COMPETITION ON THE WHOLESALE MEDICATION DISTRIBUTION MARKET IN ROMANIA

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Abstract: *Wholesale distribution of medicines in Romania was in the constant attention of the competition authority. In order to analyze the operation of the distribution system practiced in Romania, but also changes that may occur in this system on short and medium term, the Competition Council conducted a sector inquiry after which they found some malfunctioning mainly chained to distributors access to certain medications. Conducted on a sample of 23 pharmaceutical groups operating on the Romanian market and holding approximately 80% of the pharmaceutical market in Romania in 2009, the sector inquiry aimed at two objectives, namely:*

- *Legislation analysis with impact on the wholesale distribution of drugs;*
- *Market analysis of drug distribution.*

Following the findings of the high concentration of markets analyzed, due to significant market shares held by innovative drugs under investigation were analyzed also the penetration of generics in the market and the factors that led to this situation.

Key words: generic drugs, innovative drugs, competition, wholesale distribution.

JEL Classification: I10, I11

1. INTRODUCTION

To achieve a representative analysis on the wholesale distribution market, the Competition Council started from the top 50 best-selling drugs in Romania, drugs that cover approximately 40% of the Romanian market, and that any distributor wants to have in the portfolio to be competitive in the market. Therefore, to achieve the objectives, we identified 92 markets at ATC 4 level, the value representing 70% of total market in 2009.

After analyzing how distributors have access to existent drugs on the 92 markets identified at ACT 4 level, but also at the best seller drug from each relevant identified market (In the situation in which on a relevant identified market exists more than 1 medicine from Top 50, has been analyzed the distribution of each medicine that is in Top, thus, finally, have been analyzed 107 medicines) has been discovered that, in general, there are no significant problems on the distribution market. Thus, in more than 55% of cases the distribution is made by a number of over 10 distributors, while in only 9,5% of the cases the distribution is made by a number smaller than 5 distributors.

Regarding the identified market, after making the analysis, has been discovered that at whole level, the exclusive distribution agreements does not cover a significant part of the market. Therefore, in 2009, the value of drug sales distributed on the basis of exclusive relations represented aprox. 8.75% from the total value of 92 analysed markets by the Competition Council. From 78 exclusive relations identified, only for 11 of them the share of

exclusive relations in total market exceeds a level of 30%, while for 49 exclusive relations the share is under 1%.

Most of exclusive relations are in class L (Antineoplazic and imunomodulators), respective 34, followed by the class J (Anti-infection and systemic use), with 12 exclusive relations, and class N (Anti-infection and systemic use), with 9 exclusive relations. Moreover, the highest share of exclusive relations, 48 from 78 identified, represents less than 1% from the total market value, being conjectural, mainly because of sporadic sales of some drugs.

After a limit of over 30% of share market it can't be supposed that vertical agreements, which enter under the incidence of article 5 line (1) from law and of article 101 line (1) from TFUE, will usually generate objective advantages of such a nature and dimension that they will compensate the prejudice that competition creates. Therefore, in the case of above identified situations in which the manufacturers use exclusive distribution systems, even if the owned shares on the market exceeds 30%, is necessary that they will make an auto-evaluation for establishing if the agreements meet the conditions from article 5 (2) from law, respective article 101 (3) from TFUE, leading to a real increase of efficiency that counters the intra-brand competition reduction.

Concluding, the access to wholesale distribution market is not limited in a significant measure by the existence of exclusive relations or by the distribution made by a reduced numbers of distributors. Even so, after investigating the case have been identified certain markets on which the access of distributors and, in general, of smaller ones, is difficult.

2. INOVATIVE VERSUS GENERIC

Provision of innovative medicines

The price of innovative drugs new-authorized for the market, inclusive the orphan ones or those that have paediatric use, is proposed by the APP owner or by the representative by comparing the price of those drugs in reference countries. If after investigations is revealed that the drug has not a registered price in the list of reference countries, the proposed price is validated, and after 1 year the situation is again evaluated by a submission from APP owner or by the documentation representative.

In the case in which, after the re-evaluation, it will be discovered that the price proposed for Romania is higher than in other paired countries, the APP owner or the representative is announced to reduce the price in 60 days. If the APP owner or representative will not accept the change, the product is excluded from the National Catalogue, with commercialisation right until the stock is finished, but not more than 1 year. Anytime in the period that the price is valid, the APP owner or the representative can decrease the price for innovative drugs that was initially validated by the Government. The reduced price will be communicating MS for establishing the wholesale price and en-detail price, with the scope of being included in the National Catalogue.

