Intergovernmental Group of Experts on Competition Law and Policy

18th SESSION

10-12 July 2019

Room XVII, Palais des Nations, Geneva

Friday, 12 July 2019

COMPETITION ISSUES IN THE PHARMACEUTICAL SECTOR

Submission by Romania

Intergovernmental Group of Experts on Competition Law and Policy

COMPETITION ISSUES IN PHARMACEUTICAL SECTOR

Submission by Romania

A. Points of interests

1. The right and access of patients to medicines

The availability of safe medicines at an affordable price should be one of the objectives[1] of the health system in Romania. As funding sources for health spending are limited, funds must be efficiently allocated to allow for an increased number of patients to receive treatment.

To this end, the cost effectiveness on medication for which generic equivalents are available may allow new medicines showing that therapeutic benefits should be included in the reimbursement circuit as soon as they are available on the market.

The importance of generic medicines for European healthcare systems has also been highlighted in the High Level Pharmaceutical Forum - the European Commission, where it has been suggested that "generic medicines offer an opportunity to obtain similar treatments at lower cost for patients and for insurance systems while at the same time relieving budgets for financing innovative medicines."

2. The disappearance of medicines on the market

As a result of the price differences of medicines at the level of the European Union, the parallel trade represents an attractive business activity for enterprises, so Romania faces shortages of medicines due to exports on markets that are more attractive in terms of price.

As a result of the analysis, the Competition Council found that the situations of shortages of medicines on the market may be due to several factors:

- placing on the market by the drug companies of insufficient quantities for the needs of the population;
- the exports made by distributors to the detriment of the supply mainly of the demand from the national market.

In this matter, the Competition Council advocated to better regulation of the public service obligation. Thus, following the CC's recommendations, the Health Ministry has improved the legislative provisions on the availability of medicines.

The Law of Health Act: *Public Service Obligation - "Obligation of the Marketing Authorization Holder / Marketing Authorization Holder and Wholesale Distributors to permanently ensure an adequate range of drugs that will meet the needs of a particular geographic space and to deliver on the entire amount of the quantities requested as soon as possible after the receipt of the order, as well as the obligation of the pharmaceutical units to supply medicinal products if they do not exist at the time of application in stock; the specific conditions for the fulfillment of the public service obligation are set by order of the Minister of Health. "*

OMS 269/2017 regulates the public service obligation.

General provisions of OMS 269/2017:

[1] According to the substantiation notes accompanying the legislative drafts submitted to the Competition Council in view of formulating opinions / notices / points of view.

- the MAHs (Marketing Authorization Holders in Romania) have the obligation to ensure a minimum stock equal to the average monthly turnover[2] for each medicinal product for which they are authorized to market in Romania;
- the wholesale distributors must constitute inventories equal to the average monthly turnover for each medicine they distribute;
- wholesale distributors have the obligation to honor any justified order received from the healthcare establishments and pharmacies with which they have a contract within the delivery terms[3];
- healthcare establishments and pharmacies are required to pass the warranted order to wholesale distributors with whom they are in a contract, at least once for each wholesale distributor, until the order is honored.

3. Claw-back Tax

Applying differentiated claw-back tax.

The Competition Council supports the application of a differentiated claw-back tax. The Competition Council has repeatedly recommended the application of a differentiated contribution for the medicinal products that benefit from the protection of the patent against the other medicinal products, with the main arguments:

- the claw-back tax is not calculated at the producer price but at the retail price including the add-ons of distributors and pharmaceutical retailers;
- reduce medical expenses from the Health Insurance Budget;
- maintaining generic medicines on the market;

B. Concluded investigations

1. The sector inquiry on the Pharmaceutical market (2017)

The findings of the investigation

- the generic medicines have low market shares, although they are 35% cheaper than innovative medicines and are on the market for many years;
- there are markets where, with the emergence of generic variants of an innovative medicine, the market share of other innovative medicines is growing, for which there is no generic equivalent yet;
- there is a high degree of concentration of certain markets, mainly because of the marketing of innovative medicines;
- although the prescription of medicines is made on an active substance, and only in exceptional, justified cases, commercially, *57% of patients require a given trade name* following a doctor's recommendation. Main cause: *Intensive promotion* by innovative medicine manufacturers: scientific congresses, promotional meetings, advertising materials and objects, sponsorships;
- 9% of the turnover of the innovative medicine producers is dedicated to promotion, compared to 5% of the generic producers;
- the cheapest generic medicine is missing from the market or is sold in small quantities;

[2] the average monthly turnover of that medicine for the past three months.
[3] maximum 24 hours for justified order related to a medical prescription for acute and subacute illness, respectively 48 hours for the justified order related to a medical prescription for chronic diseases.

