THE USV ANNALS OF ECONOMICS AND PUBLIC ADMINISTRATION | VOLUME 20, ISSUE 1(31), 2020

# SOME CONSIDERATIONS REGARDING THE PRICE SETTING OF MEDICINES IN THE REPUBLIC OF MOLDOVA

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**Abstract:**

*In this article, the authors describe some approaches to medicine price formation in the Republic of Moldova. Following the study, we can say that the health system of the Republic of Moldova (Moldova) is part of the social sphere, and medicines are an important element in the treatment of various diseases. Thus, at the same time with the reform actionsand development of the pharmaceutical sector, a high-priority issue is the price setting of medicines, which is influenced by a number of factors. The research was based on the multitude of normative acts and the specialized literature, where the priority problem was established - the development of the pharmaceutical sector.*

*The authors, through this research, using the methods of observation, analysis and deduction, aimed to analyze the normative basis at national level and the literature, to distinguish some problematic aspects in the field, to estimate the current state of medicine pricing quality. In order to achieve this goal the authors used the following methods: analysis, observation, comparison, etc. The following indicators were analyzed in this paper: the indicators on healthcare expenditure in the consolidated budget; the fundraising mechanism to support the activity of the health sector; the dynamics of the development of the medical institutions network in the Republic of Moldova; the mechanism of supply and regulation of medicines.*

**Key words:** medicines, price, compulsory health insurance, health system.

**JEL classification:** M40, M41

## 1. INTRODUCTION

The health system of the Republic of Moldova (Moldova) is a component part of the social sphere that aims to ensure the health of the whole society and of each citizen, as well as to prolong the longevity of human life (Safta, Brumărel, 2012). Its development imply the medical assistance of the citizens on the principles of equality. Medicines are an important element in the prophylaxis, diagnosis and treatment of various diseases. The coordinated development of the pharmaceutical sector, especially in relation to its social importance, is one of the high-priority issues of health care. The state policy in the field of medicine is an important component of the national health policy (HP RM no.1352 of 03.10.2002).

The Republic of Moldova has promoted fundamental reform actions in the medical system, in order to obtain performance. These reform actions were based on new principles of financing and organizing primary and secondary health care, with the beginning of the development of private medicine, etc. They included the gradual transition from the stage of providing health care services provided entirely free of charge by the State to the stage of providing the minimum free medical care guaranteed by the State, in parallel with the provision of paid medical services.

*The importance and actuality of the study* is conditioned by the abundance of changes in national legislation, which requires complex investigations into the mechanism of medicine pricing and its reflection on accounting, as medicine prices rise at a staggering rate and pharmaceutical companies spend more money on advertising than research. In this context, the article reflects an

examination through a normative investigative technique. This implies an analysis in the light of the national accounting, fiscal, medicinal, pharmaceutical provisions.

*The purpose of the research* is to investigate the composition of medicine pricing and ensure the medication process of each individual with effective, harmless medicines and at a fair price established according to the legislation of the Republic of Moldova.

To achieve this goal, the authors set themselves the following objectives:

- to provide a research on national legislation on price formation for domestic and imported medicines.
- to distinguish the problematic aspects and their causes in establishing the price of medicines.
- to study the normative regulation regarding the evolution and the size per capita of the compensating medicines within the Compulsory Medical Assistance Fund.
- to estimate the de facto state, quality and coverage of the legislation on medicine price formation in the Republic of Moldova.

## 2. RESEARCH METODOLOGY

For this research, we have made a documentary investigation of the legislative and regulatory acts in force, using an evolutionary approach based on methods of observation, document analysis and comparison of regulations in the field of pricing for domestic and imported medicines. *The research support* included the study of the following normative acts of major importance: Regulation on authorizing the import of medicines, Order of the Ministry of Health of the Republic of Moldova, on the Regulation of authorizing the import of medicines, other pharmaceuticals, parapharmaceuticals and unauthorized medicinal raw materials in Moldova; The Regulation on the prices formation for medicines and other pharmaceutical and parapharmaceutical products, the Government Decision on the approval of the Regulation on the prices formation for medicines and other pharmaceutical and parapharmaceutical products; State policy in the field of medicine, as well as the State Nomenclature of medicines, etc.

