

IURIE GOTIȘAN

A SHORT RADIOGRAPHY OF THE PHARMACEUTICAL MARKET IN MOLDOVA

Policy Brief



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POLICY BRIEF

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Iurie Gotișan



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For more information on this publication or about the subscription for publications issued by IDIS, please contact directly the Mass Media and Public Relation Service of „Viitorul”. Contact person: Diana Lungu – diana.lungu@viitorul.org

Adresa de contact:

Chişinău, Iacob Hîncu 10/1, 2004, Republica Moldova

Telefon: (373-22) 21 09 32

Fax: (373-22) 24 57 14

www.viitorul.org



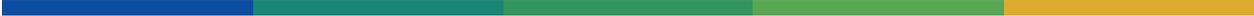
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Tel.: +373 22 885830

E-mail: fes@fes.md

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EXECUTIVE SUMMARY

This policy brief is intended to describe the general situation on the pharmaceutical market in the Republic of Moldova, and a comprehensive approach of key reforms in this area, in particular in terms of pricing. The analysis attempts to highlight the drug market volume in Moldova, including a regional comparative tint. It is described the legal and institutional framework regulating this market, some international experience in this field, operational aspects of the pharmaceutical market as well as some stipulations of the new Regulation on pricing. The study concludes with a set of conclusions and recommendations that should be considered by both those regulating the drug market and those who activate on this market, traders, manufacturers and pharmacies.

1. General context

In recent years the pharmaceutical market in Moldova has grown quite pronouncedly, especially after improving the legal framework in the field and with the creation in 2005 of the Medicines Agency¹. It is this body that has been assigned, by law, functions to elaborate policies in the field, and also to supervise, monitor, regulate and ensure the quality of pharmaceutical products.

However, despite upward growth and development, the Moldovan pharmaceutical market is considered to have a relatively low attractiveness for multinationals from Europe. Thus, according to an annual

ranking developed by *Pharmaceuticals & Healthcare Business Environment*² Moldova pharmaceutical market was valued at USD 211 million and ranked 19th of the 20 markets analyzed in Central and Eastern Europe. Furthermore, forecasts for 2012 are decreasing and that is why it is estimated at USD 206 million. It is interesting that in 2008 the same assessment organization of the pharmaceutical markets estimated the local market at a value of 242, ranking on the 17th place of the 20 markets.

Thus, although *Business Monitor International*³ in 2008 forecast an annual growth of 13% in the pharmaceutical field, the small value of the local market, apparently influenced by

1 www.amed.md

2 <http://www.marketresearch.com/Business-Monitor-International-v304/Moldova-Pharmaceuticals-Healthcare-Q3-7043895/>

3 <http://www.businessmonitor.com/>

the economic crisis effects, is one of the major factors that decrease its attractiveness. Among other reasons that reduce the attractiveness of the pharmaceutical market in Moldova we might cite the protectionism, a relatively low level of legal tools concerning intellectual property and limited reimbursement options.

According to official sources, including the Ministry of Health and Medicines Agency, over the past five years, a significant progress in combating trade of counterfeit medicines has been achieved, particularly of those that are imported into the country, and a major factor in this process was the introduction of automated accounting systems at over 90 of the pharmacies in the country. However, overall, the number of pharmaceutical institutions that are in charge of marketing pharmaceutical drugs in the local market is estimated at over 900 community units with branches. If we relate this to the size of population then a pharmaceutical unit would serve approximately 3,900 people on average, which is a relatively small level compared to Romania, where the same pharmacy serves nearly 2900 people on average.

According to several studies and analyses in the field, particularly those of the Centre for Health Policies and Studies⁴, the pharmaceutical market in Moldova consists of 85% of import drugs and about 15% of medicines are produced in the local market. Apparently the proportion may vary from year to year, but roughly speaking the current share is more or less suggestive. According to data of the Medicines Agency, on the Republic of Moldova market, there are currently

4 Health Monitor: Express Analysis „Effectiveness of policies to improve access to medicines through approval and registration of producer prices for medicines”, author Rita Seicas, February 2011.

operating about 30 pharmaceutical companies producing drugs.⁵

2. The legislative framework governing the pharmaceutical (drugs) market in the Republic of Moldova

In general, the access to basic medicines and pharmaceutical products in Moldova is implicitly guaranteed by the Constitution as part of citizens' rights to health. Or, ensuring that access to essential, efficient, safe and quality medicines for all categories of people is one of the responsibilities of the state⁶, under the *State policy in the field of medicine*⁷, approved in 2002 (Government Decision no. 1352 of 03.10.2002). According to Law on Healthcare no. 411 of 28.03.1995⁸ and the Law on pharmaceutical activity no. 1456 of 25.05.1993⁹, the prerogative of determining the way to provide the population with pharmaceutical drugs and products lies with the Government.

