

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE**

**Excessive Pricing in Pharmaceutical Markets – Note by Ukraine**

**28 November 2018**

This document reproduces a written contribution from Ukraine submitted for Item 9 of the 130<sup>th</sup> OECD Competition Committee meeting on 27-28 November 2018.

More documents related to this discussion can be found at  
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**JT03438178**

## Ukraine

### 1. Excessive Pricing

1. The Ukrainian legislation on protection of economic competition contains provisions that address exploitative price abuses<sup>1</sup>. In general, the Antimonopoly Committee of Ukraine (further - AMCU) decides to start investigation under the following conditions:

- the sector regulator is absent or recently created;
- the dominance is obtained as a result of special exclusive rights, or it is a case of delegation of state function to administrative monopolist;
- there are high barriers to entry to the market;
- there are signs of collusion.

2. Most of cases against exploitative price abuses are started on a basis of claims from customers or consumers. From time to time such cases are brought as a result of market study.

3. In some cases the AMCU enforces concerted practices on regulated markets which are aimed to avoid specific price regulation which lead to an anticompetitive effect and consumers' harm.

4. Within past two years the AMCU made decisions in cases against exploitative price abuses in such spheres, as cigarettes distribution, airport and port services, public transport and gas transportation area. The main features of such cases are an absence of sectoral regulator (in cigarettes distribution and public transport) and obtained exclusive or administrative rights by the dominant undertaking (airport and port services).

5. The question whether the price is fair or unfair in practice appears rather challenging. In order to determine the exploitative pricing, the AMCU uses the following methods:

- a price comparison with the similar product or geographic market with competitive conditions;
- an analysis of price dynamics within the past time period is used, especially if the company did not obtain the dominant position in previous periods;

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<sup>1</sup> 2. Thereof:

- Article 6 “*Anticompetitive Concerted practices of Economic Entities*” part 2 “*Concerted practices shall be considered as anticompetitive ones if they, in particular, concern:*

1) *setting of prices or other conditions with respect to the purchase or sale of products*”

- Article 13 “*Abuse of a Monopoly (Dominant) position*” part 2 “*The following actions, in particular, shall be considered as abuses of a monopoly (dominant) position on the market:*

1) *setting of such prices or other conditions for the purchase or sale of a product that would be impossible in case of the existence of substantial competition on the market*”

- if the similar market or price data are not available, a price-cost comparison or profitability analysis is used;
  - a simulation of *but-for* prices and further comparison with actual prices.
6. Earlier cases involving allegations of excessive pricing for domestic customers employed comparison of prices set by the dominant company on the internal market with its export prices. The rapid 3-digit growth of prices and margin by a monopolist was a point of analysis in some cases.
7. In case of rapid price growth, the prompt reaction of the AMCU is an organizing a round table with regulator (if any) or respective Ministry, main market players (suppliers and buyers) and associations (if any) in order to define the reasons of the price peaks and see the big picture of the situation. Further actions such as a market study, advocacy measures or opening the investigation depend on concrete situation on the market, its competitive structure, a regulation and signs of collusion between market players.
8. The AMCU underlines that competition authority is not a price regulator as itself. An investigation of high prices and further intervention of the AMCU is appropriate on the markets with limited competition, structural signs of monopolization or signs of collusive behaviour. Regarding regulated markets and natural monopolies, the role of AMCU is to ensure that the regulatory acts doesn't distort competition (in a way of competition assessment of draft laws and secondary legislations) rather than control if the price is fair or not.
9. Within past two years the AMCU initiated and signed memorandums with several sector regulators, which foresee the split of responsibilities in order to avoid overlap in powers. Among them are the Energy and Utilities the National Regulatory Commission, the Ministry of Agriculture and the National Securities and Stock Market Commission.
10. According to the Ukrainian legislation on protection of economic competition, the fines may be imposed up to 10% of the previous year annual revenue of the undertaking for the infringements such as abuse of dominance and anticompetitive concerted actions. Also the compulsory split-up of a monopolist is foreseen by the law, but it was not applied within past decade.
11. In addition to fines, the AMCU may set obligations in its decisions aimed to eliminate reasons of infringement with concrete deadlines, for example, an obligation to a monopolist to develop a transparent pricing policy within three months. However, the concrete way of fulfilment of these obligations is defined by the undertaking.
12. The AMCU may issue recommendations to state authorities and undertakings that provide for the termination of actions having signs of violations of the laws on the protection of economic competition, that provide for the removal of causes of the violations and their facilitating conditions.
13. As a competition advocacy measure, the AMCU may issue recommendations aimed to termination of activities or inactions that lead or may lead to violation of the legislation on protection of economic competition and recommendations regarding elimination of their causes and contributing conditions.

