an equivalent pattern of use, but a different name, for example, “injection solution” vs “solution for intravenous and intramuscular administration”;
- procurement officials specifying only one dosage of the drug, for example, “1000 ME”, thereby preventing manufacturers from participating in the auction of an equivalent drug, the dosage of which was indicated in the form “1.0 mg”;
- procurement officials specifying only one dosage of the drug, for example, “500 mg”, excluding the possibility for generic manufacturers to bid with a multiple dosage, for example, “2x250 mg”;
- procurement officials only allowing the manufacturers of multicomponent (combined) drugs (mostly for the therapy of HIV, Hep-B, Hep-C) to participate in bids, thereby excluding the manufacturers of single-component drugs with a similar combination of active ingredients;
- procurement officials stipulating that the medicine must be packaged in a specific way, when the equivalent generic drug was packaged differently, for example, “ampoule” vs “bottle”, “prefilled syringe” vs “bottle + syringe”;

- procurement officials requiring the consumer packaging of medication to contain a specific number of units of medication, thereby preventing the manufacturers of generic drugs that were packaged differently from bidding, for example, “100 tablets in 1 box” vs “50 tablets in 2 boxes”;
- procurement officials requiring the drug and the solvent to be placed together in one package, thereby preventing the participation of generic manufacturers that provided the drug with the solvent, but in different packages, or with a solvent from another manufacturer;
- procurement officials requiring the medicine to have a certain colour, taste, and geometric shape, for example, “white powder”, “lemon-flavored tablets”, “round biconvex tablets”, etc.;
- procurement officials requiring the medicine to be packaged in a specific material, for example, “glass only”, “dark glass only”, “plastic only”, etc.

In order to promote more efficient public procurement and reduce the risk of anti-competitive actions, the Federal Antimonopoly Service of Russia issued a specific regulation, the Procurement Regulations for Drugs (hereinafter - Drug Purchase Rules). This regulation was approved by Decree No. 1380 of the Government of the Russian Federation dated November 15 2017 “On the requirements for the description of medicines for medical use that are procured for state and municipal needs”³⁴. The Rules are mandatory for all government procurers.

As a result of the abovementioned regulation, the stipulation of therapeutically insignificant requirements in public tenders with the aim of

³⁴ Source: <http://static.government.ru/media/files/hoNXj8exUEVL8AfDV5YeQGms0I0oEeA5.pdf>

restricting competition has been prohibited. For example, in the public procurement of drugs it is now prohibited to stipulate requirements relating to the colour, taste, geometric shape and the residual shelf life of drugs as a percentage of the nominal shelf life. Furthermore, procurement officials may not require the presence or absence of excipients or set out specific requirements relating to packaging material, number of units of the drug in consumer packaging, markers of pharmacodynamics and pharmacokinetics, storage mode and other unreasonable and undocumented characteristics corresponding solely to specific brand-name drugs. Government officials are obliged to enable participation by firms offering equivalent dosage forms and equivalent dosages, as well as to ensure the possibility of simultaneous participation in the bidding by manufacturers of combined and single-component drugs. At the same time, the Drug Purchase Rules provide for exceptions in the case of those patients whose treatment is only possible with a specific medicine, provided that this need has been proven in accordance with the requirements established by the Russian law on public procurement.

In addition, the Government of the Russian Federation has empowered the Federal Antimonopoly Service of Russia with the authority to provide official explanations on the use of the Drug Purchase Rules. In 2018, the Federal Antimonopoly Service of Russia prepared 17 such public explanations for all bidders, an action that helped generic companies to participate in tenders.

The Drug Purchase Rules, developed by the Federal Antimonopoly Service of Russia, are aimed at increasing the number of manufacturers of equivalent drugs, especially generic manufacturers, which are able to participate in public procurement procedures by ensuring equal conditions for competition.

This should lead to lower prices for medicines obtained through auctions, savings in public spending on health care and increased availability of medicines for patients.

The Russian Drug Purchase Rules have received the highest commendation at the international level: in 2018, for the first time in the history of the Russian competition authority, the Federal Antimonopoly Service of Russia won the Competition Advocacy Contest, jointly organised by the World Bank and the International Competition Network (ICN), in the category “Creating Markets for private sector development”³⁵.



