THE PHARMACEUTICAL REFORM IN THE REPUBLIC OF MOLDOVA DURING THE PERIOD OF INDEPENDENCE

Over the last two decades, the Republic of Moldova has gone through a complex and controversial way of its development. Determining its vector of development based on the democratic values of Western culture the legal framework has been practically completely revised and created. The concept of reforming the pharmaceutical sector in the Republic of Moldova included: liberalization of prices and freedom from the planned system of economic management while creating the necessary mechanisms for the functioning of the market economy – creating the banking system, establishing the capital market, introducing the national currency, creating other institutions, as well as the huge process of creating a new legal framework.

Aim. To analyze the main pharmaceutical reforms carried out in the Republic of Moldova during the period of independence, highlight their impact on the expected effects and develop recommendations for improving of the pharmaceutical care.

Materials and methods. As the research tools, analytical and sociological methods (questionnaire) were used.

Results. The survey involved employees with at least 25 years of work experience who had certain professional competencies: a higher professional category, published scientific articles or an academic degree, work experience in the coordination and control system, as well as experience as a head of a pharmaceutical enterprise/organization. As experts 93 specialists were selected, including pharmacists: 7 Doctors of Medicine, 5 specialists with the published scientific papers, 78 holders of the higher professional category, 3 – former and current officials with experience in the coordination and control system. After the survey, the experts analyzed the main pharmaceutical reforms taken place in Moldova over 25 years (1990-2015).

Conclusions. It has been shown that the negative impact of pharmaceutical reforms exceeds the positive impact by 1.46 times. Recommendations have been developed and proposed for: elimination of the negative consequences of pharmaceutical reforms; the study / the possibility of initiating a number of pharmaceutical reforms/regulations proposed by the experts who participated in the study.

Key words: pharmaceutical reform; pharmaceutical system; pharmaceutical services; competence; degree of the reform achievement; drug consumer.
Over the last two decades, the Republic of Moldova has gone through a complex and controversial way of its development. Becoming a sovereign state, the “democratic” centralism was soon abandoned; the administrative management system of the “coordinated” economy was destroyed.

Determining its vector of development based on the democratic values of Western culture the legal framework has been practically completely revised and created.

In the context of the economic transition, the reforms had to be implemented in accordance with the following principles: liberalization, privatization and creation of institutions and mechanisms of the market economy.

The concept of reforming the pharmaceutical sector in the Republic of Moldova included: liberalization of prices and freedom from the planned system of economic management while creating the necessary mechanisms for the functioning of the market economy – creating the banking system, establishing the capital market, introducing the national currency, creating other institutions, as well as the huge process of creating a new legal framework. By reviving private property, there was a massive privatization of state property, which constituted the essential foundation for the starting of reforms in the national economy and the society as a whole.

The pharmaceutical system, as well as the entire health system, is a subject for several studies. The concept of the pharmaceutical reform as a part of the economic reforms in Moldova was presented in the article. The main idea of the reform was to implement the needed changes in the country’s health system, which included liberalization of prices and freedom from the plan, introducing the national currency, creating other institutions, as well as the huge process of creating a new legal framework. By reviving private property, there was a massive privatization of state property, which constituted the essential foundation for the starting of reforms in the national economy and the society as a whole.

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reforms, which can be classified into four groups [1] depending on the factor that has conditioned them:

- changes in medicine and healthcare;
- the results of scientific research;
- changes in the social and economic life of the country;
- recommendations or requirements of international institutions.

Throughout the years, the process of reforming of the pharmaceutical system of the Republic of Moldova has faced and continues to face many problems: obstacles, barriers, opposition, nonconformities, etc. However, some positive, successes, small victories have been achieved.

Some analyses have been carried out and identified various specific problems hindering the effective development of the pharmaceutical reform [2-5], but a comprehensive analysis that would highlight the situation regarding the evolution of the pharmaceutical reform in the Republic of Moldova has not yet been done.

The aim of this study was to analyze the main pharmaceutical reforms carried out in the Republic of Moldova during the period of independence, highlight their impact on the expected effects and develop recommendations for improving the pharmaceutical care.