## 2. Pharmaceutical Markets, Pharmaceutical Regulation and Price Regulation

14. Pharmaceutical markets are in permanent focus of the AMCU due to its social importance, specific market structure and sophisticated regulation as well as ongoing medical reform. In 2016-2018 the AMCU presented results of two comprehensive market studies, issued a number of recommendations to regulators, proposals to government, took decisions in four cases on anticompetitive conduct of pharmaceutical producers<sup>2</sup> and distributors<sup>3</sup>, one case on abuse of dominance of pharmaceutical producer<sup>4</sup> and number of cases on unfair competition.

### 2.1. Market studies.

15. The AMCU conducted a comprehensive study of the pharmaceutical markets in Ukraine that covered all levels of drugs turnover, from a state registration of the drugs to retail sale. Analysis of each level included an impact of external and internal factors on competition, thereof, economic, political, behaviour of participants and market regulators. A local approach was compared with analysis of the world best practices of pharmaceutical market functioning.

16. The market study report was approved on an open AMCU Meeting in 2016 and contained a detailed description of:

- a system of pharmaceutical markets functioning in Ukraine;
- an analysis of peculiarities and problematic issues;
- proposed measures to advocate competition (mainly recommendations to the Ministry of Healthcare (MHU) and the authorized MHU's specialized institution - the State Expert Centre.

17. Proposals to government were aimed to improve the competitive environment in the pharmaceutical market due to:

- the introduction of referential pricing for medicines;
- a gradual transition to the reimbursement system;
- an introduction of electronic registers of patients by types of diseases treated for budget funds;
- a review of certain requirements of licensing conditions for conducting business activities;
- an introduction of the term "medical service" into the legal basis and approval of the method of its calculation;
- an introduction of health insurance.

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<sup>2</sup> Thereof Sanofi Aventis Ukraine LLC, Roche Ukraine LLC, Servier Ukraine LLC, Alkon Pharmaceuticals LLC

<sup>3</sup> Thereof BaDM LLC, Optima-Farm LLC, JSC Alba Ukraine, Venta LLC, A'STA LLC, Lyudmyla-Farm LLC, Business centre Pharmacia LLC

<sup>4</sup> Pharmchim LLC

18. Proposals for pharmaceutical market participants included:
- the introduction of mechanisms for the self-regulation of commodity markets with the launch of common rules of professional ethics.
19. The report on the results of the market research was sent to the President of Ukraine, the profile Parliamentary Committee, the Government of Ukraine, the Regulator for the use within the competence of measures aimed at the development of competition.
20. Another example is a hemodialysis equipment and spare parts market study. The market study report was approved on an open AMCU Meeting in 2017 and contained a detailed description of:
- peculiarities of hemodialysis equipment and spare part market in Ukraine;
  - actions of state authorities and healthcare facilities, provided a medical care to patients with chronic kidney disease in stage V;
  - a behavior of market participants;
  - actual problems prevented effective competition on the market.
21. An obligatory recommendations to Ministry of Healthcare and Ministry of Economic Development and Trade were issued regarding:
- elimination of the gaps in legislation of technical regulation, standardization, unification of substitutability of spare parts and equipment as well as definition of control procedures.
22. Already in 2018 on the working meeting organized by the AMCU the Ministry of Healthcare presented concrete steps towards more efficient kidney disease treatment and development of competitive environment on a hemodialysis market, thereof:
- an introduction of the electronic register of patients;
  - a change of the existing financing mechanism for treatment by hemodialysis;
  - an establishment of a single tariff for hemodialysis services for all health facilities regardless their ownership;
  - a creation of conditions for the development of competition in the markets of hemodialysis
23. The drafting of respective legislation is in process.