³⁵ The results of the competition were announced on February 16 2018 in Washington, DC (USA), the awards were presented to the winners on March 21 2018 in New Delhi, India. Source: <https://www.worldbank.org/en/events/2017/11/08/the-2017---2018-competition-advocacy-contest#04>
<http://en.fas.gov.ru/press-center/news/detail.html?id=52822>

Restrictions By State Bodies – Are Recommendations Really a Useful Tool? The Case of the Parallel Import of Drugs in Georgia



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When it comes to competition in pharmaceuticals markets and the prices of drugs in a deregulated pharmacy market (like the Georgian one), the issue of parallel imports is always important. Between February 16 and September 30 2016, the Competition Agency of Georgia (GCA) carried out an investigation under Article 10 of the Georgian Law on Competition (GLC) on this very issue. Article 10 of the GLC prohibits state and municipal bodies from preventing, distorting and/or restricting competition on any relevant market. The investigation in question concerned the behaviour of the LEPL State Regulation Agency for Medical Activities (RAMA). The investigation was initiated on the basis of a complaint received by the GCA alleging that RAMA had misinterpreted relevant normative acts and restricted the parallel import of drugs to Georgia.

According to the Georgian Law on Medicines and Pharmaceutical Activities (MPA), there are two basic regimes under which a particular drug can be registered (and imported) in Georgia – a national regime and a recognition regime.

Under the national regime, a producer (manufacturer) or a trade license holder (marketing-authorisation holder) of a particular drug is able to register this drug in Georgia. The national regime involves a full administrative and scientific assessment of the qualities of a particular drug before registration is allowed. The process is comprehensive and can take up to several months.

Under the recognition regime, any person interested in the import of a drug is able to register a particular drug in Georgia, provided that this drug has already received appropriate authorisation: a) internationally or b) from one of the selected state regulators of pharmaceutical products. These regulators are established in so-called “high reliability” countries³⁶, and Georgia recognises their strict standards of pharmaceutical production and product evaluation. As a result, the registration of a drug under the recognition regime requires less time and documents, compared to the registration under the national regime. Once a drug has been registered under either the national regime or the recognition regime it can be imported by any interested person, regardless as to whether this person is a producer, marketing-authorisation holder or somebody else. Importing under the recognition regime is sometimes called **“Parallel Import by Recognition”**.

In addition to the two above-described regimes, *there is a specific regime under*

³⁶ The list of countries where these regulators are established is given in Regulation N188 of the Government of Georgia (issued on October 22 2009), and includes Australia, Canada, EU Member States, Iceland, Israel, Japan, New Zealand, Norway, South Korea, Switzerland, and the USA

Article 11⁸ of the MPA concerning pharmaceutical products that are **identical to the ones registered either under the national regime or the recognition regime, save for the way they are packaged and/or labelled.**³⁷

However, this is not a separate type of the registration regime. According to the MPA, this is just a notification procedure – a person who imports a pharmaceutical product that is identical to a registered one (where the only difference between registered and imported products is their packaging and/or labelling) should notify RAMA about this and present certain documents, indicating that the registered and imported products are identical, save for their packaging/labelling. Unlike the national and recognition regimes, this procedure is simpler, takes only 5 working days, and is free of charge. Importing under this regime is sometimes called **“Parallel Import by Notification”**.

The provisions relating to Parallel Import by Recognition, and especially those concerning Parallel Import by Notification were enacted in order to support the parallel import of pharmaceutical products, the quality of which have been assessed by the regulators of advanced countries in the pharmaceutical business. As a result, the Georgian pharmaceutical market has been open to quality drugs that are much cheaper than those imported directly by producers. Consequently, over the years, the average prices of specific drugs have dropped in Georgia.

It should be noted that the legal provisions regarding both regimes are strictly monitored by RAMA, in order to avoid any risk of having falsified or otherwise harmful drugs circulating in Georgia.

³⁷ From the way in which legislation is formulated, this type of import applies only to the drugs produced and manufactured in one of the countries listed in Regulation N188 of the Government of Georgia (issued on October 22 2009). See Footnote 3 for more information.