The beginning of any scientific approach is the directing of general research attention to the sphere of scientific knowledge divided into specific research areas. The research area of this paper was the issue of medicine price formation, a topic that can be included both in the field of accounting research and medical research. In the foreign literature, this field was developed more deeply by Russian economists (Parhomenko, 2005), (Ivanov, 2008), by Romanian economists (Pătrușcă, 2018). The academic research environment in the Republic of Moldova, capitalized on this topic in the works of teachers (Safta, 2016), (Buliga, 2016), (Preașcă, 2017), (Chițan, 2016), (Brumărel, 2014).

## 3. BASIC CONTENT

The health system in the Republic of Moldova aims to ensure fair and non-discriminatory access to a package of health services for the entire population of the country. One of the basic pillars of the health system is the compulsory health care provision (CHCP) (NHIH, 2018). In order to achieve the objectives of the CHCP, the Compulsory Health Insurance Fund (CHIF) is created, which is managed by the National Medical Insurance Company (NMIC).

The main indicators related to the compulsory health insurance system are presented in dynamics in table 1.

**Table no. 1. Indicators of health care expenditure in the consolidated budget**

| Indicators | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|
| CHIF expenses, thousand lei | 4679,5 | 5152,5 | 5673,4 | 6260,8 | 6714,1 |
| Share of expenditures in GDP,% | 4,2 | 3,5 | 3,5 | 3,5 | 3,5 |
| Share of expenditures in the National Public Budget,% | 79,4 | 79,8 | 87,2 | 86,1 | 86,1 |

Source: http://cnam.md/httpdocs/editorDir/file/RapoarteActivitate_anuale/2019/Raport_anual_2018.pdf

The table above shows that CHCP expenditures increased dynamically by 1.4 times, although as a share of total public expenditures and GDP they remained the same.

For the human being, health is a vital value that occupies the highest step in the hierarchy of values, as well as in the system of categories of human existence, an asset necessary to achieve its creative potential throughout life (Buga, Damascan, 2013).

One of the peculiarities that influences the economic and accounting system of the medical entities **is the fundraising mechanism to support the activity of the health sector.**

The main sources of funding may be taxes, social security contributions, private insurance premiums or direct payments from consumers. There may be other sources such as external funding in the form of grants and subsidies. Most systems are mixed, so it is impossible to place an entire country in a certain category.

If the sources of funding are fees and taxes or health insurance contributions, a third party pays between the patient and the provider. In the real situation, most health systems have a mixed financing, but the typology of the system is given by the predominant financing method. Given the importance of financing of the health system for the performance of other functions, as well as the impact it has on the performance of the health system, financing is the main criterion for classifying health systems.

In accordance with the Health Care Law no. 411-XIII of March 28, 1995, medical institutions may be **public or private**, except for those which, in accordance with the legislation in force, can only be public (figure 1).

