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Competition - Romania

Council launches new pharmaceuticals sector enquiry

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Introduction

The Romanian Competition Council recently launched its second sector inquiry into the pharmaceuticals industry. The first sector inquiry was conducted between 2009 and 2011 and focused on the distribution levels of the production-distribution chain. The new sector inquiry will highlight certain aspects raised by producers' commercial activities in Romania – specifically, the causes of delays in generics entering or penetrating the market (including strategic patenting, patent disputes and litigation, licence agreements and non-compete clauses) and the extent to which the direct-to-pharmacies (DTP) model fits into the legal framework.

Whereas the first issue was already well known, and a sector inquiry based on this issue was largely anticipated, the second issue took many market players by surprise. This update examines the concerns of the Competition Council.

Delay in generics penetrating market

In its report on the first sector inquiry, the Competition Council highlighted certain preliminary findings. The majority of product markets are highly concentrated due to the absence of generic products, in spite of patents expiring. Of the 36 blockbuster drug markets examined by the council, 29 markets are limited to innovative medicines, three have both generic and innovative medicines and four offer only generic products.

Moreover, in some product markets generics are now available to patients following patents' expiry. However, although the generic products are significantly cheaper than the innovative medicines, the former could still not gain any of the market share of the innovative products. The report offered examples of relevant product markets where, although patents expired seven years ago, the generics' market share was still below 1%.

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

Some of the aspects cited by the Competition Council as possible explanations were:

- the legal framework;
- aggressive marketing by originator companies, particularly around doctors; and
- the degree to which the competition between the originator and generic companies took place due to their market behaviour.

The 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*."

Thus, the new sector inquiry is expected to go into the details of this issue and to

provide conclusive findings and recommendations.

Taking the European Commission's findings as guidance, in particular the reports published as a result of the three monitoring exercises conducted by the commission following its sector inquiry, it may be said that the anti-competitive agreements consist mainly of arrangements that may lead to a delay in the market entry of the generics in return for a value transfer (eg, a payment) by the originator company to the generic company (so-called 'pay-for-delay' settlements). This is the most obvious kind of arrangement, almost always amounting to an anti-competitive agreement contrary to the competition rules. However, other kinds of indirect arrangement may trigger the same effects and therefore provide sufficient grounds for monitoring (eg, discontinuation of a patent challenge in exchange for certain advantages provided by the originator company).

The Competition Council was called on to decide whether arrangements between originator companies and generic producers, whereby the latter undertakes to wait to apply for the administrative endorsements necessary to put the generic on the market until the patent has expired, should be deemed to constitute an anti-competitive agreement delaying market entry.

Romania has stringent rules applicable to price control. Retail drug prices in Romania are among the lowest in the European Union because, according to national law, 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 that is highly debated by 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 in order to comply with the 35% maximum limit. As a consequence, although unable 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 has applied for and obtained a marketing authorisation 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 authorisation should not affect the normal exercise of the patent holder's exclusive rights, a price decision obtained before the patent expiry date (in some instances, two to three years beforehand) may lower the price of the equivalent innovative medicine if the price for which the generic company applied and was granted is below the 65% maximum threshold.

In *Novartis v Actavis* the Competition Council decided that an agreement between the originator company and the generic producer, whereby the latter undertook not to apply for a price decision until 90 days before the patents' expiry date, did not amount to sufficient grounds for the opening of an investigation, given that 90 days was the maximum time necessary to obtain a price decision from the Ministry of Health. Consequently, the agreement as such would not be capable of delaying generic entry.

There are numerous instances in which the exclusive rights of the originator company come into play and the 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 on its holder. The *Novartis v Actavis* decision is a clear example of a coherent approach of the competition authority to a particular novel situation.

Direct-to-pharmacies distribution

DTP is a distribution model under which the producer sells directly to pharmacies rather than through wholesalers. This kind of distribution system has already been implemented in various countries inside and outside the European Union, and some competition authorities have already assessed the impact on competition and final consumers (eg, the United Kingdom, Australia). However, in Romania it is still a novelty. It is well known that some producers have seriously considered the idea; however, the regulatory framework and the Competition Council's expected reaction have posed significant challenges, delaying producers' moves in this direction.

This accords with the Competition Council's press release announcing the sector inquiry, which confirmed rumours that several producers approached the Competition Council to get the green light for this type of distribution model. In its press release the council recommended that all market players put on hold any plans or steps undertaken to that effect until the sector inquiry reaches its final point and the council

publishes its guidelines on how and to what extent DTP is compatible with the competition rules. Given that a sector inquiry usually takes years, according to a recent public statement of the chairman of the Competition Council, the council may try to split the two matters under investigation and issue its DTP guidelines before the conclusion of the sector inquiry, should the market require it to do so.

Pharmaceutical sector under continuous antitrust scrutiny

The pharmaceuticals sector has been under close antitrust scrutiny for a number of years. In addition to the first sector inquiry, which focused mainly on distributors and partially on producers, not to mention investigations into sensitive markets (eg, insulin, dialysis and oncology) which resulted in the council imposing fines, 2011 saw a number of council decisions giving rise to fines amounting to around Lei60 million (€14 million). Among the companies fined by the Competition Council were Bayer, Baxter and Belupo and their respective distributors for the controversial and much-debated contractual prohibitions on parallel exports, as well as Labormed Pharma for implementing an economic concentration in breach of the standstill obligation.

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

In 2012 further developments occurred in a 2008 case concerning 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 2012 and the final decision is expected soon.

Comment

The pharmaceuticals industry is highly regulated by the state, given the large amounts that the government spends on medicines and the interests of the patients in having access to innovative, safe and affordable medical treatment. Cheaper generic drugs being kept out of or delayed in entering the market may lead to the inappropriate allocation of public funds, and ultimately cause consumer harm. Given the preliminary findings of the Competition Council regarding the first sector inquiry, which revealed that many pharmaceutical markets were still highly concentrated due to the absence of 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 past three years covered the entire European Economic Area. Thus, the extent to which the antitrust inquiry of the Competition Council will overlap with the European Commission's continuous assessment will largely depend on the exact matters that the council decides to investigate.

As regards the council's unexpected investigation of DTP, it could be argued that the council's recommendation to market players (to refrain from making any progress until further guidance) has been seen by producers as another attempt by the state to regulate the market further. One key question arises: whether giving market players the chance to keep pace with commercial reality while intervening only when a distortion of competition takes place (rather than anticipating such distortion) would not have been a more appropriate approach towards protecting competition.

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