As noted above, the investigation undertaken by the GCA concerned an alleged misinterpretation by RAMA of the rules of the notification procedure, thereby resulting in a restriction of Parallel Import by Notification. Following the investigation, the GCA identified four instances in which RAMA had taken a restrictive approach and excluded the possibility of establishing that the registered and imported products were identical, namely:

1. Difference №1 - Pharmaceutical products to be imported by notification differed from the registered ones by the name under which they were marketed;
2. Difference №2 - Pharmaceutical products to be imported by notification differed from the registered ones in size (number of drug units inside the package);
3. Difference №3 - Pharmaceutical products to be imported by notification differed from the registered ones in terms of the information in the Patient Information Leaflet (most of the time the differences related to the use of the pharmaceutical product by children – for example, differences in the age requirements for use);
4. Difference №4 - Pharmaceutical products to be imported by notification differed from the registered ones in terms of marketing-authorisation holders (for the purposes of RAMA, marketing-authorisation holders differ when pharmaceutical products are marketed by different legal persons in different countries, even if the marketing-authorisation holders are subsidiaries of one and the same international pharmaceutical company. For example, GlaxoSmithKlein France and

GlaxoSmithKlein Germany are deemed to be two different marketing-authorisation holders, even though they both belong to the GlaxoSmithKlein group).

During the course of the investigation, RAMA claimed that both the MPA and the Parallel Import Order justified these restrictions. The investigation found that RAMA was right: the legislation in place did not allow for a different interpretation during the relevant period, when all the refusal decisions were issued. Both the MPA and the Parallel Import Order constituted binding normative acts. According to Article 10 of the GLC, an activity by a state body may be considered as a breach of competition rules only if it is not bound by other Georgian normative acts. Therefore, the application of the four above-mentioned reasons for refusal could not in itself be considered a breach of Article 10.

However, the GCA also assessed whether RAMA had applied the above-mentioned four reasons in a non-discriminatory manner, i.e., in the same way towards every person who wanted to use the procedure of Parallel Import by Notification. The GCA found one case where, under similar conditions, one importer was granted a permission to import a particular drug while the other was not. Therefore, it established an infringement of Article 10 of the GCA. RAMA remedied the situation in a very short time.

In addition, the GCA used its power under Article 18, point 2, sub-point “c” of the GLC, in order to issue recommendations (which must be considered by the state and/or municipal bodies subject to them) regarding the improvement of the competitive environment

on the pharmaceutical market of Georgia. Among other recommendations, RAMA was asked to urge the Ministry of Labour, Health and Social Protection to make amendments to the law, in order to make the provisions regarding parallel imports more precise and to provide an exhaustive list of situations where Parallel Import by Notification is or is not allowed.

In February 2017 the Ministry of Labour, Health and Social Protection made changes to the Parallel Import Order, further specifying the conditions of the Parallel Import by Notification. Namely, Articles 9³ and 9⁴ of this order set out more clearly which differences in the Patient Information Leaflet shall, or shall not, constitute a basis for refusing Parallel Import by Notification. In all cases, if the drug to be imported by notification differs from the registered one by the level of concentration (i.e. the amount of active ingredient in a single unit of drug such as a tablet), as well as by content (either qualitatively and/or quantitatively), the parallel import will be refused. However, minor changes in the Leaflet shall not constitute as a basis for refusing Parallel Import by Notification.

The highlighted case is a good example of constructive problem solving in a situation where a state body restricts competition despite acting in compliance with the relevant legislation. The recommendations given by the competition authority proved to be a useful tool for improving the competitive environment or for at least encouraging steps to be taken to amend the law in support of competition.

Market Definition in the Pharmaceutical Sector: The Experience of the Serbian Merger Control



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Introduction

According to the [Development Agency of Serbia \(RAS\)](#), the Serbian pharmaceutical sector is one of the largest in the Central and Eastern European region and is constantly growing both in terms of the value and volume of the products sold in the domestic market. Being one of the most important industries in Serbia, the pharmaceutical sector is closely connected to the transformation of the overall political and economic environment. Changes in this area follow changes in the state policy towards healthcare in general, as the pharmaceutical and healthcare sectors are of particular societal and economic importance.

