Cornerstones of Pharma Market Antitrust Investigations

Svitlana PANAIOTIDI is a State Commissioner at the Antimonopoly Committee of Ukraine

Galyna ZAGORODNIUK is a Partner, Head of Antitrust, Head of Life Science at DLA Piper Ukraine

The year 2016 saw the adoption of two important decisions by the Antimonopoly Committee of Ukraine on the pharmaceutical market. These were the cases of Alcon and Servier and their distributors. Apart from these decisions, a number of investigations against other international pharmaceutical producers and distributors are currently on-going, so additional AMCU decisions could be expected.

The above decisions, along with comprehensive Report of Pharmaceutical Market Study for the period 2014 - first half of 2016 issued by the AMCU at the end of 2016, enable a better understanding of the stance taken by the AMCU towards a number of important issues related to commercial practices on the pharmaceutical market. In this article we will provide two alternative views on certain issues: market definition, restriction of re-export provisions in the distribution agreements and retro-bonuses.

Market Definition- Cornerstone of Competition Assessment

There is no doubt that precise definition of the market, in terms of products, geography and time, is a breakpoint for all competition cases. Depending on how the market is defined, one may calculate its market share and assess whether its behaviour complies with antitrust laws. Those actions which are perfectly allowed for a company possessing a minor share of the market and strong competition, would be limited or completely restricted once the same company possesses a dominant or monopolistic position. All decisions and conclusions of the competition authorities begin with a definition of the market, followed by determination of the market share of the parties involved.

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The same is true for the cases in the area of pharmaceuticals. However, the AMCU and market players have different view on how exactly the product market in the case of pharmaceuticals should be defined.

Svitlana Panaiotidi: The pharmaceutical market is one of the priority markets in the Committee's activities. Definition of the market is a key factor in the investigation of cases, and we, together with the investigative department, have tried to take into account both Ukrainian market conditions and EU experience. In the course of its investigations, the AMCU communicated with the EC in order to identify the existing EU approaches to the definition of product and geographic boundaries of the market. While drawing our own conclusions, the Committee has taken into account that the pharmaceutical markets, unlike many other industries, are strictly regulated by provisions relating to the conditions of merchandise turnover, requirements of product quality and permits, pricing, and intellectual property rights. As far as public procurements for Government and/or local budget funds are concerned, the consumer (patient) does not take any decision about the product he/she gets, such a decision is rather taken by the ordering entity, which forms the scope of procurement based on its own experience, existing treatment protocols, etc.

At the same time, the Ukrainian healthcare system and its regulation is principally different from healthcare systems in the EU countries, therefore, any literal comparison of approaches, in my opinion, is not quite correct. Thus, Ukraine does not have the concept of a "medical service" similar to that in Europe, the state procures pharmaceutical products using trade margins applicable to a particular international nonproprietary name (previously, and even now, by the product brand name). Furthermore, the application of treatment protocols by doctors is quite specific in Ukraine, which have only recently become widely developed and applied. Moreover, the application of international clinical treatment protocols in Ukraine only began to be implemented from 28 April 2017.

It would be incorrect to ignore the specifics of the Ukrainian pharmaceutical market in defining the relevant market. Whilst taking such specifics of the pharmaceutical sector into account, the AMCU's definition of the market is based on therapeutic and economic interchangeability.

The AMCU has taken into account the fact that, as noted in EC correspondence, certain product markets for pharmaceutical products may emerge as a result of various elements, such as indications, efficacy, contraindications or side effects; dosing frequency may be different; medications may be long-acting or short-acting with immediate release or sustained release. In addition, different pharmaceutical products may be indicated for different types of disease or states of disease, etc.

In addition to the aforesaid, the AMCU also takes into consideration the results of EC sectoral research (Sector Inquiry of 2008/2009),

which confirms that real significant competition, which stimulates significant reduction of prices for a medication, occurs only when a generic enters the market. This means that, in fact, it is this interchangeability that exists for the original product and its generics that significantly determines the behavior of market participants.

In view of the above, the AMCU determines that the product is a pharmaceutical product that contains one or more active pharmaceutical ingredients and excipients, which are not found in any other pharmaceutical product registered in Ukraine or a group of pharmaceutical products that meet the following criteria, in particular:

— contain the same amount of the same active ingredient (same active ingredients) in the same dosage forms;

— have the same dosage form;

— administered the same way;

— have the same safety, quality and efficacy measures;

— meet the same or comparable standards;

— have the same bioavailability measures.

The approaches of the said Committee are confirmed by the conclusions of the leading Ukrainian healthcare institutions, particularly in the fields of cardiology, neurology, psychiatry and narcology, oncology, epidemiology, traumatology and orthopedics, rheumatology, dermatology, etc.

In merger clearance cases, AMCU begins its analysis based on ATC3 level and goes deeper if expedient depending on the concentration subject to further levels, including the INN level. INN level is of particular importance in the case of merger clearance involving an originator company and a company producing corresponding generics.