Also, the *State policy in the field of medicine* states that the Ministry of Health and the Ministry of Economy will promote the concepts of reducing costs, applying

5 <http://amed.md/Darea%20de%20seama%20AM%202011.pdf>

6 According to the WHO definition, essential drugs are those drugs that satisfy priority needs of the population.

7 <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=307874>

8 http://www.ms.gov.md/_files/982-legea%2520411.pdf

9 <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313276>

differentiated pricing mark-ups and other interventions designed to help reduce drug prices and ensure their economic accessibility. At the same time, under this policy, the government is committed to take steps including: “protecting the local producer of medicines” and “promoting the concept of reducing costs, applying differentiated price mark-ups and the like, designed to help reduce drug prices and ensure their economic accessibility”. Thus, besides the main laws there are more regulations and internal decisions, both of the Ministry of Health and the Medicines Agency, which regulate the pharmaceutical market in the Republic of Moldova.

In 2005 was created the Medicines Agency that is subject to the Ministry of Health and aims to achieve the policy in the field. The medicines policy addresses such aspects as *selection of essential pharmaceuticals, finance and pricing, procurement and distribution, efficient use of drugs, human resource development, pharmacovigilance* and other aspects. Within the Agency activates the Pharmaceutical Inspection that operates under art. 26 of the Law no.1456-XII of 25.05.1993 “On the pharmaceutical activity” and GD no.1252 of 01.12.2005 “On approval of Regulation, structure and staff limit of the Medicines Agency”. The main tasks which guide the activity of the inspectorate are:

- Pharmaceutical activity in pharmacies, regardless of legal form of organization and ownership;
- Pharmaceutical activity in pharmaceutical warehouses;
- Production of indigenous medicines;

- Quality supervision of indigenous and imported medicines.

So, broadly speaking, the legislative and regulatory framework of the pharmaceutical market in the Republic of Moldova is appropriate. However, a key issue that is not sufficiently regulated, as it is officially declared, is monitoring and policies impact analysis.

3. Developments and reforms in the field.

International experience

As we have mentioned in the summary, the pharmaceutical market in Moldova is made up of 85% of imported drugs and about 15% of drugs are produced by local companies. For example, the importation of drugs in 2009 was USD 140.7 million and in 2011 it increased to over USD 208 million.¹⁰ According to data collected by the Medicines Agency at the beginning of 2011, drugs imported and registered in the State Nomenclature for 2005-2010 were classified according to groups of countries as follows:

- Medicines produced by local companies - 14.4%;
- Medicines produced by companies from CIS - about 23%;

¹⁰ <http://www.marketresearch.com/Business-Monitor-International-v304/Moldova-Pharmaceuticals-Healthcare-Q3-7043895/>

- Medicines produced in Western Europe - 31%;
- Medicines produced in Central and Eastern Europe - about 15.6%;
- Medicines produced at the enterprises of Asian countries - 13%;
- Medicines produced by U.S. companies - about 2%;
- Medicines produced in other countries - about 1%.

Generally, this partition can vary from year to year, but overall 80% of medicines sold in the local market are imported and less than 20% are produced internally. So the situation is more or less suggestive. According to the market situation in early 2011, the drug supply system consisted of 71 pharmaceutical warehouses and nearly 900 community pharmacies with branches. We should mention that most pharmacies are located in cities and district centers and in many rural areas of the country they are practically absent. Some of the statistical data and media sources indicate that the number of pharmacies in rural areas is a little over 300 units.¹¹ The main reasons are their low profitability, continuing depopulation of villages, but also the lack or unwillingness of pharmaceutical professionals to work in rural areas.¹²