As in other countries, the pharmaceutical sector is heavily regulated, with drugs and medicines subject to strict rules at every stage of the process before being authorised for patient use. This can be reasonably justified by the fact that hardly any other area of law has such a direct connection to human health as pharmaceutical law. The [Medicines and Medical Devices Agency of Serbia \(ALIMS\)](#) is responsible for regulating the Serbian pharmaceutical market. The Agency is in charge of issuing marketing authorisations for medicinal products and medical devices;

performing quality control of medicinal products; determining the classification of medicinal products and medical devices; providing information and promotion of rational use of medicinal products and medical devices; etc.

Serbian merger control in the pharmaceutical sector

Serbian merger control rules mandate the [Commission for Protection of Competition of the Republic of Serbia](#) (hereafter, Commission) to intervene where a merger is likely to significantly restrict, distort or prevent competition in a market. To ensure that pharmaceutical markets do not get too concentrated due to mergers, during 2006-2017 (following its establishment in 2005), the Commission investigated more than 90 mergers in the pharmaceutical sector out of more than 1200 notified mergers – around 8 mergers a year on average. Notably, the chemical and pharmaceutical sectors are the second industry, after telecommunications and IT, in terms of the number of notified mergers to the Commission.³⁸ There were no competition concerns detected in these cases and the Commission cleared all mergers in Phase I, without imposing remedies.

The pharmaceutical sector in Serbia has been witnessing a privatisation process led by foreign companies and increasing consolidation, which is likely to continue in the

³⁸ See the Commission's annual reports and decisions, available at <http://www.kzk.gov.rs/izvestaji> and <http://www.kzk.gov.rs/odluke/tipovi/koncentracije>.

coming years. Transactions between manufacturers, wholesalers and retailers (pharmacies) of pharmaceutical products have generated a significant number of new merger cases. The market is characterised by a split between domestic production and imports from a wide variety of multinational pharmaceutical companies. The country is home to several, large generic drug makers, such as [Stada subsidiary Hemofarm](#), [Teva/Actavis subsidiary Zdravlje](#) and the most recently privatised [Galenika](#), which was sold to a new owner as a result of the privatisation. Most multinationals are involved in the Serbian market through imports of their product portfolios or through licensing and marketing agreements with local players. More than 30 pharmaceutical companies carry out their business activities in Serbia.

The market is dominated by the sale of prescription drugs, primarily generic medicines. Over-the-counter (OTC) medicines make up the smallest segment of the market. The sale of any pharmaceuticals, including OTC medicines, is prohibited outside of pharmacies.

Market definition

According to the practice of the Commission, pharmaceutical mergers relate to a number of affected markets within the meaning of the merger control rules, with the following identified as relevant markets: market for manufacturing and marketing of pharmaceutical products, market for the wholesale of medical products (prescription medicines, over-the-counter medicines (OTC) and medical devices) and the market for the retail sale of pharmaceuticals in Serbia.

The analysis of the approach of the Commission to market definition in pharmaceutical merger cases provided below shows that it tends to follow the European

Commission's approach to market definition in the sector. In addition, since 2008, the Republic of Serbia and its competition law have been formally exposed to the influence and case law of the EU because, under the [Stabilisation and Association Agreement with the EU](#), Serbia formalised its commitment to harmonise its legislative framework with that of the EU.

Product market

As a general rule, the Commission uses the [Anatomical Therapeutic Chemical Classification System \(ATC classification\)](#), as a reference for the definition of the relevant product markets. The ATC classification was devised by the [World Health Organization](#) (WHO) to serve as a tool for drug utilisation research in order to improve the quality of drug use. In the ATC classification system, active substances are classified in a hierarchy with five different levels – medicinal products are classified according to the main therapeutic use of the main active ingredient. The system has fourteen main anatomical/pharmacological groups or 1st levels. Each ATC main group is divided into 2nd levels which could be either pharmacological or therapeutic groups. The 3rd and 4th levels are chemical, pharmacological or therapeutic subgroups and the 5th level is the chemical substance. The ATC classification is also used by [ALIMS](#), in accordance with [the law](#).³⁹

The Commission generally defines the product market on the basis of the third level of the

³⁹ See <http://www.kzk.gov.rs/kzk/wp-content/uploads/2018/08/Teva-PGT.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2014/08/Hemofarm-Pharmanova.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2015/08/Hemofarm-ad-Srbija-Ivancic-i-sinovi-doo-Srbija.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2018/09/540-Re%C5%A1enje-CVC-Capital.pdf>.