Provision of generic medicines

The generic reference price is proposed by the APP owner or representative, by comparison with their prices in other countries, without exceeding 65% from the price of innovative drug that his generic is (http://www.consiliulconcurentei.ro/uploads /docs/items/id7162/ report_on_competition_in_romania_2011.pdf).

In the case in which, after comparative analysis, is revealed that the drug does not have registered price in the comparison countries, the price is approved in conformation with the demand, without exceeding 65% from the price of the innovative drug, and when the term is expiring (1 year) the comparative situation is re-evaluated after the documentation submission by the APP owner or the representative.

Anytime when the price is still valid, the APP owner or the representative can reduce, for generic drugs, the producer price initially agreed by the ministry.

For bio-similar products, the price is agreed in the same way as the generic ones, and the reference price will be established at a maximum level of 80% from the price of the biological reference product.

After making the analysis, has resulted that, because of commercialising mainly innovative drugs, a high degree of concentration exists in some markets. Thus, from the 36 markets in which we can find drugs from Top 50:

- 29 markets contain innovative drugs;
- 3 contains both innovative and generic drugs;
- 4 contains generic drugs.

Generic drugs are equivalent with the original ones when the brevet for exclusivity period is expiring. Generic drugs offer the opportunity to obtain similar treatments at lower costs for clients, liberating in the same time budgets for financing new innovative drugs.

Concentration of analysed markets can mainly have 2 causes:

- Existence of intellectual property rights which don't allow the entrance of the drug on the market and
- Generic drugs could not erode the market share of the innovative drug, even if they penetrated the market.
- There has been identified 3 different situations that concerns the generic drug position on those markets, as following:
- Generic drugs are registered and commercialised, but they don't have the same active substance as the best sold innovative drug;
- The generic drugs of the best sold innovative medicine are registered and commercialised, but the market penetration degree is limited;
- The generic drugs of the best sold innovative medicine have been registered only in 2009, and therefore, they could not earn a significant market share.

For the markets that have generic drugs with the same active substance as the innovative drug and that have been commercialised in 2009, has been analysed the price difference between the innovative drug and the less expensive generic drug with the same active substance, but also their share in the total market.

From the analyse has resulted that even if exists significant differences on the prices, up to 253%, excepting only one market (C01EB), on all the markets where exists generic alternatives for best sold innovative drugs, not only they could not penetrate the market, but the sales of the less expensive generic ones represent under 1% from the total market share. Even if in the particular case of generic drugs that conquered an important share of the market, from the analysis resulted that their price is bigger than other generics with same active substance. And in those situations, the cheaper medicines with same active substance make marginal sales, which are not bigger than 1% from the total market share.

The factors that affect the penetration of generic medicines on the market or to obtain a significant share from the total market are influenced by:

- Regulation frame;
- Intense promotion of innovative drugs ;
- The level of competition between innovative drugs and the generic ones determined the manufacturer behaviour.

Concerning the regulation frame, in 2009, the in place regulations stipulated the drug prescription for which the insured people beneficiates in the frame of insurance medical system on commercial designation, and not on DCI, which means that the doctors where the ones that determined the demand, and consequently, the structure of analysed market. Even in

the case of compensated medicines, for which clients should pay the difference between the en-detail sale price and the correspondence amount applied to the compensation percentage on the reference price, the regulations did not stipulated rules for drug sellers, which can be able to stimulate the generic prescription.

For facilitating and quicken the generic drugs consumption, the regulation frame in Romania has been modified in 2010. Thus, in the case of compensated drugs, doctors have been obliged to recommend medications on DCI and not on commercial name as in 2009, and the medicines sellers have been obliged to release the drug that gives the reference price.

But concerning the medicines settled that are offered in the national health programs, in 2009 and also in present, their prescription is made on DCI. Even so, CNAS does not support the whole value of sale price of each drug that is given in the frame of national health programs. Because patients don't support any part of the drug cost, they don't have any interest to ask for generic drugs or even innovative drug substituent, but cheaper. Also, because the government supports the maximal wholesale price for those drugs, the pharmacies don't have any stimulus to commercialise at a smaller price, even if they can obtain significant discounts from medicine dealers.