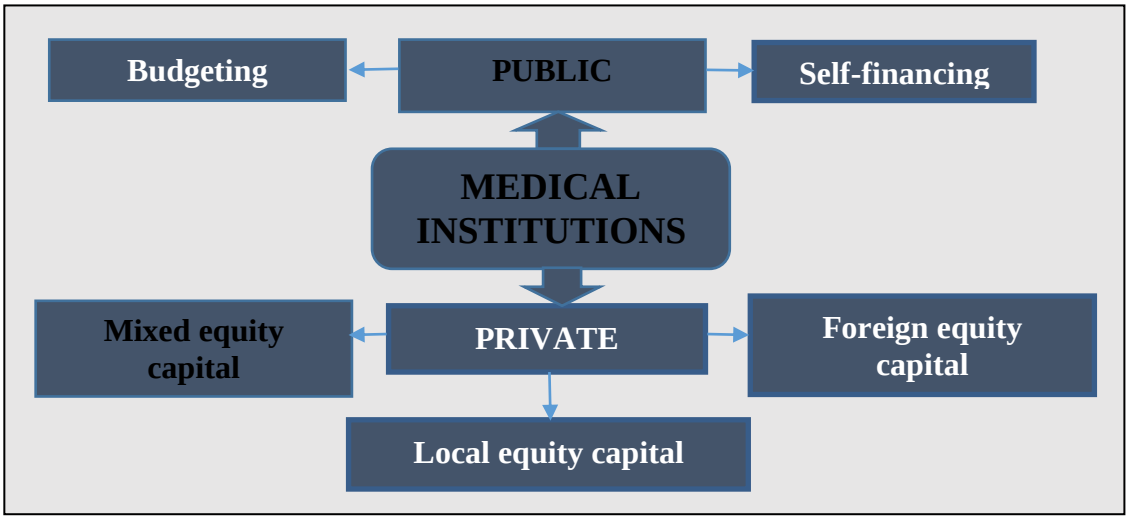


**Figure no. 1. Classification of medical institutions according to the form of ownership**
Source: developed by the authors on the basis of 6.Legea ocrotirii sănătăţii nr.411-XIII din 28 martie 1995. În: Monitorul Oficial al Republicii Moldova, 1995, nr.34, art.373

The health system of the Republic of Moldova is composed of all medical institutions and enterprises, medical staff, additional and maintenance services, necessary information, medical and information technologies, scientific researches in this field and the most important component - the human with his individual health that should be the first and most important protector and promoter of his own health. The dynamics of the network of medical institutions is shown in diagram 1.

A problem is **setting medicine prices.** *Medicinal products* are substances or mixtures of authorized substances, in the prescribed manner, for manufacture, import, export and use, to treat, alleviate, prevent, diagnose a disease, an abnormal physical or mental condition or their symptoms for humans, or animal, as well as to restore, correct and modify their organic functions (Law no. 1409 of 17.12.1997).