Galyna Zagorodniuk: First of all, it should be stated that the approach of the AMCU in terms of definition of the product market, the same as in European practice, differs in cases of merger control, on the one hand, and law-enforcement, on the other. For merger control cases the ATC 3 class approach used by the applicants is, generally, accepted by the AMCU.

The ATC 3 class approach also represents a starting point for definition of product market by the European Commission. This approach is confirmed by a number of cases, e.g. No COMP/M.7276 - GLAXO-SMITHKLINE/ NOVARTIS and others[1]. In particular, the Commission has used the Anatomical Classification Guidelines devised by the European Pharmaceutical Marketing Research Association as a reference. The Commission has relied on the third level of the ATC classification which allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. Of course, in some cases, where the Commission found that the ATC3 level classification was too broad, it, based on the factual evidence collected during the market investigation, has defined the relevant product market at the ATC4 level or at a level of molecule or a group of molecules that are considered interchangeable.

In contrast to the above, in case of the law-enforcement control the AMCU follows the INN[2] approach. Moreover, the Committee bases its definition of the market for medications (including generic and branded medications) that share the same INN, pharmaceutical form, method of administration, dosage, package size and even price level. Naturally, such approach artificially narrows the market and, if applied, automatically puts a number of companies in a dominant position.

Why did this happen? The AMCU has not literally followed EU experience as an example. Instead, it applied to the Ministry of Health of Ukraine for guidance on how to define the substitutability of pharmaceuticals and, expectedly, received a definition existing with the aim of licensing generic products. The latter enables the simplification of entrance to the market for generic products which fully correspond to the original ones, those having passed all the necessary registration and clinical studies procedures in the past. To enjoy such simplified entrance, the products should be identical. But this is absolutely not the same "substitutability" as in the case of competition assessment. It would be fair to say that medications with different INN but having the same therapeutic effect both from the standpoint of patients and doctors are interchangeable.

Prohibition of Re-Export

The majority of distribution agreements existing in Ukraine with an international producer, on the one hand, and the distributor, on the other, contained a provision disallowing a distributor to re-export medicines beyond the borders of Ukraine. The AMCU's position is that such a ban on re-exporting constitutes an anticompetitive provision and, as such, should not be included in the agreement.

Svitlana Panaiotidi: The problems of prohibiting re-export in the pharmaceutical industry are only a part of relations between importers and distributors on the Ukrainian pharmaceuticals market. Rather than an independent element, the Committee views the prohibition of re-export in combination with other contractual terms and their direct application taking into consideration their impact on competition and price levels. Prohibition of re-export as one of many factors provided for in contracts may enhance the effect of control over goods in the market.

Galyna Zagorodniuk: The reason for the ban on re-export is obvious: in order for the pharmaceutical product to be sold in Ukraine the markings on it must meet requirements of the law: the language of the markings, registration data, content of the certified pharmacopeial description, etc. Similar requirements are established in other countries, i.e. the packaging and markings must comply with the requirements of a particular country, where such pharmaceutical product is sold. Secondly, most of the countries prohibit distribution of drugs which have not been registered under the local law. In case certain pharmaceutical products supplied in Ukraine are not registered in other countries they may not be sold there. In view of above sale of a pharmaceutical product designated for Ukrainian market to any other country is virtually impossible and illegal.

Thirdly, in case a distributor nevertheless manages to export pharmaceutical products which were specifically packed for sale in Ukraine, international producers may be fined and subjected to liability by the state authorities of such countries for the failure to prevent export of pharmaceutical products that do not comply with applicable regulations of such countries. Mere disclaimer placed on the products packing would not indemnify the producer should the product marked and registered in Ukraine is sold in another country.

Lastly, ban on re-export contributes to maximum filling of the Ukrainian market with pharmaceutical products resulting in stronger competition.

Speaking about European experience, indeed many of the EU Member States have adopted measures to limit export of medications to ensure the availability of pharmaceuticals in their local markets. However, given that the EU is a single market, imposition of such restrictions violates the

[1] №COMP/M.1846 – GLAXO WELLCOME / SMITHKLINE BEECHAM dated 08 May 2000, №COMP/A. 37.507/F3 AstraZeneca dated 15 June 2005, №COMP/M.5295 – TEVA/BARR dated 19 December 2008, №COMP/M.5253 SANOFI-AVENTIS/ZENTIVA dated 04 February 2009, №COMP/M.5865 – TEVA/RATIOPHARM of 3 August 2010.

[2] International Non-proprietary Name (i.e. the main chemical compound of the medications).

principle of free movement of goods from one Member State to another. Ukraine, on the other hand, is not a part of any single market, thus, a different approach should be taken to ensure that the needs of patients are satisfied in full. The approach used by some of the European countries could be used as guidance. In particular, the Governments of Poland, Slovakia, Bulgaria have adopted additional measures to control or limit the export of medications to other countries where such medications are sold at higher prices.