Findings related to innovative-generic relation

After analysing the identified markets, resulted the fact that exist a high degree of concentration of certain markets, mainly due to commercialisation of innovative drugs. Therefore, from 36 markets in which we can find medicines from Top 50, 29 markets contain innovative drugs, 4 are containing generic drugs, and 3 contain both generic and innovative drugs. Next, we will refer to the 32 markets that are containing innovative drugs, inclusive the 3 that are mixed.

Generic drugs are equivalent with the original ones in the moment of brevet expiring and exclusivity period of data for innovative product that already exists. Usually, those prices are much lower than the innovative ones.

At European level is well recognised the fact that public budgets, inclusive the ones allocated for covering the expenses from health sector, are put under significant constrains. The concurrence, especially the one from generic part, is essential for maintaining public budgets under control and to allow the access on a large scale of drug consumers/patients.
Generic drugs offer the opportunity to obtain similar treatments at lower costs for patients and payers, releasing in the same time the budgets for financing new innovative drugs. After how was stipulated in the Communication for a new vision on pharmaceutical sector (Commission Communication from 10th of December 2008 [COM (2008) 666 from 10.12.2008: Safe medications, innovative and accessible: a renewed vision of pharmaceutical sector), numerous member states recognise the fact that generic medicines have an important role by contributing to the expense limitation for medical assistance chained by reimbursement and prescription practices.

Competition with unprotected products by brevets allows the treatment in a durable mode of a high number of patients that have less financial resources. The savings generated ensure the necessary funds for innovative medicines. Therefore, all the interested factors should ensure the entrance of generic drugs on market, once the brevet and legal protection for exclusivity is expired, and also the competition efficiency of those medicines.

The concentration of analyzed markets can have 2 causes: 1) the existence of some property intellectual rights that don't allow the entrance of generic drugs on market and 2) the generic drugs did not eroded the market share of the innovative one, even if the penetrated the market.

Concerning the markets that have only innovative drugs, they contain medicines designated to the treatment of serious affections, as diabetic, cancer, HIV, Hepatitis, etc.

These ones are usually given in the frame of national health programs. After the made analysis, have been identified 9 markets in which are commercialised only innovative drugs, as follows: A10AE, J05AE, L01XC, L01XE, L03AB, L04AB, N05AH, N07XX şi R03DC.

Considering the markets that have registered and commercialised generic medicines, is noticed that in the big majority of cases, even if exists an important number of producers on each market, the innovative medicines have kept significant market share, as follows:

Table 1. Market shares for innovative products

Market ATC4	No. Of Producers	Best seller medicines	Producer	Market share
C05CA	9	Detralex	Servier	85-95%
C09BA	7	Noliprel	Servier	85-95%
N07CA	9	Betaserc	Abott	85-95%
R03AK	6	Seretide	GSK	75-85%
L01CD	5	Taxotere	Sanofi-Aventis	75-85%
C10AB	6	Lipanthyl	Solvay	75-85%
B03XA	4	Neorecormon	Hoffmann la Roche	75-85%
C04AE	6	Sermion	Pfizer	65-75%
C01EB	6	Preductal	Servier	55-65%
L01XX	10	Velcade	Jemssen - Cilag	55-65%
C03BA	14	Tertensif	Servier	55-65%
N06DA	7	Aricept	Pfizer	55-65%
N05AX	17	Rospolept	Jenssen Pharmaceutical	55-65%
J01BC	14	Augmentin	GSK	45-55%
L01BC	7	Xeloda	Hoffmann la Roche	45-55%
B01AB	8	Clexande	Sanofi-Aventis	45-55%

Source: http://www.consiliulconcurentei.ro/uploads/docs/items/id6495/raport_total.pdf pag. 141.

After making this analysis, have been identified 3 different situations concerning the generic drug position on those markets, as follows:

- generic drugs are registered and commercialised, but those ones don't have the same active substance with the innovative drug best sold;
- generic drugs of the best sold innovative drug are registered and commercialised, but his penetration degree is low;
- generic drugs of the best sold innovative drug have been authorised in 2009, and therefore, they couldn't won an important market share.

A first situation is founded in the cases in which, even if generic drugs are on market, those ones don't have the same active substance as the innovative drug that is best seller, In the made analysis, has been identified a number of 5 markets like that- even if generic drugs exists, their share in the total market is very low, as shown in Table 2.