ATC Classification system (i.e., by therapeutic indication / intended use of medicines) in order to assess therapeutic interchangeability. However, in certain cases, it may be necessary to analyse pharmaceutical products at higher or lower levels than ATC 3 or to combine ATC 3 classes on the basis of demand-related criteria.⁴⁰

The Commission has often defined separate markets for prescription and OTC pharmaceuticals where this has been possible and relevant as many of the aspects relating to these categories tend to differ even if the active ingredients involved are identical, for example concerning patient choice and accessibility, medical indications (as well as side effects), legal framework, marketing and distributing, advertising, packaging and labeling, pricing and reimbursement. According to the [Law on Medicinal Products and Medical Devices](#), medicinal products are dispensed strictly upon prescription. However, medicinal products that have low toxicity, high therapeutic range, safety in overdose, minimal interaction, indications that are well known by patients and users and that are used for self-treatment, shall be dispensed without a prescription. For OTC pharmaceuticals, the Commission also took note of the ATC Classification system.⁴¹

In addition, the Commission also defines separate product markets for active pharmaceutical ingredients (API), which are

⁴⁰ In some cases (e.g. [Al Sirona/Zentiva](#), [Teva/Allergan](#), [CVC Capital/Fimej/Recordati Industria Chimica e farmaceutica](#)), the Commission has applied the Anatomical Therapeutic Chemical classification devised for marketing purposes by [EphMRA \(European Pharmaceutical Marketing Association\)](#) and has stated that the third level of the ATC classification allows medicines to be grouped in terms of their therapeutic indications and can therefore be used as an operational starting point for market definition.

⁴¹ See <http://www.kzk.gov.rs/kzk/wp-content/uploads/2018/08/Teva-PGT.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2015/08/Hemofarm-ad-Srbija-Ivancic-i-sinovi-doo-Srbija.pdf>.

input products for finished pharmaceuticals. The Commission has generally found that API markets might be as narrow as each individual API.⁴²

Geographic market

The Commission has consistently found the relevant geographic markets for the manufacturing and marketing of pharmaceutical products (including OTC products), as well as the distribution and wholesale market of pharmaceutical products, to be national in scope.⁴³ This is largely due to the regulatory requirements that pharmaceuticals must meet in Serbia and to the role of ALIMS in the regulation of the Serbian pharmaceutical sector. The ALIMS oversees the research, development, marketing authorisations and quality control of pharmaceuticals on a nationwide basis, and its regulatory framework virtually controls every aspect of the pharmaceutical sector.

The market for wholesale of pharmaceutical products in Serbia is considered as a “full-line” wholesaling, i.e. a market comprising the whole range of pharmaceuticals.⁴⁴

As regards to the geographic market definition for retail sales of pharmaceuticals, the

⁴² See <http://www.kzk.gov.rs/kzk/wp-content/uploads/2018/08/539-Bain-Capital-Gist-Brocades.pdf>.

⁴³ See <http://www.kzk.gov.rs/kzk/wp-content/uploads/2017/05/356-Nidda-i-Stada.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2016/04/Teva-Pharmaceutical-Industries-Ltd-Izrael-Allergan-Plc-Irska.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2017/11/669-Aleius-Galenika.pdf>; <http://www.kzk.gov.rs/kzk/wp-content/uploads/2016/01/Feniks-Farma-DOOEL-BJR-Makedonija-Gazmend-Abra%C5%A1i.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2014/01/638-FENIX.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2017/01/98-732-Hemofarm.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2017/07/470-Sopharma-Lekovit.pdf>.

⁴⁴ See <http://www.kzk.gov.rs/kzk/wp-content/uploads/2016/10/628-Evropa-Lek-Pharma.pdf>.