### 3. Examples of competition advocacy measures.

#### 3.1. Referential pricing introduction.

24. Based on pharmaceutical market study 2016 AMCU proposed to government to introduce a referential pricing, both internal and external, as the most effective tool for reducing prices.
25. As of today, referential pricing in Ukraine and the reimbursement mechanism are introduced:

- to insulins as a pilot project of state price regulation. It enables patients with diabetes type 1 to receive insulin in pharmacies for free or with a small additional charge;
  - the list of medicines with INN included in the "Available medicines" Government's program. It enables patients with cardiovascular diseases, bronchial asthma and type II diabetes to receive medicines in pharmacies for free or with a small additional charge. The list included 23 INN, a further increase of drugs under this program is under discussion.
26. As a result of these measures, the prices decreased.

### **3.2. Removal of administrative barriers for participation in state programs.**

27. In 2015 the Ministry of Healthcare included a drug with active substance Docetaxel exclusively in doses of 80 and 140 mg in the National Program for the control of cancer. Hence, other available dosages of this drug (20, 120, 160 mg).

28. However, in Ukraine a Docetaxel is represented by the following number of trade names: 20mg - eight, 80mg - six, 120mg - two, 140mg - four, 160mg - two. So the number of possible competitors to participate in this program was artificially reduced.

29. The AMCU concluded that the Ministry of Healthcare of Ukraine created administrative barriers to participation in procurement and made purchases irrational and recommended to prevent the restriction of competition in the markets of docetaxel in April 2016. Already in June 2016 a new Nomenclature of Drugs for Procurement was introduced including Docetaxel with a dose of 20 mg and 80 mg. as a result, the price of 1 gramm of Docetaxel decreased. The ex-post evaluation of annual economic impact amounted to 145 000 EUR.

### **3.3. Recommendation to establish a transparent and fair promotion practices**

30. 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 AMCU issued recommendations the Ministry of Healthcare to develop and approve a regulatory act with main principles of clear, transparent and non-discriminatory promotion of pharmaceutical products for all market players in order to:

- Avoid distortion of competition due to non-transparent promotion mechanisms;
  - Ensure independent consumer choice in pharmacies;
  - Eliminate a possibility of excessive pricing as a result of promotion schemes, which, in particular, may overrule the state price regulation.
31. Based on the AMCU's letter, the Prime Minister issued a mandate to Ministries of Healthcare, Finances and Economic Development and Trade to fix this issue in close cooperation with the AMCU.

### 3.4. Competition advocacy examples.

32. One of the ways to promote generic medicine is a removal of administrative barriers to entry. An important step towards is a definition of a subject of public procurement by an international non-patented name, which allows generics to compete with original drugs on public tenders. The AMCU actively promotes competition in public procurement of medicines as a way to avoid excessive pricing.

33. In 2018 the AMCU issued recommendations to the Ministry of Healthcare of Ukraine and the Ministry of Economic Development and Trade of Ukraine aimed at the development of a competition in public procurement of pharmaceutical products, thereof:

- to improve the Procedure of subject of purchase definition, in particular, by development a methodological framework or introducing amendments to current Procedure.

34. According to the current procedure, the purchases are formed in a way when one lot contains a wide list of product up to several hundred drugs with different nosology, which can be provided by the wholesale suppliers of widely assortment of sets of medicines. As a result, a number of possible competitors decreased only to large distributors. Thus, the discriminatory conditions could be set in the tender documentation by the seller. This possibility is confirmed by a substantial number of public procurement appeals in this sphere. One of the possible ways to eliminate this could be a "one INN - one lot" principle.

35. Two recommendations aimed to support new product entry to the market were given by AMCU to the State Expert Center, a specialized expert institution authorized by the Ministry of Healthcare.

36. These recommendations were based on application of different approaches to equal applications during state registration of similar medicaments, thereof:

- upon the determination of the type of application, the form of request for additional data, type of additional research;
- upon the examination of the instructions for use.

37. The conditions for the anticompetitive actions of the regulator were the imperfection of the regulatory framework, the uncertainty and non-transparency of the procedural issues of conducting the examinations, which leads to:

- the possibility of administrative pressure on individual applicants at all stages of the examination;
- a complication of the procedure of state registration / re-registration,
- a delay of the terms of examination of registration dossier materials,
- a significant increase of financial expenses from applicants (for additional examinations, research)
- a delay in the release of the medicinal product on the market.