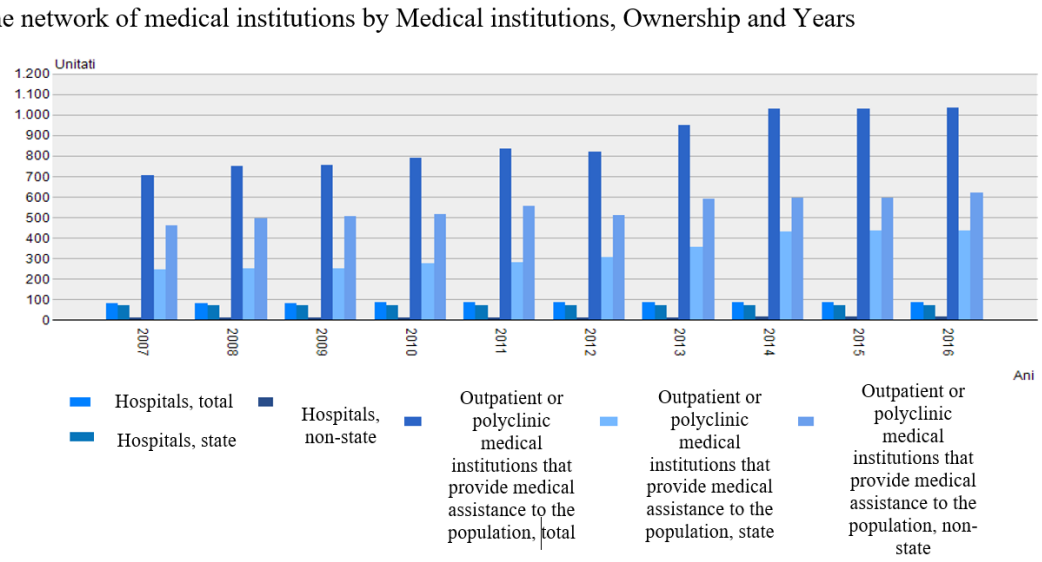


**Figure no. 2. Dynamics of the development of the medical institutions network in the Republic of Moldova**

Source: developed by the authors based on http://www.statistica.md

Medicine pricing is one of the most complex and difficult processes. In the conditions of transition to the market economy this process becomes even more difficult due to the influence of the essential changes that take place in the health system, in the social and economic life. The process of creating the single pharmaceutical market in Europe is taking place, which is why the European Economic Community (EEC) has issued Directive no. 89/105 EEC "On obvious and precise measures to regulate the formation of prices for production used in medicine and on their inclusion in the competence of the national systems of insurance medicine".

The policy of most states in the field of medicines prices regulation is reduced to the protection of the manufacturer and the consumer and the limitation of the intermediaries actions, because the decrease of production reduces the amount of tax revenues in the state budget. At the same time, price formation is not free in any country in the European Community. In both medicine circulation systems (wholesale and retail) certain regulations are laid down.

According to Law no. 1409 of 17.12.1997 regarding medicines in the Republic of Moldova, is used the A.T.C. (Anatomical Therapeutic Chemical) classification of medicines, proposed by the World Health Organization. Medicines are classified into:

a) prescription medicines;

b) medicines without prescription.

The monitoring, state control and supervision of the activity in the field of medicines is exercised by the Agency for Medicines and Medical Devices, Law no. 1456 of 25.05.1993.

All medicines that are sold in the Republic of Moldova must be registered in the National Catalog of manufacturer's prices for medicines, which is an official register were are recorded the manufacturer's prices for medicines. According to the Catalog, the prices can be at manufacturer's prices for both imported and local medicines. The manufacturer's price for medicines, which is included in the Catalog, is the average price for medicines calculated on the basis of the three lowest manufacturer's prices in the countries with which it is compared and does not coincide with the price in pharmacies.

Medicines should only be sold at the price set by law. The agency has the responsibility to control the correctness of the price formation of medicines and to sanction people (pharmacies) who do not comply with the legislation. To ensure the possibility of tracking the medicine, each package has a registered bar code, which offers the possibility to check the medicine and manufacturer's price, comparing it with the one in the Catalog. If the medicine is not included in the catalog, the

person can submit a petition to the Agency and request the verification of the product and the sanction of the respective pharmacy.

Prices for medicines are established by the enterprises and pharmaceutical institutions of the Republic of Moldova (manufacturers, warehouses, pharmacies and their subsidiaries) in accordance with the provisions of the Regulation on the approval and registration of manufacturer's prices for medicines, approved by Government Decision no. 525 of June 22, 2010.

Prices for medicines and other pharmaceuticals and parapharmaceuticals (hereinafter - medicines) are set by the pharmaceutical companies as follows:

- medicines produced in the Republic of Moldova are sold on the domestic market at delivery prices, with the application of the commercial surcharge. The commercial addition covers the operational, investment and financial expenses;
- the imported medicines are traded on the territory of the Republic of Moldova at purchase prices, with the application of the commercial surcharge.

