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The Romanian Competition Council launches a new sector inquiry into pharmaceuticals industry

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Recently the Romanian Competition Council has launched the second sector inquiry into the pharmaceuticals industry. The first sector inquiry was conducted between the years 2009 - 2011 and was focused on the distribution level of the production-distribution chain. This new sector inquiry will spotlight certain aspects raised by the producers' commercial activities in Romania, more precisely causes of delays in the generics entering or penetrating the market (which can include strategic patenting, patents disputes and litigations, licenses agreements, non-compete clauses) and the extent to which the Direct-to-Pharmacies (DTP) fits into the actual legal framework.

Whereas the first concern of the Competition Council was already well-know and a sector inquiry on this basis was largely anticipated, the last issue triggering the attention of the council caught many market players by surprise. Here are some fine points about the Competition Council concerns:

Delay in the generics penetrating the market

In its Report published with the occasion of the first sector inquiry, the Competition Council highlighted certain preliminary findings, as detailed below.

The product markets, in their majority, are highly concentrated, due to the absence of any generic product, in spite of the patents' expiry that occurred several years in advance. Out of the 36 markets of blockbusters examined by the council, 29 markets are limited to innovative medicines, in 3 markets are to be found both generic and innovative medicines, whereas 4 markets offer only generic products.

Moreover, there are product markets where following the patents' expiry the generics are now available for patients. However, although the generic products are significantly cheaper than the innovative medicines, the former still was not able to gain any of the market shares of the innovative

products. The Report offers examples of relevant product markets where although the patents expired seven years ago, the market share of the generics is still below 1%.

According to the European Commission's findings in the wake of its own sector inquiry into pharmaceuticals, after entering the market a generic medicine normally attained about 30% market share (in volumes) at the end of the first year and 45% after two years. The Romanian Competition Council found in 2011 that this was not the case for the Romanian markets.

Some of the aspects illustrated by the Competition Council as possible explanations are (i) the legal framework, (ii) the aggressive marketing of the originator companies, especially around doctors, and (iii) the degree to which the competition between the originator and generic companies takes place due to their market behavior.

The Competition Council concluded by stating that "due to the low degree of market penetration by generic medicines, the Competition Council will pay special attention to this issue during its next examination, for the purpose of ensuring that the generics' market entry is by no means limited through anticompetitive agreements".

The new sector inquiry is thus expected to go into the details of this topic and provide conclusive findings and recommendations.

If we are to use the European Commission's findings as guidance, and in particular the Reports published as a result of each of the three monitoring exercises conducted by the European Commission following the end of its sector inquiry, we may say that the anticompetitive agreements consists mainly in the arrangements that may lead to a delay of the generic entry in return for a value transfer (*e.g.* a payment) by the originator company to the generic company (the so called "pay-for-delay settlements"). This would be the most outright kind of arrangement, almost always amounting to an anticompetitive agreement contrary to the competition rules. However, other kinds of indirect arrangements may trigger the same effects and therefore provide sufficient grounds for being monitored, such as discontinuation of a patent challenge in exchange of certain advantages provided by the originator company.

The Competition Council was called upon to decide on whether arrangements between originator companies and generic producers, whereby the latter undertake that until the patent's expiry date it shall not apply for the administrative endorsements necessary for putting the generic on the market is deemed to constitute an anticompetitive agreement delaying generic's entry.

Romania is known to have stringent rules applicable to price control. Retail drug prices in Romania are among the lowest in the EU. This is due to the fact that as per the domestic laws, the reference price of a medicine in Romania must be lower than or equal to the lowest price of the same medicine approved in any of the 12 reference countries. Another legal requirement highly debated by the producers, is the generic price benchmark of 65% from the innovator's price. Thus, the generic reference price cannot exceed 65% of the price of the equivalent innovative medicine, while the price of the innovative medicine cannot exceed by more than 35% the approved price of the generic product. In other words, should a generic company obtain a price decision for its own product (which cannot be launched on the market because the patent is still in force) and should the price obtained be cheaper than the 65% maximum limit, the originator company must automatically

decrease the already approved price for its innovative medicine so as to comply with the 35% maximum limit. As a consequence, although not being able to enter the market, because the patent is still in force, a generic drug can influence the price of the equivalent innovative medicine. This can be achieved following a premature application for a price decision by the generic company.

A medicine can be sold in Romania only after the producer applied for and obtained a marketing authorization and a price decision from the competent authorities. Many generic companies apply for these two administrative approvals long before the expiry date of the corresponding patent. While the marketing authorization should not impact anyhow upon the normal exercise of the exclusive rights by the patent holder, the price decision obtained by the generic company before the patent expiry date (in some instances even 2-3 years prior to the expiry day) may trigger the price of the equivalent innovative medicine down, if the price for which the generic company applied and was granted is below the 65% maximum threshold.