**Material and methods.** Considering that the study is oriented towards the appreciation of the pharmaceutical reform during the period of independence of the Republic of Moldova we propose to argue a variant of the questionnaire method, which would correspond to the designated purpose. Thus, it is logical to involve in the process of questioning the experts, who have work experience for at least 25 years, i.e. the professional activity in the pharmaceutical domain during the entire period of reforming of the pharmaceutical system under the conditions of independence. The requirement for the selected experts concerned the level of professional competence: a higher professional category, published scientific articles or an academic degree. Additionally, the priority was given to the experts with work experience in the coordination and control system, as well as experience as a head of a pharmaceutical enterprise/organization. Applying the above requirements, 93 pharmacy professionals were selected as experts, including:

- Doctors of Medicine and Pharmacy – 7;
- specialists with the published scientific papers – 5;
- holders of the higher professional category – 78;
- former and current officials with experience in the coordination and control system – 3.

Expert questionnaires filled out by 93 pharmacists experts served as the research material. 100 questionnaires were distributed, 7 were canceled for various reasons (incomplete, inadequately completed, unclear).

The questionnaire consisted of 3 sections. The first section listed 10 reforms of the pharmaceutical system:

a) privatization of pharmacies and liquidation of the state pharmaceutical sector;

b) the permission to create a community pharmacy for people without a pharmacy qualification;

c) a warehouse permit for a pharmacy chain;

d) the transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber;

e) application of accreditation of pharmaceutical companies;

f) reorganization of NIF into AM (AMDM);

g) provision of basic pharmaceutical services;

h) application of the CTD format in the process of drug authorization;

i) changing the pricing system for medicines;

j) implementation of good practice rules (GMP, GDP).

In the second section of the questionnaire the experts assessed the level of implementation of these pharmaceutical reforms using the following scale: A – achieved; P – in the process of implementation; H – come to a halt; NA – not achieved.

After completing the last section we assessed the impact of all pharmaceutical reforms by applying the following qualifications: S – successful; M – moderate; Z – zero; D – destructive; PI – in the process of implementation; NC – not the case.

**Results and discussion.** The first 6 reforms included in the questionnaire to assess their
The degree of their implementation were identified by all experts as “achieved”: privatization of pharmacies and liquidation of the state pharmaceutical sector; the permission to create a community pharmacy for people without a pharmacy qualification; a warehouse permit for a pharmacy chain; the transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber; application of accreditation of pharmaceutical companies; reorganization of NIF into AM (AMDM).

The introduction of basic pharmaceutical services regulated by the Order of the Ministry of Health of the Republic of Moldova No. 489 dated 15.07.2010 [6] was evaluated differently (Fig. 1): 55 experts (59.14 %) considered that this reform was in the process of implementation, 33 (35.48 %) noted that the reform was at the “come to a halt” stage, meaning the complexity of the implementation of basic pharmaceutical services (BPS). However, 3 specialists (3.23 %) considered that BPS as a pharmaceutical reform was not achieved, and 2 experts (2.15 %) rated it as a goal achieved.

Application of the CTD format in the process of drug authorization regulated by the Order of the Ministry of Health of the Republic of Moldova No. 739 dated 23.07.12 [7] accumulated 2 evaluation criteria (Fig. 2): achieved – 36 experts (38.71 %) and in the process of implementation – 57 experts (61.29 %).

The reform in the pricing system for medicines is of particular interest. It is noted that over 25 years the pricing of medicines in the Republic of Moldova has changed and been completed 16 times: Resolution of the Parliament (RP) 1072/27.12.1996; Government Decision (GD) 603/02.07.1997; 533/11.06.1999; 1282/19.11.2001; 85/25.06.2006; 491/14.06.2010; 525/22.06.2006; 720/10.08.2010; 1115/06.12.2010; 259/21.12.2010; 63/04.02.2011; Law 60/01.04.2011; GD 32/12.01.2012; 403/13.06.2012; 868/19.11.2012; Law 150/30.07.2015 [7-20].

The experts assessed 3 criteria the degree of achievement of the reform in the pricing system for medicines (Fig. 2).

The majority of experts (73.12 %) considered that the reform of the pricing system for medicines was in the process of implementation. 22.58 % of the experts thought that this reform was at the “come to a halt” stage, while 4.3 % of the experts still believed that it had been achieved.

The last proposed reform was the implementation of good practice rules (GMP and GDP) in the pharmaceutical activity (Fig. 3).

