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Competition Issues in the Pharmaceutical Industry of Kosovo

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Abstract

The pharmacy sector in practice is subject to competition law where its implementation finds its role in the prevention and combating of various abusive practices which undermine the pharmaceutical market and competition. Undoubtedly, the liberalization of the market for the pharmaceutical industry, the creation of market entry opportunities for young competitors, the increase of productivity, innovation and technology has an impact on increasing the quality of medicines and reducing their costs. Therefore, the protection of competition and its growth are some of the important goals for sustainable development of this sector. It can be said that the protection and development of competition in the sector is realized through two main pillars: competitive pharmaceuticals policies and enforcement of the law on competition.

Key words: Pharmaceutical product, agreement, abuse of dominance, concentrations.

INTRODUCTION:

The pharmaceutical sector is unique sectors in terms of competition, but being in the range of regulated sectors brings it in line with the other sectors; the competition factor and the related damages are treated somewhat different from the usual competition [1]. The establishment of the pharmaceutical sector, the production of pharmaceutical products with low price and high quality, imports and distributions through the functioning of the market mechanisms are important set objectives for the health of the population and also for sustainable economic development. Pharmaceutical sector in Kosovo is divided in public and private one. The level and nature of competition in each therapeutic class depends on two factors – the number of independent producers and the nature of demand for pharmaceuticals [2]. In some therapeutic classes there are very few independent manufacturers. Under some insurance schemes pharmaceutical spending is fully or almost fully reimbursed, with relatively few controls on quality or quantity of that spending. In those therapeutic classes where there are a large number of rival producers and where the demand for pharmaceuticals is sensitive to price there can be a high degree of effective competition [3]. In those therapeutic classes with few rival producers, or where demand for pharmaceuticals is insensitive to price, competition is not focused primarily on price, but on non-price dimensions. For many products which face few rivals in their therapeutic class, the primary competitive threat is the threat that rival firms will develop substitutes. However, barriers to entry are substantial. In almost all countries the pharmaceutical sector is subject to the competition law although the ubiquitous impact of regulation may, in practice, limit the application of the competition law in this sector [4].

AIM AND OBJECTIVE:

The purpose of the paper is the treatment and the summary of some of the issues that have arisen and the problems that have been addressed in competition law enforcement in pharmaceutical sector. The pharmacy market analysis in Kosovo, combating, protecting and developing competitiveness based on the competition law involves several basic issues related to the definition of the pharmaceutical market, the relevant market, the product market, the geographic market, the agreements, abuse of dominance and concentration.

Relevant Market – is the field of trade for which competition is restricted to a certain geographical area, including all replaceable products and services in relation to which consumers may be directed within a short period of time, in case restrictions or abuse results in increased prices [5]. The relevant market has two dimensions: the relevant goods or services (the product market) and the geographic extent of the market (the geographic market).

Product Market- The relevant product market for competition analysis in the pharmaceutical industry is, for any given condition, the set of drugs which are substitutes in the treatment of that condition. There is often a relatively close correspondence between the relevant product market and what is known in the industry the therapeutic class. The relevant product market is also affected by the nature and extent of insurance reimbursement. Even though two high-priced drugs are medically substitutable, the extent of competition between them may be small if one is reimbursed by the health insurer and the other is not [6]. On the other hand, in the presence of co-payments, a low-priced over-the-counter drug could act as a competitive constraint on a prescription medicine. In competition law, a relevant market is a market in which a particular product or service is sold. It is the intersection of a relevant product market and a relevant geographic market. The European Commission defines a relevant market and its product and geographic components as follows: a) relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer by reason of the products' characteristics, their prices and their intended use [7]. The relevant product market is determined according to three criteria: demand-side substitution, supply-side substitution, potential competition; and b) relevant geographic market comprises the area in which the firms concerned are involved in the supply of products or services and in which the conditions of competition are sufficiently homogeneous.

Geographic Market- The geographic market is an area in which the conditions of competition applying to the product

concerned are the same for all traders. The same factors used in delineating relevant product markets should be used to define the relevant geographic market. The elements to be taken into consideration when defining the relevant geographic market include the nature and characteristics of the concerned products, the existence of entry barriers, consumer preferences, differences among the market shares of undertakings in the neighboring geographic areas, as well as significant differences between suppliers' prices and transport costs level [8]. The notion of relevant market is used in order to identify the products and undertakings which are directly competing in a business. Therefore, the relevant market is the market where the competition takes place. The enforcement of the provisions of competition law would be not possible without referring to the market where competition takes place. The extent to which firms are able to increase their prices above normal competition levels depends on the possibility for consumers to buy substitute goods and the ability for other firms to supply those products. The fewer the substitute products and/or the more difficult it is for other firms to begin to supply those products, the less elastic the demand curve is and the more probable is to find higher prices. For all these reasons it is necessary to define the relevant markets for the different cases which fall under the law. The relevant market contains all those substitute products and regions which provide a significant competitive constraint on the products and regions of interest. This can only be possible if the products in this "market" are not subject to significant competitive constraints by products outside that market. In the United States, there exist a set of merger guidelines—written by the Antitrust Division of the Department of Justice (DOJ) and the Federal Trade Commission (FTC)—which specify methods for analyzing and defining markets [9]. A relevant market comprises a product or group of products and the geographic area in which these products are produced and/or traded.