In case *Novartis vs. Actavis*, the Competition Council decided that an agreement between the originator company and the generic producer, whereby the latter undertakes not to apply for a price decision until 90 days prior to the patents' expiry date does not amount to sufficient grounds for the opening of an investigation, given that 90 days is the maximum time necessary for getting a price decision from the Ministry of Health and consequently the agreement as such would not be capable of delaying the generic entry.

As can be inferred from the above, there are numerous instances in which the exclusive rights of the originator company come into play and the actual legal framework may not provide a solution. In the absence of clear legal obligations, contractual conditions entered into by various producers may provide the necessary guarantee around the exclusive rights conferred by the patent upon its holder. The Decision of the Competition Council cited above is a clear example of a coherent approach of the competition authority to a particular novel situation.

Direct to Pharmacies (DTP)

DTP is a direct distribution model which consists in the producer selling directly to pharmacies rather than through wholesalers. This kind of distribution system has already been implemented in various countries inside and outside the EU and some competition authorities already delivered assessments on the actual impact on competition and final consumers (*e.g.* UK, Australia). However, in Romania it is still a novelty. It is well-known that some producers seriously considered the idea, however the regulatory framework and the Competition Council's expected reaction posed significant challenges that delayed the producers' moves into this direction.

This comes in accordance with the Competition Council's press release announcing the sector inquiry, which confirms the rumors that several producers approached the Competition Council for getting the green light in relation to this type of changes into the distribution of their respective products. In its press release, the Competition Council recommends all the market players to put on hold any plans or steps undertaken to that effect, until the sector inquiry reaches its final point and the council makes available its guidelines regarding how and to what extent DTP is compatible with the competition rules. Given that a sector inquiry normally takes years, according to a recent public statement of the chairman of the Competition Council, the latter may try to drive a wedge between the two investigated matters, and issue its DTP guidelines sooner than the conclusion of the sector

inquiry, should there be any requirements from the market to do so.

The pharmaceuticals sector under continuous antitrust scrutiny

The pharmaceuticals sector has been under close antitrust scrutiny for a number of years. Besides the first sector inquiry focused mainly on distributors and partially on producers, not to mention the investigations on sensitive markets, such as insulin, dialysis, oncology, which ended up in a number of fines imposed by the council some years ago, the year 2011 brought up a number of decisions issued by the council, which gave rise to fines amounting to around 60 million RON (14 million EUR). Among the companies fined by the Competition Council, we can mention *Bayer, Baxter, Belupo* and their respective distributors for the controversial and far debated contractual prohibitions on parallel exports, as well as *Labormed Pharma* for implementing an economic concentration in breach of the *stand-still* obligation.

In 2011, the Competition Council delivered its assessment into a potential breach of competition law by the members of the Association of Distributors and Importers of Medicines and the members of a different association established by distributors in Romania, consisting in a concerted refusal to supply the pharmacies and hospitals as a result of the Ministry of Health's failure to review the drug prices on the basis of the evolution of exchange rate. The Competition Council found no anti-competitive practice given that once the prices were raised as a result of the exchange rate evolution, the distributors resumed the deliveries.

In 2012, further developments have been achieved also in an old case, from 2008, concerning the alleged anti-competitive agreements between *Antibiotice Iasi* and its distributors in the form of resale price maintenance. The debate on the investigation report took place at the end of the last year and the final decision is expected to come in the near future.

Final remarks

The pharmaceuticals industry is an industry highly regulated by the State, given the large amounts spent by the governments for medicines and the interests of the patients to have access to innovative, safe and affordable medical treatment. Cheaper generic drugs being unduly kept out or delayed into the market may lead to inappropriate allocation of public funds and ultimately cause consumer harm. Given the preliminary findings of the Competition Council listed in the Report regarding the first sector inquiry, which revealed a great number of pharmaceuticals markets still highly concentrated due to the absence of the generic products, a proper and thorough examination into the causes of such delay is more than justified. However, it is noteworthy that the monitoring exercises carried out by the European Commission over the last three years covered the entire EEA. Thus, the extent to which the antitrust inquiry of the Competition Council will overlap with the European Commission's continuous assessment will largely dependent on the exact matters that the council will decide to look into.

As regards the sudden inquiry of the Competition Council into DTP, one could argue that the recommendation of the council towards the market players, to refrain from making any progress until further guidance, has been sensed by producers as another attempt of the State to further

regulate the market. In any circumstances, one question arises, namely whether giving the chance to market players to keep pace with the commercial realities while intervening only where (rather than anticipating) a distortion of competition takes place wouldn't have been a more appropriate approach towards protecting competition.

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