Regarding this parameter, the opinions of expert pharmacists were divided into three evaluation criteria: most of them considered that the introduction of the GMP and GDP rules was in the process of implementation (79.57 %), 16 experts believed that this reform was at the “come to a halt” stage (17.20 %), and only 3 experts (3.23 %) considered that the process of reforming the pharmaceutical system through the implementation of these rules (GMP and GDP) had been already achieved.
Further, there was the analysis of the impact of pharmaceutical reforms on:

- drug consumers (Tab. 1);
- the quality of the Pharmaceutical act (Tab. 2);
- the activities of pharmaceutical companies (Tab. 3);
- the efficiency of the entire pharmaceutical system (Tab. 3).

The data presented in Tab. 1 show the following assessments of the impact of pharmaceutical reforms on drug consumers:

- Reforms b), c) and d) had a serious destructive effect;
- Reforms a) and i) had a partial destructive effect;
- Reforms (a) and (g) had a positive effect;
- Reforms c), e) and g) were evaluated as partially effective actions;
- Reforms e), f) and i) were mostly assessed as zero actions.

The results of the analysis of expert opinions regarding the impact of pharmaceutical reforms on the quality of the Pharmaceutical act (the concept of “Pharmaceutical act” includes specific types of pharmaceutical activities related to the supply of medicines, their storage and sale, the communication with the patient and other professional activities of a pharmacist) are presented in Tab. 2. The data in Tab. demonstrate that 4 out of 10 reforms were destructive in relation to the quality of the Pharmaceutical act. All experts indicated that 2 reforms (b) and (c) had a destructive effect, the reform (a) was indicated as destructive by 15.05 %, while the reform (d) was indicated as destructive by 26.43 %.

The “effective” impact was mentioned for the other 4 reforms: j), f), g) and e). The value of the indicators ranged from 3.22 % to 77.42 %. The most frequent assessment used by experts to estimate the impact of the reforms on the Pharmaceutical act was “moderate” (7 reforms out of 10).

Expert opinions on the impact of pharmaceutical reforms on the activities of pharmaceutical enterprises (Tab. 3) ranged from 3.23 % to 82.80 %. 6 out of 10 reforms (a), b), c), f), g), and j)) had an effective impact (from 32.26 % to 82.80 %) on the activities of pharmaceutical companies. However, the experts also mentioned “destructive” assessment in 7 out of 10 reforms, but the value of the destructive action was

### Table 1

<table>
<thead>
<tr>
<th>Pharmaceutical Reforms</th>
<th>The assessment of indicators (%)</th>
<th>S</th>
<th>M</th>
<th>Z</th>
<th>D</th>
<th>PI</th>
<th>NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Privatization of pharmacies and liquidation of the state pharmaceutical sector</td>
<td></td>
<td>50.54</td>
<td>49.46</td>
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<tr>
<td>b) The permission to create a community pharmacy for people without a pharmacy qualification</td>
<td></td>
<td>100</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>c) A warehouse permit for a pharmacy chain</td>
<td></td>
<td>1.09</td>
<td>22.58</td>
<td>76.34</td>
<td></td>
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</tr>
<tr>
<td>d) The transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber</td>
<td></td>
<td>6.45</td>
<td>93.55</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Application of accreditation of pharmaceutical companies</td>
<td></td>
<td>29.03</td>
<td>12.9</td>
<td>58.07</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Reorganization of INF into AM (AMDM)</td>
<td></td>
<td>74.19</td>
<td></td>
<td></td>
<td>25.81</td>
<td></td>
<td></td>
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<tr>
<td>g) Provision of basic pharmaceutical services</td>
<td></td>
<td>70.97</td>
<td>29.03</td>
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<tr>
<td>h) Application of the CTD format in the process of drug authorization</td>
<td></td>
<td>3.22</td>
<td></td>
<td></td>
<td>96.78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) Changing the pricing system for medicines</td>
<td></td>
<td>78.49</td>
<td>16.13</td>
<td></td>
<td>5.38</td>
<td></td>
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</tr>
<tr>
<td>j) Implementation of good practice rules (GMP, GDP)</td>
<td></td>
<td>32.26</td>
<td>34.41</td>
<td>33.33</td>
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</tbody>
</table>

Note: S – successful; M – moderate; Z – zero; D – destructive; PI – in the process of implementation; NC – not the case.
### Table 2