38. An examination of registration materials of medicinal products with active substance extract of root althaea in medicinal syrup was conducted. During this examination it was found that since 2011, different requirements for the age of children were set in the instructions for medical use of the similar composition of the active

substances and dosage form. Such actions of the Center created unfavorable conditions for competition in the market for individual manufacturers of medicines in the form of a restriction of the circle of consumers in the segment of children under the age of two years.

39. The Center has been advised on the establishment of the same requirements for instructions for the medical use of medicinal products with althaea extract in medical form of syrup that have been performed. The Center informed all applicants of these medicines about the need to amend the guidelines for the application of age restrictions for children under two years of age. Applicants were provided with relevant applications for amendments.

40. As a result, a discriminatory condition was removed.

2.2. The different approach of the Centre to consideration of applications for state registration of similar drugs with the active substance Citicoline.

41. The AMCU found that since 2010 all applicants of medicinal products with active substance - Citicoline, in medicinal form with a solution for injection, strength of action (dosage) of 1000 mg / 4 ml at the time of filing an application for state registration of medicines, classified them as statements «for a generic drug».

42. During the examination of the materials of the registration dossier for certain medicines, the Center changed the classification of the types of individual applications for statements such as "for a similar biological medicines ", which required additional research and increased material costs. This created unfavorable conditions for entry into the market of manufacturers of those medicines, the type of application for state registration of which has been changed.

43. The Center provided recommendations to ensure during the examination of applications for state registration of medicines the use of unified approaches to establishing the type of applications for state registration of similar quantitative, qualitative composition and pharmaceutical form of medicinal products.

44. As a result, transparent criteria have been established for the applicant to determine the type of medicinal product, in the format of the registration dossier and in the types of necessary research for each type of medicinal product. This allows the applicant to independently prepare a dossier and eliminates the factor in the various qualifications of the application by the Regulators, that is, the administrative pressure is eliminated.

### **3.5. Enforcement example.**

#### ***Decision of the AMCU dated November 14th 2017 № 628-P.***

Defendants: Sanofi-Aventis Ukraine LLC, BaDM LLC, Optima-Farm, Ltd

45. Conditions of purchase agreements concluded by Sanofi-Aventis Ukraine LLC with Optima-Farm, Ltd LLC and BaDM LLC included such pricing mechanisms that stimulated restriction of competition in the markets of Sanofi medicines by cheaper generics, related to the distribution of the range of goods, and also provided the opportunity to raise prices for Sanofi medicines sold through public procurement procedures.

46. The retroactive discount system was designed in a way that turnover of a wide list of unique products was a base of calculation of a discount, further allocated on a short list of drugs which have several substitutes. As a result, margin of these products rises up to

300%. Such approach stimulated distributors to prefer original drugs to generics within a supply chain, thus limiting the generics distribution.

47. Sanofi-Aventis Ukraine LLC, Optima-Farm, Ltd LLC, and BaDM LLC were found to be in breach of Article 6 (1) and Article 50 (1) of the Law of Ukraine «On Protection of Economic Competition» in the form of anticompetitive concerted actions that were capable of restricting competition and increased prices for Sanofi medicines sold through public procurement procedures.

Total fine imposed – UAH 139.09 million (over USD 5 million).

48. Since 2016 AMCU has made decisions in four cases on anticompetitive conduct of pharmaceutical producers and distributors.

## 4. Examples of cases

### 4.1. Market sharing agreements

#### *Decision of the AMCU dated September 29th 2016 № 448-P.*

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

49. According to the agreement between Servier Ukraine LLC and local distributor JSC Alba Ukraine, the additional 20% discount was given to the distributor on a selected drugs assortment to concrete state-owned pharmacy, which was the biggest in the region. So JSC Alba Ukraine got a competitive advantage to win at public tenders of this pharmacy.

50. According to the agreement between Servier Ukraine LLC and local distributor Lyudmyla-Farm LLC, the individual customer-specific discounts were given to the distributor on a list of 27 healthcare facilities. As a result, prices to Lyudmyla-Farm LLC were lower at 30-50% than to another distributors.