Retro-Bonuses

The commercial terms of distribution agreements may provide for volume discounts whereby a distributor is entitled to receive a certain discount only if it achieved or exceeded certain threshold during particular term, e.g. a quarter. It is not possible to always forecast the exact volume of future purchase. Thus, the availability and exact amount of such discount could only be determined at the end of the period. Because of this the seller may not provide the discount to its distributor in advance and include it in the invoice. Therefore, in practice the seller provides to their distributors off-invoice discounts at the end of the period. These are also called retro-bonuses. The AMCU's position is that such retro-bonuses distort real prices for pharmaceuticals and, therefore, should not be used in commercial operations.

Svitlana Panaiotidi: A common practice for foreign producers supplying pharmaceuticals to Ukraine through distributors is to provide discounts/bonuses/special rebates. Particularly, we see those specifics in the mechanism of their provision. For instance, an agreement provides for a possibility to discount the cost of the goods that have already been received and sold by the distributor; or to provide a discount for promotion of a new product which is not sold yet, while a discount is allocated for a particular product, etc.

As a result, a distributor pays for the goods acquired, on the one the hand, and a foreign manufacturer returns the funds paid "in excess" by providing discounts based on the volumes of previous supplies, bonuses, financial aid, etc.

This results in two types of price used in the supply of pharmaceuticals:

The first type is a nominal price fixed in a supply agreement and serving as a basis for accrual of customs fees, trade markups and an increment for public procurement (up to 10% as envisaged by law). The price of pharmaceuticals for end users depends on the nominal price.

The second type is real price, which is lower than the nominal price and is actually paid by the distributor to the supplier as it incorporates the discount to be provided after the sale of relevant pharmaceuticals.

The AMCU's investigations prove that the discounts received by distributors do not contribute to reduction of prices for buyers and consumers and this effect is particularly observed in the course of government (public) procurement.

Today, I would articulate the following reservation on discounts. In the motivation of sales to distributors one should avoid:

— using a substantially different approach to the same deal depending on individual distributors;

— dividing the markets by territories, circle of buyers, mix of goods, etc.;

— providing non-transparent discounts, particularly, retroactive discounts that enable the maintaining of overstated price levels;

— reducing the competition by way of these incentives on the markets where generics are already present;

— reducing the imports by way of these incentives (specifically, under patent protection);

— imposing certain mixes of pharmaceuticals due to the incentives.

Galyna Zagorodniuk: Ukrainian law in general does not provide for prohibition of retro-bonuses or off-invoice discounts. At the same time, the retroactive discounts in some cases could, indeed, have an anticompetitive effect. But this only concerns cases where such discounts are provided by companies holding a dominant market position and, thus, potentially creating a foreclosure effect. This view is confirmed by the position of the competition authorities in European Union (e.g. the UK Competition and Markets Authority warning letter, June 2015).

The AMCU has a negative view on all retro-bonuses, regardless of the market share of companies or specific terms. But the argument that retro-bonuses distort the real prices has nothing to do with competition law. The major concern of the AMCU is that because of such retro-bonuses pricing regulation existing in Ukraine is not complied by market players. However, the main question here is that this issue is beyond the competence of the AMCU.

Ukraine should have regulations in place which enable it to control prices for medications and prevent pharmaceutical companies from establishing excessive prices. The Committee is often seen by the Government as a tool to influence prices at different product markets and is often assigned with the task to pursue market participants for excessive pricing. Similarly, the competition authorities in Europe also sometimes face the same pressure from Governments. However, they are often reluctant to open investigations especially in the pharma sector as pricing of medications is a very complex matter and it is usually hard for the authorities to determine what is the correct or fair price for a particular medication. Therefore, I welcome the conclusions drawn by the AMCU in the Committee's Report of Pharmaceutical Market Study and its recommendations to the Ukrainian Government to reconsider the existing pricing regulation, switching from existing non-efficient mark-up regulation to the system of benchmark prices and reimbursement.

Closing Remarks

Galyna Zagorodniuk: The above analysis of two alternative views gives the following alarm signal not only to the pharmaceutical sector. There could be commercial practices existing on the market for years. During a probe of the market the AMCU may indeed come to the conclusion that some practices are not compatible with competition law requirements. But the question is: if the AMCU advocates fair competition maybe it is worth to come up with its conclusions and clear recommendations what should be amended and improved, instead of imposing multi-million fines on the companies? Because the majority of companies would happily follow such recommendations to be on a safe side in lieu of being fined for something they hardly treated as a violation in the past.

Svitlana Panaiotidi: I'd like to say that we should focus on the changes in legislation which regulate the pharmaceutical market and make the 'medical service' real. We are open to discuss our approaches and I clearly declare this in the Committee's Report on Study of the Pharmaceutical Market where, as Galyna mentioned, we made a recommendation to the Ukrainian Government to reconsider the existing pricing regulation, firstly in public procurement, switching from existing non-efficient mark-up regulation to a system of benchmark prices and reimbursement, and I hope we can do it together. We are ready to be transparent and find the best way out in order to make our pharmaceutical market competitive, fare and interesting for investments.

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