Also, provision of drugs to the population is carried out by about 1,050 sections of assistance with drugs of the Family Medical Centers (FMC) with its subsidiaries and by 76 pharmacies in public hospitals. According to “The Report” of the Medicines Agency

11 <http://www.europalibera.org/content/article/24291662.html>
 12 http://www.publika.md/sate-fara-farmacii--oamenii-se-trateaza-cu-ierburi-naturale_608621.html

for 2011 in Moldova are registered 28 local companies producing pharmaceuticals. The wholesale distribution system of pharmaceutical products includes a warehouse that is 99.11% state-owned.¹³

According to the *Law on pharmaceutical activity* only pharmaceuticals that are authorized and registered in the Medicines State Nomenclature (MSN) are permitted to be used in medical practice. This law also provides for some special cases of marketing of unregistered drugs on the pharmaceutical market. As legal support, Article 11 of this Law stipulates that unregistered products can be accepted on the market only in case of *disasters, catastrophes, epidemics, epizootics, mass poisoning*, and other cases that threaten human health, lack of analogues or substitutes on the pharmaceutical market. Drugs are approved for import in the country by the Ministry of Health Commission in charge of the authorization of imports of unauthorized medicinal products. Statistics indicate that by the end of 2011 in the MSN were registered over 6500 names of drugs.

Of course, one of the main reforms in this area refers to establishing drug prices. In 2010, the Government adjusted and amended the policy to control drug prices, approving the Regulation on the setting and recording producer prices on drugs (GD no. 525 of 22.06.2010). The decision specifies that since the fall of 2010 in Moldova is launched the registration procedure of the producer prices on drugs. It is worthwhile mentioning that Moldova was the only country in the region that, until the approval of this Regulation, had

13 Monitorul Sănătății: Analiză Expres, 2011 Health Monitor: Express Analysis, 2011

not had such a price registration procedure. Moreover, in order to avoid risks related to foreign exchange fluctuations, the producer price is registered at the beginning of each calendar year in MDL with reference to the currency proposed by the manufacturer (Euros or U.S. dollars), according to the exchange rate of NBM on the date of producer price registration.

In international practice there are known several methods to regulate drug prices, among which may be mentioned: a) registering producer prices, b) applying differentiated mark-ups c) negotiation of prices depending on the amount agreed for the contract; d) list of drugs reimbursed / compensated, whose prices are set in comparison with prices in different reference countries; e) regulating the prices of new or expensive drugs; f) freezing the prices of old drugs, etc..

However, the registering of producer prices which was accepted by the Republic of Moldova is a practice used by many countries. And, in taking the decision of approving the producer price, the countries that have accepted the practice of recording producer prices use different benchmarks. For example, Austria has used the maximum price justified by the economic situation of the country after consultation with the Committee on Prices in the country. Since 1999, in the result of amending the normative acts, the Ministry of Health sets the price only for the higher priced medicines. Greece sets the price for imported drugs, as compared with the lowest prices in the European Union.¹⁴

According to experts in the field¹⁵, the most recent amendments made in the regulations of Romania provide for the procedure of approval of producer prices, on the basis of comparing the price with the lowest price or at most equal with the average of three lowest prices of the same drug in the countries included in the list of reference countries, set by the Regulations on the mode of calculation of prices for medicinal products for human use. Basically, the legislation regulating drug prices in Romania is still being adjusted. As for the CIS space the latest amendments in the pricing regulations are in the Russian Federation. The legislative adjustments initiated by Russia are aimed at strengthening control over the essential drugs producer prices, by recording the producer price, complementary to regulation on the approval and recording of the mark-up size of distributors and pharmacies.

Thus, it is expected that eventually the reform would have an impact not only in terms of assistance with medications by community pharmacies, but also of supplying public medical institutions with medicines. In Moldova purchase of pharmaceutical products from public funds is governed by procurement procedures, annually being determined the suppliers for providing drugs for the next year. The timing of annual tenders includes the months from August to November, before the start of a new budget year. The main criterion in defining the tender winner is the offer, described as the most economically advantageous.