Commission considers that the market has to be defined much more narrowly – it is local in nature, e.g. limited to a particular city or municipality.⁴⁵

⁴⁵ See <http://www.kzk.gov.rs/kzk/wp-content/uploads/2014/06/269-Benu.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2015/07/Benu-doo-Republika-Srbija-Neopharma-Republika-Srbija.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2015/09/Benu-doo-Farmeks-apoteke.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2015/11/Benu-doo-Beograd-%E2%80%93-Apoteka-Zen-Smederevo.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2015/12/Benu-doo-Republika-Srbija-VIVA-B-plus-Republika-Srbija.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2016/06/371-Hemofarm.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2018/01/678-Benu.pdf>, <http://www.kzk.gov.rs/kzk/wp-content/uploads/2018/11/655-Re%C5%A1enje-Benu.pdf>.

Eurasian Economic Commission - Supranational Antitrust Regulator



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The Eurasian Economic Union is in a stage of taking shape, barriers to trade of goods are being gradually eliminated, more and more markets are becoming common and open for entrepreneurs of all EEU Member States.

In this regard, the promotion of competition and competitive environment are key to creating favorable conditions for the development of national economies. The priority areas for the Commission in fostering competition and antimonopoly regulation in the year under review were:

The first. Monitoring compliance with general rules of competition in cross-border markets, including reviewing applications, conducting investigations, initiation and handling of cases if evidence suggests possible violation of general rules of competition in cross-border markets, i. e. within geographical boundaries covering the territory of two or more EEU Member States.

In 2018, 27 applications received from authorized bodies and economic entities of EEU Member States were under review of the Commission, including 11 applications in connection with abuse of dominant position, 12 applications concerning signs of unfair competition, 3 applications on the grounds of anticompetitive agreements, 1 statement

regarding the actions of the government authorities.

The applications were reviewed by the Commission in accordance with the requirements of the EEU regulatory framework in force for competition and antitrust, and according to the results of consideration, the procedure upon 14 applications was discontinued due to transfer of jurisdiction over cases or non-compliance with the requirements of the Review Procedure, investigation procedure upon 7 applications was initiated, of which 1 case was brought to action and upon 6 applications the procedure was suspended due to proposals put forward to eliminate perceived violations by the potential offenders.

In 2018, the Commission in the framework of implementing a *soft law tool* issued 6 proposals for actions aimed at eliminating signs of violations of the general rules of competition and fostering competition in cross-border markets, 2 of which are already being implemented. As a result, on the one hand, competition in the relevant markets is voluntarily restored by potential offenders, and on the other hand – potential offenders are not subject to high penalties, and do not suffer reputational losses.

In order to increase the efficiency of the Commission's work in ensuring equal competitive conditions in the UEE cross-border markets the Commission continued in the year under review to apply a risk-based approach, within which the conditions of competition in some commodity markets were studied.

Meanwhile in order to make a comprehensive assessment of the risk-based approach, an agreement was signed at the end of 2018 to carry out a research work on *Developing a system to improve the effectiveness of control (risk-based approach) over compliance with the general rules of competition in cross-border markets when conducting proactive research, assessing competition and carrying out investigations*, the implementation of which will be completed in 2019.

A description of the results of applying the risk-based approach in 2018 is presented in Section 4 of this report.

In addition, the Commission at a meeting of the heads of competition agencies of the EEU Member States with the Member of the Board (Minister) on competition and anti-monopoly regulation in the “5 + 1” format, held on October 23, 2018 in the city of Yerevan (Republic of Armenia) in the course of *The Eurasian week*, the idea of joint implementation of the *Public Initiative* was presented, as a mechanism for detecting, identifying and suppressing competition restrictions in the EEU cross-border markets.

The *Public Initiative* is a mechanism for receiving a “feedback” or “signals” from business, state bodies and other players on issues concerned with competition, the consequences of which will be anti-monopoly response measures and the restoration of fair competition.

The *Public Initiative* is designed to ensure timely response to actual problems with competition and to take into account the interests of stakeholders in all EEU Member States through joint cooperation with all competition authorities of the EEU Member States.

The implementation of the *Public Initiative* will be carried out, among other things, by posting on the websites of the Commission and of EEU

Member States’ competition agencies of the statements on behalf of the Commission and the competition bodies of the EEU Member States on the implementation of the *Public Initiative* and on possible electronic questioning on harmonized competition issues in cross-border commodity markets.