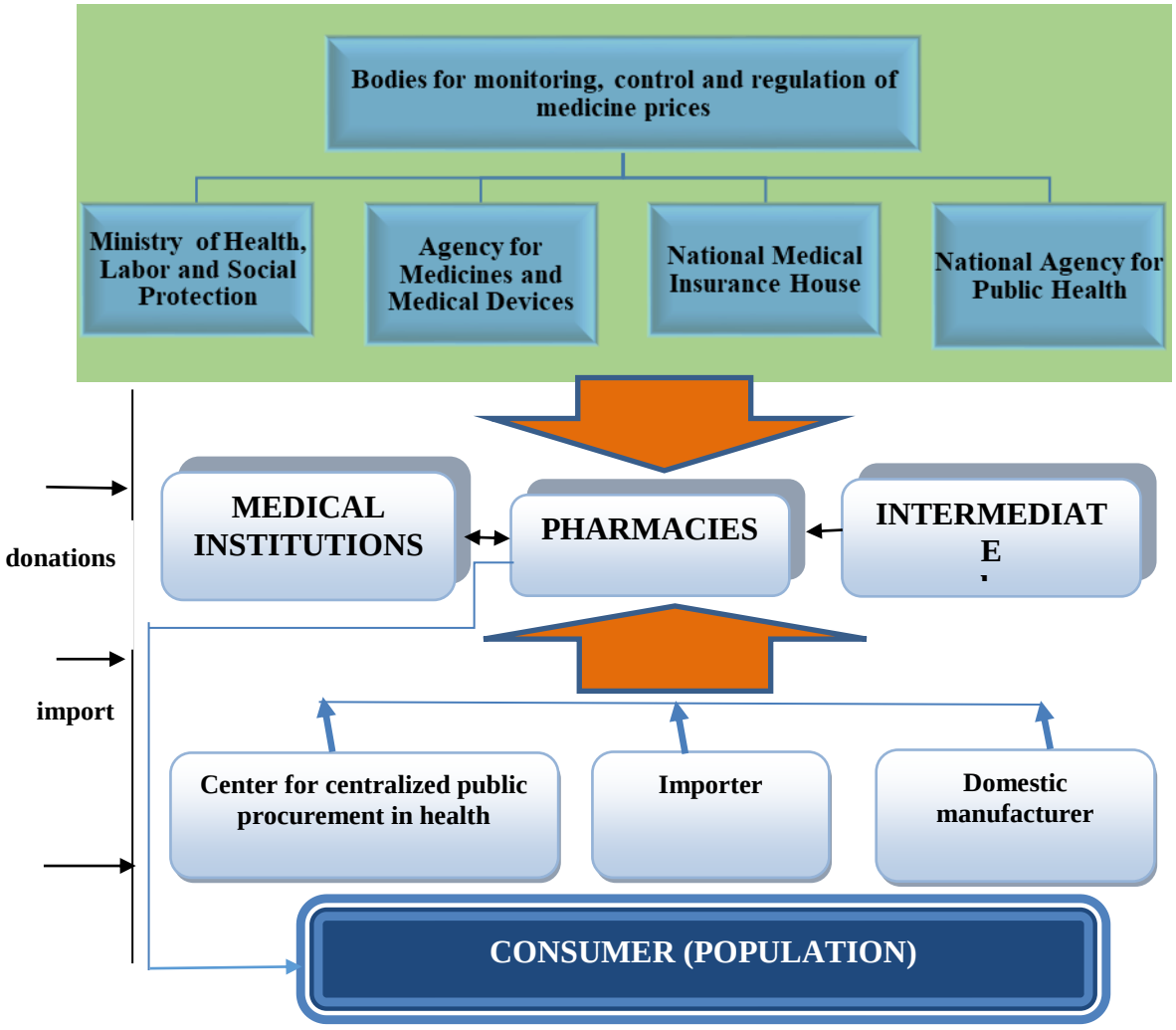


**Figure no. 3. Mechanism for the supply and regulation of medicines**

Source: developed by authors

The price at which medicines can be sold is formed on the basis of the rules established in the Regulation on the formation of prices for medicines and other pharmaceutical and parapharmaceutical products, approved by GD no. 603. It provides that imported medicinal products are traded on the territory of the Republic of Moldova at purchase prices, with the application of the trade surcharge, which may not exceed 40% of the purchase price from the manufacturer. That increase is divided between the pharmacy and the company that imported the medicine, of which 15% belongs to the importing company and 25% to the pharmacy.

The sale of medicines at a price other than the one established by the legislation is complicated, because all pharmacies are obliged to use an information system for the circulation of medicines, which ensures the record of prices. However, if the obligation to sell medicines at prices calculated in accordance with the rule described is violated, there is the possibility of sanctioning pharmacies and their managers by imposing fines under the provisions of the Contravention Code (art. 77) and even by revoking the license pharmacy activity. The person concerned may notify the Agency of the existence of infringements and request the sanction of the pharmacy concerned, as well as its managers.