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

52. Thus, competition between distributors for concrete healthcare facilities list and pharmacy was distorted, and in Donetsk region - eliminated.

53. In its decision, among other infringements, AMCU considered such agreements as anticompetitive concerted actions concerned market sharing.

54. The High court left the AMCU decision unchanged upon appeals of Servier Ukraine LLC and BaDM LLC.

### 4.2. Refusal to supply

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

Defendant: Farmchim LLC.

55. Farmchim LLC was the only Ukrainian producer of pharmaceutical substance mebhydrolyne which is used for drugs production. Barriers to entry to the market of pharmaceutical substance mebhydrolyne are technological and administrative (necessity 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 higher purchase volume.

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

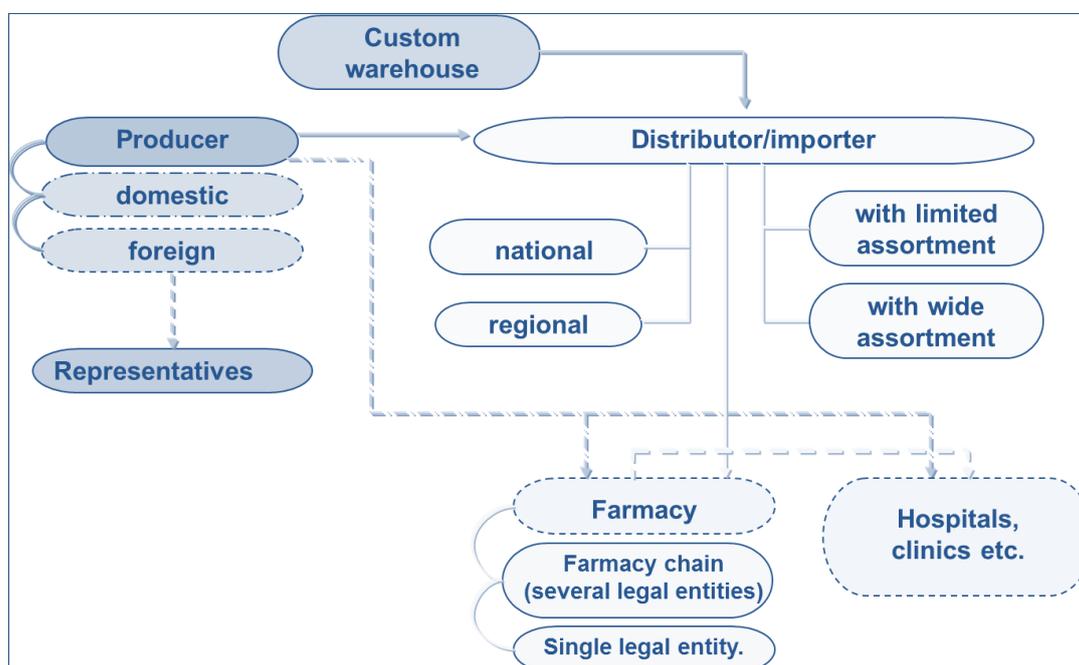
#### 4.3. Another competition restrictions in vertical agreements.

57. Foreign pharmaceutical companies use in Ukraine following restrictions in relationships with Ukrainian distributors:

- a ban on the export of goods from Ukraine;
- an obligation to prevent third parties in exporting goods outside Ukraine;
- an obligation to report and the establishing of payment conditions that provides a comprehensive control over the flow of goods in the market of medicines.

58. A market structure and the regulatory framework are assessed in antitrust cases regardless the industry. Indeed, in Ukrainian pharmaceutical markets these factors pose particular challenges on competition enforcement. The regulation is rather complicated and is described on the figure 1 below. The medical reform is ongoing. The pricing regulation is described in section III of this questionnaire.