- patients are directed to certain pharmacies for the purchase of drugs => a very small number of pharmacies concentrate a big part of the amounts settled at the county level;
- the majority of distributors are condition the delivery of highly demanded medicines and that are well sold, by the pharmacy, to purchase other medicines they do not want;

Possible solutions / Recommendations for the investigation findings:

- Doctors could be encouraged to prescribe generic medicines by providing financial incentives if they are in a monthly set budget, and the savings made against that budget could be used by physicians for other purposes such as training sessions;
- removing the medicines that are placed on the market in insufficient quantities from the lists of subsidy, being kept only to give the reference price;
- limiting the marketing costs of medicine manufacturers for certain categories of activities, for a better definition of the expenses that can be recorded for each type of marketing or promotion activity;
- eliminating the benefits that pharmacies or distributors can offer to physicians in order to distribute promotional coupons available only to certain pharmacies;
- marketing cheap medicines by distributors / pharmacies can become cost-effective by applying a fixed amount to a distribution service or pharmacy;
- inclusion of medicine in the lists of subsidy as soon as they have received marketing authorization and price decision;
- the price of the generic medicine, as well as of the innovative one coming out of the patent, should be at the same level;
- differentiated application of the claw-back tax for generic and patented medicine, compared to new medicines that are more expensive and involve a larger budget effort => lower claw-back fee for generic medicine.

Impact of DTP implementation

- If the manufacturer is in a dominant position, the pharmacy / hospital and patient benefits should be similar to those previously recorded and must be quantified;
- The Competition Council does not recommend the use of a distribution system to the detriment of another, but reserves the right to intervene through an investigation in the event of indications of distortion of competition in certain markets.

2. ***Investigations on Restriction of Parallel Trade***

In 2009, the Competition Council initiated ex officio four investigations on the possible infringement of the provisions of art. 5 of the Competition Law no. 21/1996, republished and of the provisions of art. 101 TFEU by:

- Belupo, lijekovi & kozmetica d.d from Croaţia and SC A&G Med Trading SRL, on the wholesale medicine distribution market in Romania;
- Baxter AG Elveţia and its distributors, on the wholesale medicine distribution market;
- SC Bayer SRL and its distributors, on the wholesale medicine distribution market;
- S.C. Sintofarm S.A. and its distributors, on the wholesale medicine distribution market;

The anticompetitive agreements analyzed had the object of restricting competition by isolating the Romanian market and hindering the trade of producers' products in other markets, including within the common market. Such agreements, concluded between producers and their distributors, are considered serious infringements of both the competition law provisions and the TFEU.

The anticompetitive understandings consisted of export ban clauses in distribution contracts. These represented restrictions on both active and passive sales of the distributor, constituting infringements of the provisions of art. 5 (1) c) of the Competition Law no. 21/1996 and art. 101 (1) c) of the Treaty on the Functioning of the European Community.

Following the investigations, the four suppliers and their distributors were part of the contracts containing the export limitation clauses, which were fined over 13.5 million euros.

C. Investigations in progress

1. The investigation initiated by the Order of the President of the Competition Council no. 1127/2017

- regards a possible abuse of the dominant position of Roche Romania SRL in the market for products containing the active substance Erlotinibum.
- targets a possible anticompetitive practice consisting of acts and facts of Roche Romania SRL with the effect of excluding from the market a generic version of the innovative Tarceva medicine.
- Tarceva is a medicine that contains the active substance Erlotinib and is used to treat cancer produced by Roche. Tarceva is included in the subsidy lists (The list of reimbursed medicines).

2. The investigation initiated by the Order of the President of the Competition Council no. 1138/2017

- regards a possible abuse of dominant position of Roche Romania SRL on the market of certain oncological products in Romania.
- targets a possible anti-competitive behavior consisting in the use of a margin-type practice by Roche Romania SRL practicing wholesale prices in relation to a distributor higher than the prices offered by Roche Romania SRL in the context of some tender procedures for the supply of medicines to hospitals.
- targets the possible application by Roche Romania SRL of unequal conditions in the relations with distributors, which may create some competitive disadvantages.

During the investigations, dawn-raids were carried out at the headquarters of Roche Romania SRL, and the documents highlighted are in the analysis of the Romanian competition authority under the specific procedures.

3. The investigation initiated by the Order of the President of the Competition Council no. 805/2018

- regards a possible infringement of the provisions of art. 5 par. (1) of the Law and the provisions of art. 101 par. (1) TFEU on the Romanian market for normal human immunoglobulin by the major immunoglobulin manufacturers[4]
- coordinated strategy that aimed at limiting and disrupting the supply of the Romanian market with normal human immunoglobulin
- inspections conducted in Romania, Italy and Belgium

[4] Biotest Pharma GmbH Germany, Octapharma Pharmazeutika Produktionsges Mbh Austria, Octapharma S.A.S. France, Octapharma AB Sweden, Octapharma (IP) Limited United Kingdom, CSL Behring Gmbh Germany, Kedrion Spa Italy, Baxter SA Belgium, Baxalta Belgium Manufacturing SA Belgium, Baxter AG Austria.

D. Studies in progress

Study on the production and marketing of non-prescription medicines and dietary supplements

- The structural conditions of the markets, the contractual existent relations between the different actors involved in the production and marketing of non-prescription / food supplements will be analyzed and a detailed analysis of the applicable legislative framework
- If distortions affecting the competitive environment will be identified, the Competition Council will be able to propose the modification or revision of the existing regulations, will be able to issue clarifications or warnings to the business environment or the public administration in order to improve the economic efficiency of the sector and protect the interests of consumers. Also, if it finds indicators, the Competition Authority may trigger investigations into possible infringemets.