This idea was developed during the year of review in cooperation with competition agencies of the EEU Member States and was generally supported by the leaders of the competition authorities of the EEU Member States at the said meeting.

According to the results of coordination with the competition authorities of the EEU Member States, the implementation of the *Public Initiative* will be launched in 2019.

The second. Today, not all economic entities are aware of the rules regulating the functioning of the EEU cross-border markets, the inertia of traditional behavior persists, due to the low awareness of entrepreneurs about the general rules of competition, both in terms of protecting their rights and responsible behavior in the market.

In this regard, the work on competition advocacy was a priority for the Commission in 2018, and various activities on competition advocacy were held during the period under review with the participation of representatives of government, businesses and their associations, consumers, and the academic community of the EEU Member States.

A new interaction format has been created – the *Public Reception Office*, where participants receive the necessary information on provisions of the EEU legislation in force, the violation of which is unacceptable and prohibited, as well as explanations are given on compliance with the general rules of competition in cross-border markets.

In order to lay out the values of competition and opportunities to protect the rights and interests of business entities of the Member States, the Commission developed and posted on the website a set of the documents – *Competition in the EEU cross-border markets (The White Book)*. A textbook *Competition law in Eurasian Economic Union* is being prepared by the Commission as well.

In addition, competition advocacy, including through the media of the EEU Member States (hereinafter referred to as *the media*), is an effective tool for educating the public about the current competition rules in the EEU cross-border markets, and about the work of the Competition and Antimonopoly Regulation Unit of the Commission.

The third. The Commission continued to work on improving the EEU regulatory framework necessary for the exercise of the powers to monitor compliance with the general rules of competition in the EEU cross-border markets as well as with the provisions of the EEU Treaty.

Together with the EEU Member States amendments and additions to the EEU Treaty were prepared with the aim of introducing warning and caution tools into the EEU legislative framework, which the Intergovernmental Council sent for finalization and approval by the EEU Member States.

As a result of the introduction of such *soft law* tools, the preventive focus of the Commission's activities will strengthen, the efficiency of anti-monopoly response measures will increase, the administrative burden on the business in the EEU Member States will be significantly reduced.

Also, a lot of work was done in the period under review with the aim of improving the legal basis prepared by the Commission on such issues as introduction of state price regulation, assessment of the consequences of the introduction of protective anti-dumping and countervailing measures on competition, etc.

The fourth. An important factor in increasing the effectiveness of competition policy implemented in the EEU cross-border markets is interaction with international organizations, regional integration associations, business associations and competition authorities of the third countries for closer cooperation, exchange of experience in competition law enforcement and antitrust regulation, as well as in best practice of international product markets research.

In the course of cooperative efforts during the period under review, international approaches were studied, foreign experience was used, in particular, of the European Commission, the competition agencies of the European Union Member States, the USA, other countries, as well as reviews of the Competition Committee of the Organization for Economic Cooperation and Development (hereinafter referred to as OECD), materials of the Intergovernmental Group of Experts on Competition Law and Policy, the UN Conference on Trade and Development (hereinafter referred to as UNCTAD), the most typical cases of antitrust laws violations in individual markets and factors constraining the development of competition were analyzed.

Literature Digest



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This issue of the Literature Digest for the July 2019 issue of the RCC Newsletter focuses on the pharmaceutical sector. This is a politically and economically important sector which has seen significant amounts of competition enforcement, as reflected in the papers reviewed below.

Michael A. Carrier and Carl J. Minniti III
‘Biologics: The New Antitrust Frontier’ (2018)
University of Illinois Law Review 14

This article provides a comprehensive overview of biologic medicines. Unlike chemical-based small-molecule medicines, biologics are large, complex molecules derived from a living organism. While small-molecule drugs are easy and relatively cheap to copy by generic suppliers, biologic medicines are expensive and difficult to produce.

The paper analyses a number of competition issues that may arise as regards generics, by reviewing seven common anticompetitive conducts common in the pharmaceutical industry – reverse payment settlements, product-hopping, regulatory abuse, samples’ denial, citizen petitions, disparagement and collusion – and assessing how they might apply to biologics.