Figure 1. Pharmaceutical market regulation in Ukraine

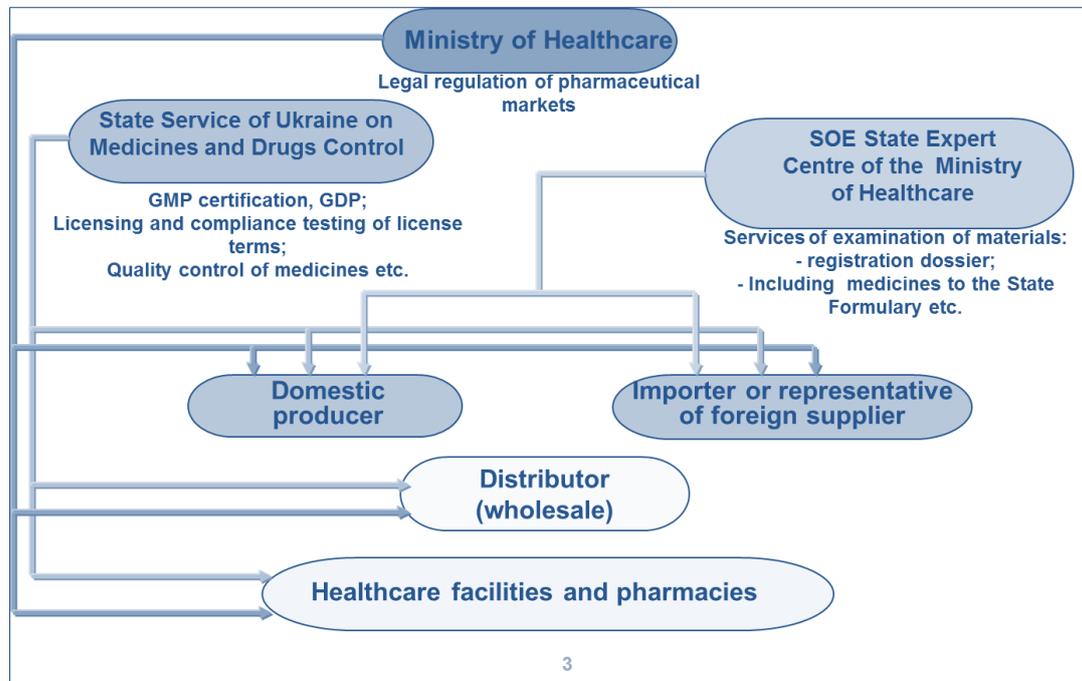


59. The market structure is described below. Main features are:

- numerous international producers and a fewer number of domestic producers;
- a wholesale distribution market is highly concentrated;
- competitive market of pharmacies on a country level, but with structural signs of monopolization in rural areas;

- a trend towards pharmacy chains development; a vertical integration of distributor and pharmacy chains.

**Figure 2. Pharmaceutical market structure in Ukraine.**



60. Main competitive concerns are:
- the establishment of administrative barriers to entry into markets by the regulators;
  - the ability of the regulator to omit or exercise power to give preference to individual market participants;
  - markets consolidation processes;
  - creation of economic barriers to entry by monopolists;
  - the possibility of transferring financial risks to the patient at each stage of the medicinal product turnover;
  - rising prices for medicines;
61. The AMCU's representatives are members of a number of permanent working groups established by the Ministry of Health of Ukraine on deregulation, health care reform, a pilot project on the introduction of state regulation of prices for insulin medicaments as well as of working groups within the Parliamentary Committee on draft laws, which, in particular, directly influence the development of competition in pharmaceutical markets.
62. The AMCU sends letters of initiative to the Profile Parliamentary Committee with comments and proposals to a number of draft laws aimed at reforming the health care system and developing the relevant pharmaceutical markets.
63. The AMCU organizes or sends its representatives to various public events, round tables, working meetings with the participants of the pharmaceutical market.

64. For a more efficient solution of the problematic issues of the competitive environment in the pharmaceutical markets, the Regulators were given recommendations on removing entry barriers to markets. Also recommendations were made to local self-government bodies to ensure competition in the implementation of the pilot project on insulin medicaments.

65. There were no special studies held by the AMCU of the impact of generics entry on pharmaceutical prices. However, these questions are studied in certain extent within case investigations.

66. The comprehensive pharmaceutical market study report, presented by AMCU in 2016, concluded the existence of trend towards higher pharmaceutical prices. One of the objective reasons is a substantial devaluation of local currency in 2014-2015. However, the enforcement identified an anticompetitive practices aimed to avoid price regulation and resulted in higher prices on public procurement and competitive harm.