14 Ibidem.

15 Rita Seicaș, PAS Center: Health Monitor, Chișinău 2011

4. Methods of operation of medicines markets. Producers, intermediaries, prices.

On the pharmaceutical market in the Republic of Moldova there are about 30 companies producing drugs.¹⁶ Most of them are approved and certified by the Medicines Agency also as the main importers of drugs. However, despite the relatively large number of local producers and those that import drugs, public's general opinion is that prices offered by traders on the pharmaceutical market are quite high; particularly for some hard to find medicines, and sometimes artificial shortage situations are created for potential price increases.

Of course, this leads to inaccessibility of pharmaceuticals. The social impact of high prices is particularly strong given the fact that the representatives of some social groups, vulnerable from the economic point of view, including children and the elderly, particularly need pharmaceutical products. Periodically there is also the dissatisfaction about the quality of pharmaceutical products. The analysis of price dynamics over the last six years shows an almost constant increase in prices.

According to the National Bureau of Statistics, the growth rate of drug prices reached a record 29.2% in 2006, following application of 8% VAT on medicines. In the following four years

the average growth index of pharmaceutical prices was 11.8%, and in 2011 was recorded a price decrease of about 3%. "The report" of the Medicines Agency in 2011 indicates similar values regarding the increase in prices on the pharmaceutical market in Moldova¹⁷, including the statements by the officials of this agency.¹⁸ However, after several years of steady increase in prices, in 2011 prices for drugs were 3.4 times higher than in 2000. For comparison, the general index of consumer prices in 2011 was 2.7 times higher than in 2000; thus, it is clear that drug prices rose by pace. In 2012, the first two months were characterized by a slight decrease in drug prices (-0.3% monthly average), effects that were subsequently lost due to price increases by 1.2% in March-April.¹⁹

The Law on pharmaceutical activity, provides the mechanism of operating and setting of drugs prices. This mechanism provides for a mark-up of up to 40% to the free delivery price of domestic producers or to the purchase price from the manufacturer (retailer) from abroad, of which: a) up to 15% for businesses that import drugs, regardless of the number of intermediaries; b) up to 25% for pharmacies. Previously, we mentioned the new regulation of registration of the producer price. Or, under this Regulation, at the stage of introducing the product on the Moldovan market; it is required to be considered the reference price of 15 European countries. Of these, three countries are selected, where the

¹⁶ <http://www.scribd.com/doc/74296856/Lista-intreprinderilor-farmaceutice-produc%C4%83toare-de-medicamente-din-Republica-Moldova>

¹⁷ <http://amed.md/Darea%20de%20seama%20AM%202011.pdf> (pag. 26)

¹⁸ <http://allmoldova.com/ro/int/interview/rita-seicas-081211.html>

¹⁹ Terms of reference. Analysis of regulatory transparency and efficiency in the pharmaceutical market, June 2012, www.soros.md

product is marketed and where the price is lower and finally its average is deducted. The same procedure applies for products from the CIS space, where as the reference countries are taken the Russian Federation, Ukraine and Belarus. Another aspect specified in the Regulation on the mode of approval and registration of drugs producer prices is the criterion for price evaluation and approval of the generic drug. The Government Decision no. 525 of 22.06.2010 states that generic drug price will be worth up to 65% of the original drug.

The prices issue on the pharmaceutical market in Moldova was addressed at the governmental level in May 2010, in particular by the Prime Minister, amid continuing price increases for medicines.²⁰ These were considered publicly²¹ and there were discussed the results of a market analysis during which it was found that *„on 22 items of drugs that are sold in Moldova and Romania, in some cases, the price difference might reach up to 862%”*. At the same public meeting it was stated that *„the Republic of Moldova is the only state in the region where, at the beginning of the year, the producer drug prices are not made public, and this allows speculation on the sale price of drugs”*. For these reasons, the Ministry of Health has proposed Government adoption of that Regulation, mentioned in this analysis, on setting and monitoring drug prices.²²

5. Some clichés of the pharmaceutical market in Moldova.

Even if the population tries to save, sometimes at the expense of health, the medicines are a product that enjoys a continuously high demand, not very dependent on price changes. This creates very strong assumptions and incitation for corrupt arrangements leading to the establishment of unusually high prices for drugs in Moldova. These incentives are compounded by the fact that 80% of medicines consumed in Moldova are imported, making these products vulnerable to some systemic problems facing Moldova in facilitating international trade (including corruption within bodies that should facilitate international trade).