When selling medicines, pharmaceutical companies indicate in the primary documents with special regime the delivery price of domestic medicines or the purchase price of imported medicines, the size of the commercial surcharge applied, the serial number of the product, the number and date of the document certifying its quality, issued by the Medicines Agency. The mechanism of supply and distribution of medicines is shown in Figure 3.

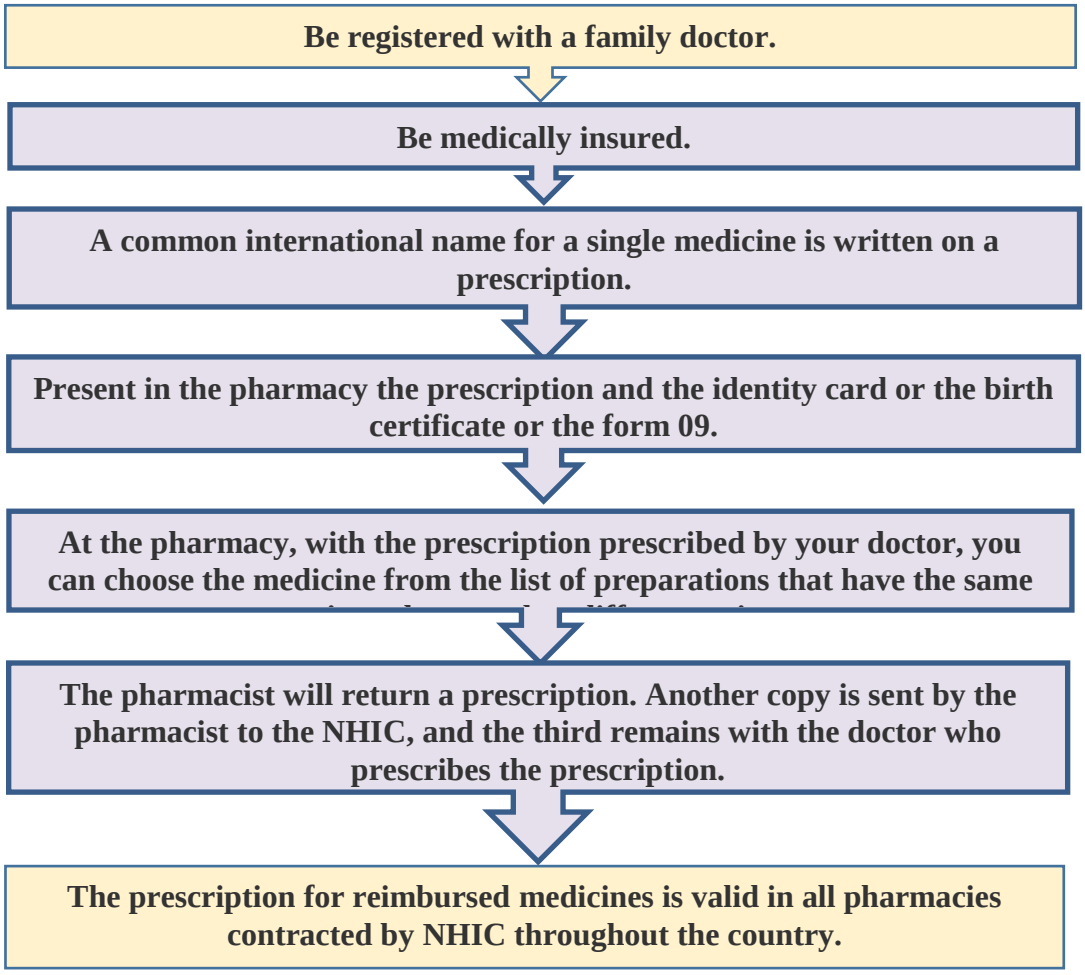


**Figure no. 4. Classification of medical institutions according to the form of ownership**

Source: developed by the authors based on www.cnam.md

In the Republic of Moldova, some medicines are partially or fully reimbursed by the National Medical Insurance Company (NHIC) based on the Order of the Ministry of Health and Social Protection No. 492/139 of 22.04.2013 regarding the medicines compensated in the funds of the obligatory medical assistance insurance. The list of reimbursed medicines has been extended from October 1, 2016 to 137 international common names. These are prescribed in long-term outpatient treatment, and from October 1, 2016 and in episodic treatment performed in day care, procedure offices, at home. For adults, the medicines are partially compensated, in proportion of

70% for the treatment of acute conditions in day care, procedure rooms, at home and 30%, 50%, 70% and 100% - in case of chronic diseases. Reimbursed medicines may benefit from:

- children up to 18 years old;
- pregnant women (for the prophylaxis and treatment of anemias, prophylaxis of malformations);