## 5. Competition Enforcement against Excessive Pricing in Pharmaceuticals

67. Since 2016 AMCU has made decisions in four cases on anticompetitive conduct of pharmaceutical producers and distributors. Among market control and market sharing agreement, these cases unfold a conduct which led to the excessive prices in public procurement due to the retroactive discount system, helped to avoid a price regulation. These cases investigated both patented and off-patent drugs. The approach to product market definition was the same for both types of drugs. The market was defined on ATC5 level including medical form and way of treatment as far as public procurement system in Ukraine is based on International Non-proprietary Name (INN).

### ***Case example: Decision of the AMCU dated August 02nd 2018 № 377-P.***

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

68. According to the agreement between Hoffman la Roche Ltd and Roche Ukraine LLC about import of medicines, from the one side, and the agreement between Roche Ukraine LLC and local distributors, from another side, the pricing mechanism was designed in a way, which set excessive prices on public procurement and harmed competition. *De-facto* retroactive discounts were given *de-jure* in a form of irrecoverable financial aid, given on a regular basis in amount, calculated as a percentage of sales. Such scheme allowed avoiding the front margin cap, set by a local regulator. Declared intend of the aid as affordable prices for drugs and lower state expenditures in public procurement were not achieved in practice as it was defined within case investigation.

69. In its decision AMCU considered that were capable of restricting competition and increased prices for Roche medicines sold through public procurement procedures.

70. It is worth to mention, that in long-term perspective such concerted actions may increase the market power of their participants and to softening and distortion of competition.

71. In addition to the described in section I methodology, in pharmaceutical sector cases the simulation of *but-for* prices and further comparison with actual prices was applied with regards to the sector-specific regulation and market prices. For example, in Ukraine, due to the state regulation, the front margin of certain drugs can't exceed certain cap from

the declared import price for wholesalers and retailers. In order to avoid this regulation, the retroactive rebates were used by the companies (high import price created a cap, then substantial retro-bonuses decreased a real buying price while cap remains the same). Table 1 shows how the off-invoice retro-bonuses were used to avoid the front margin limitation vs. the scenario, when discount is given directly in the invoice.

	Actual price with regulated margin and retro discount	But-for price with regulated margin and on-invoice discount
Declared import price	100	100-15%=85
Retro-bonus	15%	-
Front margin cap	10%	10%
Maximum selling price	100+10% = <b>110</b>	85+10% = <b>93,50</b>
Real purchase price	100-15% = 85	100-15% = 85
Real margin	(110-85)/85= <b>29%</b>	(93,50-85)/85 = <b>10%</b>

72. In fact, such pricing mechanism sets nominal and real prices:

- *nominal price*, which is specified in the contract. This type of price is the basis for the calculation of custom duties and trade margins. The price for medicines for final consumers depends on this nominal price. And what is more, on the basis of nominal price a government regulator assesses the compliance with the legislative provisions in terms of government regulation of prices;
- *real price*, which is less than the nominal and actually paid by the distributor to the supplier (including discounts provided after the selling of medicines).

73. As the market structure on a wholesale level is highly concentrated, the scheme has been used to increase prices by big distributors above regulated level, which is especially harmful in public procurement. The scheme might be also beneficial for drugs producers interested in setting the higher import prices for the referent price purposes, who announced retro-bonuses aim to decrease prices, but having all reporting from distributors, didn't react that pass-on of the discounts didn't happen.

74. According to Article 3 of the Law of Ukraine "On medicines", government provides availability of the most essential medicines. In order to achieve this, the price regulation on medicines is implemented in the following forms:

- front margin caps on wholesale and retail level for list of essential drugs<sup>5</sup>;
- free of charge medicine supply or preferential prices for certain population groups, concrete diseases under an ambulatory treatment.