Thus, the main objective the Government has set for itself in the pharmaceutical field is to establish real prices and provide population with quality medicines by strengthening institutional capacity, and formulating more clear regulations. To achieve these objectives by a government decision was adopted the National Catalogue of Prices (NCP) on drugs. Another measure taken to counter “illegal import schemes” was the decision in September 2010 to create the Service of making public and monitoring drug prices, whose tasks also include keeping the National Catalogue of Prices (NCP) on drugs. By using eminently administrative instruments, and without trying to consult parties involved,

20 Ibidem.

21 <http://gov.gov.md/md/comunicate/?nid=9039579&y=2010&m=05&p=3>

22 <http://www.amed.md/hotarire525.pdf>

the government's intervention has generated discontent reaction from some important players in the industry, including from an association of pharmacists, as well as from some importers.²³

The operative investigations of the control bodies show the presence of fraudulent schemes that lead to unjustified increase in prices for medicines. In this way, the prices of drugs in Moldova are several times higher than those in neighboring countries. The events covered are a form of „legalization” of the activity to circumvent the requirements of the pricing on the drug market in Moldova and undermine the state policy in providing people with effective, quality and affordable drugs.

However arrangements do exist, given the fact that the pharmaceutical market is one of the most profitable. Recent cases of resonance²⁴ and journalistic investigations²⁵ reveal cartel agreements and fraudulent schemes, both in terms of import and marketing of pharmaceutical products on the local market. So the procedure of registration of producers' drug prices might allow ensuring state control over prices in the domestic pharmaceutical market. The new Regulation establishes that manufacturers or their representatives declare prices at the beginning of each calendar year and, respectively, it is expected that the problems related to the „offshore” activities, through which a large part of drugs on the domestic market is imported, will disappear.

23 Ibidem.

24 <http://www.union.md/uinfo/actual/dezvaluire-socante-despre-piata-farmaceutica-din-r-moldova>

25 <http://dreptate.md/article/show/62/cadouri-de-milioane-pentru-regii-pastilelor-din-moldova>

6. Conclusions and recommendations

There is no doubt that the Government's initiative to improve access to medicines by improving the regulatory framework aimed at regulating prices is welcome. However, according to the experts in the field, the introduction of the procedure of declaring the producer's price and its recording in the National Catalogue of Prices, was carried out without a comprehensive assessment of the relevance of the mechanism borrowed from international practice to be applied in the Republic of Moldova, including the factors determined in selecting the method of price setting and controls.²⁶ Broadly, the reform refers to only one aspect (i.e. price controls) to increase accessibility to drugs, which is not sufficient without addressing other factors (prescription, opting for essential medicines, extension of compensated medicines list, etc...).

The regulatory framework on public procurement of medicines is incomplete. The Medicines Agency cannot fully ensure the proper activity of centralized public procurements of drugs, taking into account that the Pharmaceutical Inspectorate is part of the Agency, and the latter is often accused of conflict of interest. In addition, the reform implementation was realized with deficiencies in management and communication which have created tension among all participants in the supply system with drugs: pharmacies, warehouses and public medical institutions

26 Health Monitor: Express Analysis, 2011

and patients as well. Also experts believe that the selected mechanism for regulating prices has several risks, including: decrease and change of the range of drugs; disappearance of some vital drugs; decrease in the number of registered producers and respectively reduction of competition; a potential disappearance from the market of the cheap drugs due to the shift to the expensive ones, etc..

The Government should take further measures to ensure population's access to medicines by refocusing policy of recording the producer price primarily for drugs compensated by NCMA, with subsequent extension over the list of essential medicines. Despite all divergences, the reform launched has to be continued, with complex analysis to

improve tools regulating prices and avoid potential risks mentioned above. The list of compensated medicines for diseases affecting the public health should also be extended. Great attention should be paid to the price regulation mechanism. Thus, along with the producer price controls also to implement other tools to regulate drug prices, in particular to provide a differentiated VAT and set differentiated trade mark-ups. A special emphasis should be put on developing institutional capacities of the Medicines Agency, in particular, to find methods to counter the conflict of interests within the MA in the medicines procurement process, including the mechanism of establishing transparent, fair and honest assessment criteria of the bidders.



NOTE

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