- people with acute and chronic diseases, such as: diabetes and its complications, anemia, asthma, cardiovascular, ophthalmological, respiratory, mental and neurological diseases, endocrine, digestive system, urinary tract, rare diseases such as bullous epidermolysis, multiple sclerosis , cystic fibrosis, myasthenia gravis, systemic and autoimmune diseases, depression, Alzheimer's disease. In order to benefit from reimbursed medicines, it is necessary to follow the following steps (figure 4).

The procedure for drawing up and amending the List of reimbursed medicines from CHIF, the criteria for inclusion and exclusion from the List, the way of organizing the activity of the Council and the Secretariat for reimbursed medicines from the compulsory health insurance funds, the principles of compensating medicines Regulation on the mechanism for including medicines for compensation from MHI funds approved by Order 600/320 of 24.07.2015 of the Ministry of Health and NHIC. Responsible for making the decision to include a medicine in the list of reimbursed medicines from the MHI funds is by majority vote the Council for reimbursed medicines from the compulsory health insurance funds, established by the joint order of the Ministry of Health and NHIC. In order to include a medicinal product in the list of those reimbursed from MHI funds, the application shall be submitted by the manufacturer or his official representative, or the undertaking importing and / or distributing the medicinal products. qualitative and cost-effective which correspond to the principles stipulated in the regulation (the principle of human value, the principle of necessity and solidarity, the principle of cost-effectiveness and the principle of transparency), correspond to the requirements:

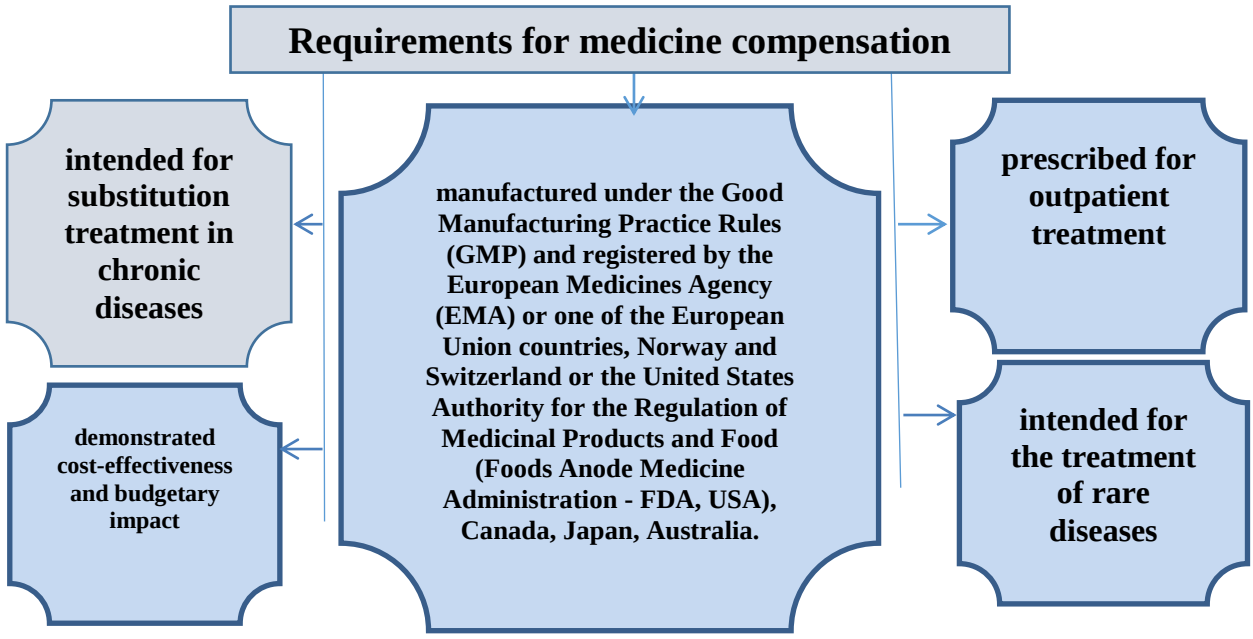


**Figure no. 5. Requirements for reimbursed medicines**
Source: developed by the authors in the database

Ensuring patients with safe, cost-effective and quality reimbursed medicines, increasing the number of beneficiaries by expanding the list of new diseases remain among the main priorities for the Company. In this respect, CHCP expenditures for reimbursed medicines amounted to about 508 million MDL, increasing by 19.5% compared to 2016 (425 million MDL), so the main indicators that characterize are presented in Table 2.

**Table no. 2. Characteristic indicators of reimbursed medicines**

| | Indicators | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|---|
| 1. | Expenses for reimbursed medicines (million lei) | 205,9 | 279,7 | 425,0 | 523,9 | 508,0 |
| 2. | Number of compensated recipes paid (thousands of recipes) | 3 476,9 | 3678,6 | 4593,6 | 5506,6 | 5260,4 |
| 3. | Average amount compensated for a prescription (lei) | 83,1 | 106,4 | 113,7 | 119,1 | 112,0 |
| 4. | Contracted medical and pharmaceutical institutions (No) | 673 | 690 | 692 | 698 | 691 |

Source: developed by the authors based on www.cnam.md

Contracted pharmaceutical institutions issued reimbursed medicines based on more than 5 million prescriptions or 666.8 thousand more prescriptions than in 2016. As a result of the decrease in medicine prices, there was a decrease in the average retail price for reimbursed medicines per prescription, respectively increased the average amount of compensation for a prescription. Thus, the average retail price for reimbursed medicines per prescription decreased from about 119 MDL in 2017 to 112 MDL in 2018, and the average amount of compensation for a prescription increased to 96.6 MDL, which is a benefit for patients, in the context of medical expenses incurred, due to reduced payment for reimbursed medicines.

Over the last three years, the list of reimbursed medicines has been expanded from 88 common international names (INNs) to 148 INNs. Respectively, the list was supplemented with new diseases: obstructive bronchopneumonia, osteoarthritis, rheumatoid arthritis, gout, depression, Alzheimer's disease. Referring to the structure of expenditures for reimbursed medicines covered by CHCP, we conclude that the largest share belonged to preparations administered for the treatment of chronic diseases - 82.8%, namely cardiovascular disease and diabetes. Thus, the financial means allocated for the treatment of cardiovascular diseases with compensated medicines amounted to 215 million MDL, which benefited 431,646 patients, about 61% of all patients suffering from cardiovascular diseases.

## CONCLUSIONS

Prices for medicines and other pharmaceutical products are established by the pharmaceutical companies of the Republic of Moldova and are sold on the domestic market at delivery prices, with the application of the commercial surcharge. The imported medicines are traded on the territory of the Republic of Moldova at purchase prices, with the application of the commercial surcharge.

Based on the monitoring of medicine prices by AMMD, to strengthen the continuous improvement of the medicine pricing system aimed at increasing their economic accessibility.

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