In the frame of sector investigation in the pharmaceutical domain made by CE in 2008, resulted the fact that, in average, in the first year from the market entrance, generic drugs

obtains 30% from the market, and in the second year they win up to 45% in volume, situation in which we don't find the markets analysed by the Competition Council. Contrary, there are markets in which the generic drugs are there from over 5 years and the innovative one still own a significant share from the market.

The factors that affect the penetration of generic drugs on the market or obtaining significant market share is because of: a) regulation frame; b) intense promotion of innovative drugs, and also c) level of competition between innovative and generic drugs determined by the behaviour of manufacturers. (http://www.consiliulconcurentei.ro/uploads/docs/items/id7162/report_on_competition_in_romania_2011.pdf)

Table 2. Market share of generic drugs

Market ATC4	No. of Producers	Best sold drug	Producer	Share of innovative drugs (%)	Share of generic drugs (%)	Share of OTC (%)
B01AB	8	Clexane	Sanofi - Aventis	[95–100]%	-	[0–5]%
C10AA	23	Crestor	Astrazeneca	[75–85]%	[15–25]%	-
		Sortis	Pfizer	[75–85]%	[15–25]%	-
C05CA	9	Detralex	Servier	[95–100]%	[0–5]%	-
L01XX	10	Velcade	Janssen - Cilag	[85–95]%	[5–15]%	-
M05BA	11	Bonviva, Zometa	Hoffmann la Roche,Novartis	[95–100]%	[0–5]%	-

Sursa: http://www.consiliulconcurentei.ro/uploads/docs/items/id6495/raport_total.pdf pag 142.

Regulation frame

A mainly characteristic of demand in the medicine case is the fact that the patient is not the decision factor. The demand in the result of a complex relation between patients, doctors, pharmacists and the national fund for health and social insurance. In general, the decision is made by doctors that prescripts the receipt and possible by the pharmacists that release the receipt. Neither the patient nor the persons that prescript/released the drugs don't support in a direct way the high part of costs, because these are compensated or entire funded.

Therefore, in the case of drugs, the elasticity of demand correlated with the price is limited for the decision factors and patients.

The main determinant factor of demand on the medicine market based on medical prescription is the doctor that, when is choosing between different medicines, he guides mainly after the therapeutic applicability and the efficiency of diverse drugs, and not after their price. The second mainly factor can be the pharmacist and the third the patient, but only in the situation in which this one needs to support a part of the medicine cost.

In 2009, the regulations in force (The framework contract on the conditions of providing healthcare within the public health insurance system for 2009) provided the prescription of all drugs received by the insurance policyholders in the health insurance system by their brand name, which means that physicians were the ones who determined the demand hence, the structure of the analysed markets. Moreover, pharmacists had the obligation not to replace the drugs prescribed by the physician, with the exception of the following cases, in compliance with the applicable provisions:

- if the drug recommended by the physician was too expensive and the patient did not have the financial resources required to bear the price difference between the reference price and the retail price of the respective drug;

- if the pharmacy did not have available in stock, at the time of the demand, the product prescribed by the physician and the patient did not want the pharmacy to bring it to the patient within 24, or 48 hours respectively, in compliance with the law.

Consequently, due to the regulations applicable in 2009, the physician was the determining factor of the demand for the prescription drugs received by the patients included in the public insurance system, while the role of pharmacists and patients was minimum.

Moreover, the relationship between the physician and the patient is characterised by an asymmetry of information because the patient relies on the physician's experience. Even in the case of reimbursable drugs, for the patients who had to pay the difference between the retail sale price and the amount corresponding to the application of the reimbursed percentage to the reference price, the regulations did not provide for rules for pharmacists meant to stimulate the release of generic drugs.

According to the findings of the EU sector inquiry "all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. Any campaigns that put this fact in question ignore the key principles for marketing authorisation in the EU and may mislead the public".

Consequently, under the regulations applicable in 2009, in which the physician was the determining factor for the demand, in addition of being an factor informed concerning the originator/generic drugs relationship, there is a low level of penetration of the generic drugs on the analyzed markets.