75. Front margin caps regulation has following peculiarities:

1. an application of 10% front margin cap on the wholesale level and 25% front margin cap on retail level to the buying price, including taxes and fees for the medicines, to the National List of Essential Medicines<sup>6</sup>;

<sup>5</sup> the Resolution of the Cabinet of Ministers of Ukraine dated October 17, 2008 No. 955 "On Measures to Stabilize Prices for Medicines and Medical Products"

<sup>6</sup> the Resolution of the Cabinet of Ministers of Ukraine dated March 25, 2009 No. 333 "Some issues of governmental price regulation for medicines and products of medical appointment"

2. a procedure of declaring changes to medicine's wholesale price, purchase of which is carried out in whole or in part at the expense of state or local budgets, and establishment of a front margin cap 10% to the declared change in a wholesale price on a wholesale level, and front margin cap 10% to the purchasing price on retail level, including taxes and fees.
  3. In case of full requirements satisfaction for medical products registered in Ukraine in accordance with a procedure established by law and included to the National List approved by this Resolution, customers may purchase medicines that are prescribed by Ukrainian law and are not included to the specified National List. In this case, preference is given to medicines included to sectoral standards in a healthcare sphere;
  4. an application of 10% front margin cap on the wholesale level and 15% front margin on retail level to the buying price for drugs, included in the international non-proprietary list of medicine's names<sup>7</sup> and in the National List;
  5. an application of 10% front margin cap on the wholesale level and 15% front margin on retail level to the buying price for insulin<sup>8</sup>.
76. Due to the complicated regulation of front margin, the undertakings may use various pricing mechanisms to avoid such regulation, as it was described in examples of enforcement.
77. The primary role in addressing high prices in pharmaceutical products belongs to the regulator.
78. Pricing for medicines proceeds in accordance with the Law of Ukraine "About Prices and Pricing", except for those that are subjected for state regulation.
79. Control over the state price discipline (implementation of state control (supervision) for compliance with the requirements for the formation, establishment and application of governmental regulated prices) is assigned to the State Service of Ukraine for Food Safety and Consumer Protection.
80. The AMCU considers medicines pricing issues only within powers, defined by Laws of Ukraine "On Protection of Economic Competition", "On the Antimonopoly Committee of Ukraine", "On Protection from Unfair Competition", other laws and regulatory acts adopted according to these laws. The Committee may intervene in medicines pricing issues only in terms of the economic subject's monopoly status existence or concerted actions that are prohibited by law.
81. It is worth to mention, that the AMCU on the regular basis evaluates drafts of laws and secondary legislation from competition perspective. The OECD Competition Assessment Toolkit for such evaluation was implemented by AMCU in 2017.
82. Market studies plays a vital role in understanding the peculiarities of the regulation which is quite specific in pharmaceutical market as well as the market structure. Actually the market is regulated on most stages of the drugs turnover from producer to consumer,

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<sup>7</sup> the Cabinet of Ministers of Ukraine Resolution dating November 9, 2016, No. 863 "On introduction of a medicines cost's reimbursement"

<sup>8</sup> The Resolution No. 955 and the Resolution of the Cabinet of Ministers of Ukraine dated 03.05.2014 No. 73 "Issues of implementation of the pilot project on the introduction of governmental price regulation for insulin preparations", from January 1, 2015

starting from the new drugs entry, patent protection and ending with regulated wholesale and retail front margin for certain list of medicines. Still, the state price control measures seem to be not sufficient.

83. The investigation within cases unfolds on a detailed level the anticompetitive practices and signals to the market which behaviour has to be avoided by the undertakings. However, such pinpoint measures may not cure the price increase trend and requires more comprehensive approach from the regulator.

84. Therefore, the AMCU actively cooperates with regulator and initiates measures for improvement of the situation on a pharmaceutical market.

85. As already mentioned in section I, according to the Ukrainian legislation on protection of economic competition, the fines may be imposed up to 10% of the previous year annual revenue of the undertaking for the infringements such as abuse of dominance and anticompetitive concerted actions.

86. In addition to fines, the AMCU may set obligations in its decisions aimed to eliminate reasons of infringement with concrete deadlines, for example, an obligation to a monopolist to develop a transparent pricing policy within three months. However, the concrete way of fulfilment of these obligations is defined by the undertaking.

87. The AMCU may issue recommendations to state authorities and undertakings that provide for the termination of actions having signs of violations of the laws on the protection of economic competition, that provide for the removal of causes of the violations and their facilitating conditions.

88. As a competition advocacy measure, the AMCU may issue recommendations aimed to termination of activities or inactions that lead or may lead to violation of the legislation on protection of economic competition and recommendations regarding elimination of their causes and contributing conditions.

89. The methods deployed by the AMCU to evaluate the excessive prices are described in the section I.