Agreements

Agreement – any kind of agreement concluded between companies, with or without obligated force, decisions or recommendations of company groups, also concerted practices between companies that operates at same level, thus horizontal agreement or of different levels, and vertical agreements that are trading ones [10]. "All agreements between two or more independent enterprises are prohibited, decisions made by business associations and concerted practices that aim or may significantly influence on disturbance of market competition in relevant market, and in particular the ones that: a) directly or indirectly impose purchase or sale price or any other condition in trade; b) limit or control production, market, technological development and investments; c) share markets or supply sources; d) implement unequal conditions for similar transactions with other enterprises, consequently placing them in an unfavorable competitive position; f) apply conditions for agreements on contracts to rely on other contracting subjects, through other supplementing conditions that do not have any natural or common trade practice connection to the object of such contract" [11]. The Article 101 of the EU Treaty prohibits agreements between two or more independent market operators which restrict competition. This provision covers both horizontal agreements (between actual or potential competitors operating at the same level of the supply chain) and vertical agreements (between firms operating at different levels, i.e. agreement between a manufacturer and its distributor) [12]. The most flagrant example of illegal conduct infringing Article 101 is the creation of a cartel between competitors, which may involve price-fixing and/or market sharing. Pharmaceutical companies have on occasion been found to be colluding. In one recent case, a number of pharmaceutical manufacturers have been found guilty of maintaining a global cartel to fix prices and allocate market shares for the sale pharmaceutical products.

Abuse of Dominance

Dominate Position and abuse of dominance - position of one or more companies that is allowed to have operation capacity, towards offers or demand, independently by other trade participants, such as: competitor's clients or consumers [13]. " Abuse of a dominant position by one or more enterprises on the corresponding market is prohibited, in particular if: a) direct or indirect setting of unreal purchase or sale prices and other unfair trade conditions, respectively; b) limitation of production, markets or technological development to the prejudice of consumers; c) implementation of different conditions for similar duties with other enterprises thereby placing them in a disadvantageous competitive position; e) agreeing on contracts under condition that other contracting parties accept additional obligations; f) setting prices or other conditions, the objective or the result of which is to prevent entering or exclude certain competitors or one of their products from the relevant market; d) refusal of entrance of another enterprise, by giving an appropriate compensation, in the network or infrastructures of the enterprise with dominant position, if this refusal for usage of the network or infrastructures prevents the other enterprise to act as a competitor of the enterprise with dominant position". The Article 102 of the Treaty prohibits firms that hold a dominant position on a given market to abuse that position, for example by charging unfair prices, by limiting production, or by refusing to innovate to the prejudice of consumers. A company can restrict competition if it is in a position of strength on a given market [14]. A dominant position is not in itself anti-competitive, but if the company exploits this position to eliminate competition, it is considered to have abused it. Examples include: charging unreasonably high prices, depriving smaller competitors of customers by selling at artificially low prices they can't compete with, obstructing competitors in the market (or in another related market) by forcing consumers to buy a product which is artificially related to a more popular, in-demand product; refusing to deal with certain customers or offering special discounts to customers who buy all or most of their supplies from the dominant company; making the sale of one product conditional on the sale of another product. Examples of abusive practices typically include: predatory pricing; loyalty rebates; tying and bundling; refusals to deal; margin squeeze; excessive pricing.

Director-general for competition of EU consider abuse of dominant position "Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States. The European Court has defined a dominant market position as: "...a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers". Given the dominant position held by some drugs in some therapeutic classes, it is not surprising that drug companies have on occasion sought to use this dominant position to restrict competition [15].

Concentration

Concentration of enterprises is created by installing permanent control, by which is acquired: a) merging of two or more independent enterprises or parts of these enterprises; b) direct or indirect control, or influence on the dominating position of one or more enterprises or parts of enterprises, as follows: c) taking over majority of shares or of a part of them; d) taking over majority voting rights; e) in another way in the sense of provisions of laws in force and other regulations. Concentrations of enterprises, which may significantly damage competition, especially when such concentration results in strengthening of current dominant position or creation of a new dominant position, is prohibited. A 'concentration' is the legal combination of two or more firms by merger or acquisition [16]. Although such operations may have a positive impact on the market, they may also appreciably restrict competition, if they create or strengthen a dominant market player. In order to preclude restrictions of competition, the competition authority's exercises control over planned concentrations [17]. It may then authorities them subject to conditions or forbid them. In determining whether a concentration is compatible with the Pharmaceutical market, the Commission takes account on a case-by-case basis of several factors, such as the concepts of 'dominant position', 'effective competition' and 'relevant market'. The basic criterion used to analyses concentrations is that of a 'dominant position' [18]. One or more firms are said to hold a dominant position if they have the economic power to influence the parameters of competition, especially prices, production, product quality, distribution and innovation, and to limit competition to an appreciable extent [19].

CONCLUSION:

The pharmaceutical industry has a key role in countries, health and economic development. It is an important source of investment, of high-paying jobs, and through the continual flow of new and innovative drugs for the treatment of all kinds of human illnesses, has made a highly significant contribution to overall health and well-being. Each actor in the pharmaceutical industry – the manufacturer, the wholesaler and retailer, the prescribing doctor, the health insurer and the health consumer – is profoundly influenced by the rules and incentives established by regulation. In particular, the nature of competition in the pharmaceutical marketplace is fundamentally influenced by the effect of health insurance and the mechanisms established by health insurers to control pharmaceutical demand. These mechanisms include the use of formularies, drug utilization review procedures, prescribing guidelines and price controls. The quality of these mechanisms and the effectiveness of overall drug spending could be enhanced by contracting out for these pharmacy benefit management services. The periodic tendering process would provide continual incentives for innovations in contracting, processes and the use of technology in the control of pharmaceutical expenditures. Such contracting out for pharmacy benefit management services would also ensure that attention is given to a host of other minor improvements in the pharmaceutical marketplace, including the use of two-part pricing schemes in contracts with brand-name drug manufacturers, and attention to the manner in which pharmacists are compensated. The careful use of tendering for pharmacy services would ensure that pharmacists are neither over- nor under-compensated.

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