In relation to the Romanian regulatory framework, this framework was amended in 2010, in order to facilitate and boost the consumption of generic drugs. Thus, in the case of reimbursable drugs, doctors were compelled to prescribe the drugs using their international non-proprietary name (INN), not their brand name as in 2009, and pharmacists were compelled to release the drug determining the reference price, i.e. the drug with the lowest price corresponding to the therapeutic unit afferent to the same pharmaceutical form within INN and for each concentration.

Under these circumstances, the patient should be the determining factor of the demand, insofar as it is correctly informed concerning his or her option, both by the doctor, as well as by the pharmacist. Given the purpose of use of drugs and the importance that patients attach to their own health, in the absence of accurate information about their options, patients will not select generic drugs and the regulation, although correct, may become inefficient.

The main beneficiary of the regulation adopted in 2010 (The framework contract on the conditions of providing healthcare within the public health insurance system for 2010) is the state who, whether the patient selects an originator drug or a cheaper generic version of it, pays the reimbursement percentage (50, 90 or 100) of the reference price. The reference price is given by the lowest price corresponding to the therapeutic unit afferent to the same pharmaceutical form within INN and for each concentration.

However, in relation to the reimbursable drugs granted within national health programmes in Romania, both in 2009, and currently, their prescription is made using the INN. Nevertheless, CNAS (the National Health Insurance House) bears the full retail selling price of each drug granted within national health programmes.

Due to the fact that patients do not bear any part of the cost of these drugs, they are not at all interested in requesting the release of generic drugs or even substitutable originator cheaper drugs. Furthermore, due to the fact that the state bears the maximum retail price of these drugs, pharmacies are not encouraged in any way to sell them at lower price, though they can get significant discounts from the medicine dealers, as significant quantities of these drugs are sold.

Consequently, by using this system, the main form of competition related to these drugs, i.e. the price competition is eliminated both at the level of the manufacturers as well as at the level of pharmacies, to the detriment of the budget allocated to national programmes and ultimately, to the detriment of the patients.

3. INTENSIVE PROMOTION OF ORIGINATOR DRUGS

A possible explanation concerning the originator/generic drugs ratio can be found in the EU Report in the case of the sectoral investigation in the pharmaceutics market, namely the intense product promotion conducted by originator companies. According to EU, originator companies allocate a significant part of their budgets to trade products through doctors and other professional staff in the healthcare area.

As part of the marketing and promotion activities, doctors' belief that they should prescribe or use a certain drug for any therapeutic indication prevails. This activity is known as "detailing activity": a sales representative of an originator company visits a doctor to discuss the characteristics of a particular drug and convinces him concerning the safety, efficacy and quality of the product. At European level, in 2007, the "detailing activity" accounted for half of the marketing and promotion expenses incurred by originator companies.

Nevertheless, the relationship between pharmaceutical companies and physicians is a controversial one due to the conflicts of interest between the commercial interest of the pharmaceutical company and the physicians' duty to prescribe the most appropriate drugs. The sector inquiry performed by the European Commission provided proof that some originator companies intended to challenge the quality of generic drugs, within a marketing strategy, even when the generic product had been authorised by the relevant authorities and was available on the market.

At national level, Law no. 95/2006 on healthcare reform (Published in the Official Journal of Romania, Part I, no.372 of 28 April 2006, as subsequently amended and suplemented) governs the various forms of drug advertising.

This law takes over the principles provided in Directive no. 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community code relating to medicinal products for human use.

Art. *797 paragraph (1) of Law no. 95/2006* on healthcare reform provides: "For the purpose of this chapter, the publicity for drugs includes any kind of information through direct contact (the "door-to-door" system), as well as any kind of promotion meant to stimulate the drug prescription, distribution, sale or consumption; drug advertising shall include in particular (http://www.consiliulconcurentei.ro/uploads/docs/items/id6495/raport_total.pdf):

- the advertising of medicinal products dedicated to the general public;
- the advertising of medicinal products dedicated to persons qualified to prescribe or dispense drugs;
- visits by medical representatives to persons qualified to prescribe drugs;
- supplying samples;
- stimulating the prescription or distribution of drugs by offering, promising or granting benefits in cash or in kind, unless they have a symbolic value;

Originator/generic drugs competition

In relation to the third factor that can contribute to the delay of the penetration of generic drugs on the market, i.e. the competition between the originator companies and the generic ones, this factor is a given special concern both by the European Commission, and by the competition authorities in the member states, thus implicitly the by the Competition Council.