This is a very good paper, and recommended reading for anyone interested on pharmaceutical markets. It contains a thorough discussion of the difference between chemical and biological medicines, and between generics and biosimilars; a detailed overview

of anticompetitive practices in the pharmaceutical sector; and a roadmap regarding potential antitrust issues for biosimilars.

Margherita Colangelo and Claudia Desogus,
‘Antitrust Scrutiny of Excessive Prices in the
Pharmaceutical Sector: A Comparative Study
of the Italian and UK Experiences’ (2018)
World Competition 41(2) 225

This article describes recent Italian and UK case law on excessive pricing in the pharmaceutical industry. It analyses the methodologies and legal tests deployed in the cases, and identifies the key challenges of applying competition law to exploitative practices in the pharmaceutical sector.

A particular area of focus concerns the justification of competition intervention against exploitative high prices. On the one hand, it is argued that high prices should not be the subject of competition law intervention because such intervention may affect innovation incentives and dynamic efficiency; because high prices will attract competitors and, hence, will self-correct; because there are high probabilities and costs of mistaken intervention with nefarious effects on innovation and competition; and because regulating prices is a task best left to specialised regulators. On the other hand, it is argued that correcting high prices increases consumer welfare, which is the goal of competition law; that high prices are not always self-correcting, particularly where high and non-transitory barriers to entry exist; and that, where the unlawful acquisition of monopoly power is not caught by competition law, there is a gap that should be filled by sanctioning exploitative abuses.

The concerns raised by direct intervention against high prices have led to a cautious approach being adopted by antitrust agencies, which either do not pursue exploitative abuses at all (as in the US) or only intervene against excessive prices in exceptional circumstances (as in Europe). Recent intervention against excessive pricing by pharmaceutical companies in Italy and the UK were carefully preceded by an analysis of whether intervention was justified. In these cases, it was found that, exceptionally, it was. In each case, the investments made for the drugs' development had already been recouped and the underlying IP rights had long expired; there was no market competition because the drugs could not, for different reasons, be replaced by other medicines; the infringing companies pursued a business strategy that sought to maximise the revenue of old drugs used to treat diseases that have a low incidence in the population, and where incentives to competitive entry were low; and, crucially, regulation was ineffective.

This article provides a good overview of recent excessive pricing cases in pharma in Europe. It should be of interest to anyone who wants to understand the factual background of the cases, the limited and exceptional circumstances where excessive pricing cases may be brought, and the challenges of bringing such cases.

Sandra Marco Colino, Niamh Dunne, Knut Fournier, Sofia Pais, Derek Ritzmann 'The Lundbeck case and the Concept of Potential Competition' (2017) Concurrences n° 2-2017

Reverse settlement payments, or pay-for-delay agreements, are agreements between an originator and a generics manufacturer where the originator pays the generics manufacturer to settle a patent injunction and agrees conditions to delay generic entry into

the market. This payment goes against the standard expectation that it is the (infringing) generics company that should pay an IP-holding originator to settle.

It may nonetheless be economically rational for both parties to enter into such an agreement because settling the dispute eliminates the potential for competition and allows the parties to share profits that would otherwise be eroded by lower prices. In other words, such settlement agreements can amount to market sharing when entered into between competitors which is anticompetitive by object. An important pre-condition for this is that the generics manufacturer is a (potential) competitor – and this is a doubtful proposition if the originator has a valid IP-right which, given that the patent suit was settled, will be the situation under IP law.

This paper contains contributions by numerous distinguished authors on recent EU cases on pay-for-delay, with a focus on the challenges that such practices raise particularly as regards the determination of whether a settling generics manufacturer is a potential competitor. It also compares the EU approach to that prevailing in the US, and engages with how the economics literature on topics such as probabilistic patent rights theory or contestable rights' theory can illuminate discussions on whether a generics company is a potential competitor.

I strongly recommend this paper to anyone interested in pay-for-delay, and particularly to anyone who may be working in this area. It not only provides a clear and interesting introduction to the topic and recent case law, but also highlights significant challenges in competition cases involving reverse patent settlement agreements and provides a framework to think about how to address those challenges.

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