**THE IMPACT OF THE PHARMACEUTICAL REFORMS ON THE QUALITY OF THE PHARMACEUTICAL ACT**

<table>
<thead>
<tr>
<th>Pharmaceutical Reforms</th>
<th>The assessment of indicators (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Privatization of pharmacies and liquidation of the state pharmaceutical sector</td>
<td>S: 4.95, M: 15.05</td>
</tr>
<tr>
<td>b) The permission to create a community pharmacy for people without a pharmacy qualification</td>
<td>100</td>
</tr>
<tr>
<td>c) A warehouse permit for a pharmacy chain</td>
<td>100</td>
</tr>
<tr>
<td>d) The transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber</td>
<td>S: 79.57, M: 26.43</td>
</tr>
<tr>
<td>e) Application of accreditation of pharmaceutical companies</td>
<td>S: 3.22, M: 89.25, Z: 7.53</td>
</tr>
<tr>
<td>f) Reorganization of INF into AM (AMDM)</td>
<td>S: 52.69, M: 47.31</td>
</tr>
<tr>
<td>g) Provision of basic pharmaceutical services</td>
<td>S: 38.71, M: 36.56, Z: 24.73</td>
</tr>
<tr>
<td>h) Application of the CTD format in the process of drug authorization</td>
<td>S: 17.2, M: 82.8</td>
</tr>
<tr>
<td>i) Changing the pricing system for medicines</td>
<td>S: 43.01, M: 56.99</td>
</tr>
<tr>
<td>j) Implementation of good practice rules (GMP, GDP)</td>
<td>S: 77.42, M: 22.58</td>
</tr>
</tbody>
</table>

Note: S – successful; M – moderate; Z – zero; D – destructive; PI – in the process of implementation; NC – not the case.

### Table 3

**THE IMPACT OF THE PHARMACEUTICAL REFORMS ON THE ACTIVITIES OF PHARMACEUTICAL COMPANIES**

<table>
<thead>
<tr>
<th>Pharmaceutical Reforms</th>
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</tr>
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<tbody>
<tr>
<td>a) Privatization of pharmacies and liquidation of the state pharmaceutical sector</td>
<td>S: 79.57, M: 20.43</td>
</tr>
<tr>
<td>b) The permission to create a community pharmacy for people without a pharmacy qualification</td>
<td>82.8, M: 12.2</td>
</tr>
<tr>
<td>c) A warehouse permit for a pharmacy chain</td>
<td>S: 37.63, M: 32.26, Z: 30.11</td>
</tr>
<tr>
<td>d) The transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber</td>
<td>S: 37.63, M: 35.48, Z: 21.51, D: 5.38</td>
</tr>
<tr>
<td>f) Reorganization of INF into AM (AMDM)</td>
<td>S: 30.11, M: 32.26, Z: 10.75, D: 26.88</td>
</tr>
<tr>
<td>g) Provision of basic pharmaceutical services</td>
<td>S: 73.12, M: 26.88</td>
</tr>
<tr>
<td>h) Application of the CTD format in the process of drug authorization</td>
<td>S: 55.91, M: 3.23, Z: 40.86</td>
</tr>
<tr>
<td>i) Changing the pricing system for medicines</td>
<td>S: 72.04, M: 27.56</td>
</tr>
<tr>
<td>j) Implementation of good practice rules (GMP, GDP)</td>
<td>S: 55.91, M: 3.23, Z: 40.86</td>
</tr>
</tbody>
</table>

Note: S – successful; M – moderate; Z – zero; D – destructive; PI – in the process of implementation; NC – not the case.
much smaller than the value of the effective action, ranging from 3.23 % and 30.11 %. The “zero” effect was for reforms (e) – 59.14 %; d) – 37.63 %; f) – 30.1 % and i) – 27.6 %. In 7 cases a “moderate” estimate was used, it varied between 52.69 % (reform (h)) and 20.43 % (reform (a)).

The last assessment of experts concerned the impact of pharmaceutical reforms on the effectiveness of the entire pharmaceutical system (Tab. 4), having a generalizing nature and requiring a careful interpretation. The “effective” estimate was mentioned 6 times, while “destructive” and “zero” – 5 times, “moderate” – 4 times and “in the process of implementation” 2 times.

Taking into account the survey results the “effective” estimate scored 163 points (17.47 %), “destructive” – 359 points (38.39 %), “zero” – 171 points (18.28 %), “moderate” – 200 points (21.38 %), “in the process of implementation” – 42 points (4.48 %).

In order to compare the positive nature of the pharmaceutical reform with the negative one as a whole, it was conventionally considered:
- “effective” + “moderate” – positive;
- “destructive” + “zero” – negative nature.