In January 2011, the European Commission launched the second monitoring exercise concerning the agreements on patents that is focused on the analysis of the agreements concluded between originator drug companies and generic drug companies throughout 2010. The first exercise of this type covered the period from mid 2008 - 2009, and revealed that the number of agreements with possible anticompetitive impact was significantly reduced compared to the period analyzed in the sector inquiry (2000 - 2007).

At the same time, the agreements aimed at preventing the penetration of competitors on the market may be violations of the competition Community and national law. Amicable agreements restraining the penetration of generic drugs on the market and including a value transfer from an originator company to a generic one, or to several such companies, constitute an example of potentially anti-competitive agreements, especially if the reason underlying their conclusion is to share profit through payments made by originator drug companies to generic drug companies, to the detriment of patients and of budgets allocated to public health.

4. WHOLESALER AUTHORIZATION

Drug wholesale distribution is carried out by Romanian legal entities, referred to as drug wholesalers, in units called drug warehouses. The wholesale distribution of drugs is carried out based on an operating license for the wholesale distribution of drugs, issued by ANMDM (National Agency for Medicines and Medical Devices).

In order to obtain the distribution license, applicants must meet the following requirements:

- to have the spaces, facilities and equipment suitable and required for the provision of the conservation and distribution of drugs;
- to have staff and, in particular, a skilled person assigned as responsible person, who meets the requirements provided by the Romanian laws;
- to be able to meet the following minimum requirements:
- to allow access to its the premises, facilities, and equipment to the persons in charge with inspecting them;
- to build up stocks of medicinal products only from the persons who, in their turn, hold a distribution license or are exempt from obtaining such authorization;
- to supply drugs only to persons who, in their turn, hold a distribution license or are authorised by the Ministry of Health to supply medicinal products to the Romanian population;
- to have a contingency plan for the provision of the effective implementation of any recall from the market regulated by ANMDM or performed in cooperation with the manufacturer or the holder of the marketing authorization for the medicinal product in question;
- to maintain the records of all the transactions performed and to make it available for the Ministry of Health for a period of 5 years;
- to observe the principles and the guidelines of good distribution practice for medicinal products.

At the request of the European Commission or of a a Member State, ANMDM must provide all appropriate information concerning the individual authorizations issued. ANMDM suspends or withdraws the distribution authorization if the authorization requirements are no longer met and notifies it.

5. CONCLUSIONS

Price competition has long been a strategy of larger companies seeking to gain a significant market segment. Companies engaged in a "price war" over a determined period of time, which had the effect of eliminating competitors. In some cases, setting a price below costs can be a strategic option pursued when the purpose is to penetrate a new market, to attract a segment of consumers, to eliminating the stock of products, to develop promotional campaigns, etc.

The healthcare system is essential for any country in the world. The drug distribution sector holds a special place in this system. In order to talk about the situation of the competition in a certain market, the respective market must first be defined. In relation to the medicinal product market, in the competition cases the ATC3 class is used as starting point in defining the relevant market. The Anatomical-Therapeutic-Clinic system (ATC) is organized hierarchically and consists of five levels.

From the point of view of the demand, the distribution of drugs includes three categories of customers (the figures represent the share of sales to the respective customers in the total drug sales, in 2009):

- pharmacies (retail sales) – 93.5%;
- hospitals – 6.5%;
- sales to other distributors - negligible.

Given the significant growth recorded in the case of the expenses with the reimbursable drugs, the Competition Council recommended the introduction of a reference price system, c at least in the cases when there are several drugs with the same INN.

The introduction of this system will lead to the reduction of the expenditure on drugs, the stimulation of the price competition from the manufacturer level to the pharmacy level and, ultimately, to charging lower prices. The proposal of the Competition Council was taken over by the Ministry of Health and included in Order no. 1275/2011. The Ministry of Health proposed that the method of calculating drug reimbursement prices for the drugs granted to patients included in national health programmes nominated by government decision, in compliance with the law, should be determined in such a way as to allow for obtaining savings to the health budget.

Thus, the wholesale price would have been the manufacturer price decreased by 15%, to which the distribution margin would have been added.

The Competition Council pointed out that this method of calculation may result in increasing the attractiveness of exports of such drugs. Consequently, this step could lead to obtaining a drug deficit on the Romanian market, with potential consequences for the health condition of the of chronically ill patients included in national health programs.

Moreover, from the point of view of the impact on the availability of drugs, the decrease by 15% of the manufacturer price could influence the commercial strategies of the manufacturers, by reducing/renouncing the sale of drugs whose low price determine diminished profit margins.

The Competition Council recommended as an alternative solution to the 15% manufacturer price decrease the implementation of this reduction of the price CNAS reimburses to its insurance policy holders. The “Sensitivity” of the distribution of drugs and its effects on the market lead to attaching special importance to this topic in the future as well, with the purpose of eliminating the possibility of the occurrence of such potential anti-competitive practices.

In order to have a sustainable health system, each country tries to balance the expenditures generated by the operation of the system and the available revenues. For this purpose, the aim is generally to decrease of the costs of drugs. A solution would be to increase

the consumption of generic drugs (when such drugs are suitable for the patients' needs) to the detriment of originator drugs (which are more expensive).

Starting with 2010, the prescription of drugs granted to the insurance policyholders within the public health insurance system is made by their international non-proprietary name (INN) and not by their brand name (As an exception, the prescription of drugs in the outpatient system is made using the international non-proprietary name, with the exception of the medically justified cases in the patient's health record, when the prescription is made using their brand name). The effect of this measure should be the increase in the consumption of generic drugs and also the decrease of the consumption of originator drugs (more expensive). Nevertheless, in order to obtain a significant effect, it should be correlated with a better co-involvement of pharmacies to release generic drugs when their INN allows that.

However, we should take into account the fact that this competition must be present at the level of each relevant market (defined according to the functional substitutability of drugs), which, more often than not, is defined at the ATC3 or ATC4 level.

From the point of view of the number of agents on the market it can be said that the Romanian pharmaceutical market is a developed one.

The first manufacturers on the Romanian market accounted in 2009 for a market share of 77.80%, or 77.20% respectively in 2010. Currently, on the drug wholesale market 350 wholesale units were authorised to operate. Taking into account that, generally, each distributor has several warehouses, a much lower number of companies operate in this market. The largest 29 distributors control 95% of the market.

At the end of 2010, according to the Ministry of Health, 6708 open-circuit pharmacies operated in the Romanian market. In addition to these pharmacies, there are the pharmacies operating in hospitals, and the companies selling OTC drugs. Both in the drug manufacturing segment and in the drug wholesale segment, the pharmaceutical market is a domestic one from the point of view of the competition principles. In the drug retail segment, the pharmaceutical market is local. An extremely important characteristic of any health system is sustainability. For this purpose patients' needs must be carefully balanced with the available resources.

It is difficult co compare various countries, because the differences in the health policy generate different systems. Nevertheless, a common element that is often used in such comparisons is the cost generated by the drug consumption.

In 2009, the total value of drug sales in Romania was 8.1 billion RON, i.e. approximately four times higher than the value recorded in 2000.

According to Business Monitor International, the value of prescription drugs and OTC sold in 2010 through pharmacies and hospitals was 11.9 billion RON.

From the point of view of the value of the drugs sold, the Romanian pharmaceutical market is a developing market, recording annual increases of more than 10% starting with 2007. On the Romanian market there are approximately 7000 drugs, but the most sold 50 drugs account for approximately 40% of the total value of the drugs sold.

Consequently, the Romanian drug market is a developed one, but with a high concentration level. According to IMS Health (Intercontinental Marketing Services Health), the cost of drugs accounts for approximately 10% of the costs of a health system, and within them the cost of generic drugs is 18% (although their consumption exceeds 50% of the drug consumption).

From the analysis of the data (Data source – the CEGEDIM report) on the drug consumption in Romania in 2010, generic drugs are 60% of the quantity of prescription drugs and 32.4% of their value.

Originator drugs are more efficient (state-of-the-art drugs), but they are also more expensive at the same time. Moreover, the originator drug market is monopolistic. From the above-mentioned facts it appears that in terms of the degree of propensity for generic/originator drugs, the degree of competition on the Romanian pharmaceutical market is high. Another difference in the price of drugs is given by their type: originator or generic. The reference price for generic drugs is the equivalent of maximum 65% of the price of the originator drug whose generic it us. Moreover, it must be less than or at most equal to the lowest price of the same drug from a list of 12 countries published by the Ministry of Health.

In the most sold 50 drugs in Romania, originator drugs prevail and the number of the generic ones is low.

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