Thus, the positive nature of the reforms scored 363 points, while the negative nature – 530 points, meaning that the negative nature of the pharmaceutical reforms over the period analyzed exceeded the positive nature of these reforms by 1.46 times.

Based on the results of the questionnaire analysis (item 2 of the questionnaire), as well as the expert proposals (item 3 of the questionnaire), the following recommendations were formulated:

1. To elaborate / correct the pharmaceutical reforms with negative effects (destructive and zero):
   - to restore the pharmaceutical coordination and control system at the interdistrict / district level;
   - to restore the state pharmaceutical network by reorganizing the pharmacies of the Centers of Family Physicians;
   - to stop the practice of creating a community pharmacy for people without a pharmacy qualification;
   - to establish a legal norm prohibiting the creation of networks of community pharmacies or limiting the number of pharmacies in a network;

Table 4

<table>
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<th>Pharmaceutical Reforms</th>
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<tr>
<td>a) Privatization of pharmacies and liquidation of the state pharmaceutical sector</td>
<td>S: 80.65 M: 19.35 Z: 19.35</td>
</tr>
<tr>
<td>b) The permission to create a community pharmacy for people without a pharmacy qualification</td>
<td>100</td>
</tr>
<tr>
<td>c) A warehouse permit for a pharmacy chain</td>
<td>18.6</td>
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<td>h) Application of the CTD format in the process of drug authorization</td>
<td>75.27</td>
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<tr>
<td>i) Changing the pricing system for medicines</td>
<td>51.61</td>
</tr>
<tr>
<td>j) Implementation of good practice rules (GMP, GDP)</td>
<td>78.49</td>
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Note: S – successful; M – moderate; Z – zero; D – destructive; PI – in the process of implementation; NC – not the case.
• to transfer the licensing procedure of pharmaceutical activities subordinated to the Licensing Chamber of the Ministry of Health and the Agency of Medicine and Medical Devices with the involvement of the Association of Pharmacists of the Republic of Moldova;
• to prevent future changes in the pricing system for medicines without an analysis of the regulatory impact evidence-based on scientific reasoning.
2. To study the possibility of initiating the following pharmaceutical reforms/regulations proposed by the experts participating in the survey:
• to reform the activities of the Association of Pharmacists of the Republic of Moldova, giving it the rights and responsibilities regarding the coordination and control of compliance with ethical and deontological standards and the professional level of pharmacists;
• to develop and implement rules of good practice (GMP, GDP);
• to establish a “mandatory minimum range of medicines and other medical products” for community pharmacies and pharmacy stores.

Conclusions and prospects of further research
1. The main pharmaceutical reforms taken place in the Republic of Moldova over 25 years (1990-2015) have been analyzed by the experts.
2. It has been shown that the negative impact of the pharmaceutical reforms exceeds the positive impact by 1.46 times.
3. Recommendations have been developed and proposed for:
• elimination of the negative consequences of the pharmaceutical reforms;
• the study of the possibility of initiating a number of the pharmaceutical reforms/regulations proposed by the experts who participated in the survey.

Conflict of interests: authors have no conflict of interests to declare.

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14. Regarding the approval of the amendments and additions to be implemented in the Government Decision No. 603 from the 2nd of 1997: Government Decision Republic of Moldova No. 720 from 10.08.2010


17. Regarding the modification and completion of the Regulation on the method of approval and registration of producer prices for medicinal products: Government Decision Republic of Moldova No. 32 from 13.01.2012


19. For amending and completing of some legislative acts: Law Republic of Moldova No. 60 from 01.04.2011.


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7. Regarding the approval of the Regulation on the method of approval and registration of producer prices for medicines: Government Decision Republic of Moldova No. 525 from 22.06.2010.

8. Regarding the modification and completion of the Regulation on the method of approval and registration of producer prices for medicinal products: Government Decision Republic of Moldova No. 525 from 22.06.2010.

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14. Regarding the approval of the amendments and additions to be implemented in the Government Decision No. 603 from the 2nd of 1997: Government Decision Republic of Moldova No. 720 from 10.08.2010

15. Regarding the implementation of the Informational system «The State Nomenclature of Medicines»: Government Decision Republic of Moldova No. 85 from 25.01.2006.


17. Regarding the modification and completion of the Regulation on the method of approval and registration of producer prices for medicinal products: Government Decision Republic of Moldova No. 32 from 13.01.2012

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