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Argumentation of the strategic directions for the development of pharmaceutical system in the Republic of Moldova

*Adaui Stela¹, Buliga Valentina¹, Safta Vladimir¹,
Brumarel Mihail¹, Lupu Mihail^{1,2}, Spinei Larisa³

¹Vasile Procopisin Department of Social Pharmacy

²Medicines and Medical Devices Agency, ³School of Public Health Management

Nicolae Testemitsanu State University of Medicine and Pharmacy, Chisinau, Republic of Moldova

*Corresponding author: stela.adaui@usmf.md. Received December 29, 2016, accepted February 10, 2017

Abstract

Background: To assess the actual pharmaceutical system in Moldova in order to show the strategic directions of the development of this system.

Material and methods: The methodology of the study is based on the systemic approach. In order to highlight the issues of Pharmaceutical system that are needed to be reflected in the development strategy, it has been elaborated a special method of questionnaires for selected specialists of the highest level of professional competence as respondents.

Results: All respondents mentioned that having a development strategy for the pharmaceutical system is a real necessity. There were determined 10 directions of the development strategy and the importance of each direction. Also, the respondents proposed additionally 21 directions and 21 another real problems to include in the strategy.

Conclusions: It has been highlighted the absence of the development strategy of the pharmaceutical system in the Republic of Moldova, which will bring to the light systematically full range of pending issues. It has been developed a special method of questionnaires for selected specialists of the highest level of professional competence taking into consideration 3 factors: theoretical and practical training, seniority and experience of elaborating legislative and normative acts in the field of medicines and pharmaceutical activity. There were argued five strategic directions of the development of pharmaceutical system in the Republic of Moldova, which include themselves about 50 issues, some more general, others – concrete, but all are towards achieving the overall goal – providing benefits to public and individual health.

Key words: pharmaceutical system, development strategy.

Introduction

The need for a development strategy of any system, especially a system involving human and his health is imperative and it is out of discussion. One of the principles of the systemic approach is the “strategic development”, which demonstrates once again the need for elaboration of the development strategy for pharmaceutical system in the Republic of Moldova.

Some motivational underlines regarding the need to develop a strategy for pharmaceutical system in the Republic of Moldova were mentioned about 7 years ago – at the 6th Congress of Pharmacists [1].

It should be noted that National Health Politics [2] addresses only two aspects of the pharmaceutical system – “The implementation of computerized technology in the health domain will provide the centralized evidence of drugs on the market and will contribute to the security of pharmaceutical products. The population will be guaranteed access to essential and qualitative medicines”. It is obvious that these two issues do not cover all the problems facing today’s pharmaceutical system.

The development strategy of the health system for the period 2008-2017 [3], as well, does not provide the development of pharmaceutical systems using systemic approach.

In this strategy, the drug and pharmaceutical activity domain is included in section 4 “Resource Management” and section 70 “The rational management of drugs”, which provide measures in two directions:

- a) Ensure pharmaceutical safety;
- b) Ensure accessibility to the drugs.

Ensuring the security of pharmaceutical system is expected to be achieved through series of concrete activities:

- the development and implementation of best practice rules – GLP, GCP, GMP, GDP, GPP;
- the improvement of computerized technology system in order to record the drugs circulation;
- the development of the mechanisms which will ensure the rational use of medicines.

In order to ensure accessibility to medicines there were provided the following activities:

- to reorganize the pharmaceutical departments in the Centers of General Physicians (GP’s);
- to expand the compensated drugs assortment and the improvement of the mechanisms in order to ensure the population with these drugs;
- to improve the mechanism of price formation for drugs;
- to stimulate the development of domestic pharmaceutical industry.

The mentioned strategic directions are still actual but the current situation of the pharmaceutical system is affected by the multitude of issues that need to be made as strategic objectives in a new term development program.

At the end of 2003 the Government approves national public health strategy for 2004-2020 [4], but in this strategy the words «drug» or «pharmaceutical» have not been found.

This strategy will not substitute any State Policy in the domain of Medicines [5], because this policy document

requires be reviewed and updated in accordance with the situation that it is created in the Moldovan pharmaceutical system [6].

The purpose of this document is to assess the actual pharmaceutical system in Moldova which is oriented to argue the strategic directions of the development of this system.

Material and methods

With the purpose to assess the situation on strategic planning in the pharmaceutical system of Moldova there was started implementing of a special questionnaire in this regard.

Special interviewing is a method of sociological research in the process of which the respondents are experts selected on the principle of the highest level of professional competence.

In order to determine the competence of respondents, there was developed an algorithm, which includes three basic criteria:

I. Theoretical and practical competence (P_{tp}):

- having degree in pharmacy and work experience at least for 2 years – 2 points;
- theoretical work (published scientific articles) and practical activities, the 1st or the 2nd professional category – 5 points;
- PhD degree in pharmacy and practical activity, the highest professional category - 10 points;
- Work experience (V_m):
- Work experience up to 5 years – 2 points;
- Work experience >5 years to 10 years – 5 points;
- Work experience >10 years to 15 years – 8 points;
- Work experience over 15 years – 10 points;

II. Experience in elaborating of legislative and normative acts in the domain of medicines and pharmaceutical activity (E_{an}):

- Underlegislative acts/projects – 2 points;
- Underlegislative acts/projects and projects of Government decisions – 5 points;
- Underlegislative acts/projects and projects of Government decisions and Orders – 8 points;
- Underlegislative acts/projects and projects of Government decisions, projects/orders and projects of politics documents – 10 points;

Using mentioned criterias in p. I-III there was elaborated the following algorithm:

$$k_i = \frac{1}{10} \left(\frac{Ptp + Vm + Ean}{3} \right), \text{ in which (1)}$$

k_i – integrated coefficient characterizing the degree of responsibility of the respondent – the expert.

In order to validate the developed algorithm, there were determined the minimum and the maximum limits;

$$\text{Minimum limit: } k_{i(\min)} = \frac{1}{10} \left(\frac{2+2+2}{3} \right) = 0,2 \quad (2)$$

Maximum limit:

$$k_{i(\max)} = \frac{1}{10} \left(\frac{10+10+10}{3} \right) = 1,0 \quad (3)$$

The acceptable limit: (k_{i(min)} + k_{i(max)}): 2 = 0,6.

Thus, in the questionnaires should be involved respondents- experts possessing the degree of competence within 0,6 – 1.0.

To collect the information on strategic planning in the pharmaceutical system there was developed a questionnaire (fig. 1).

All in total, 40 questionnaires there were printed and distributed, but there were collected only 36 or 90% of the required number.

Results and discussions

Characteristics of the respondents

In the process of questionnaires, there were involved 38 pharmacists, the competence of which was illustrated by the integrated coefficient (ki), which was calculated using formula (1). The results are presented in the table 1.

Table 1

Assessment of the respondents' competence

Number of questionnaire	Integrated coefficient of competence (k _i)	Number of questionnaire	Integrated coefficient of competence (k _i)	Number of questionnaire	Integrated coefficient of competence (k _i)
1	0,46	13	0,6	25	0,93
2	1,0	14	0,66	26	1,0
3	0,66	15	0,93	27	0,76
4	0,6	16	0,93	28	0,7
5	0,76	17	0,83	29	0,66
6	0,6	18	0,83	30	0,66
7	0,76	19	0,83	31	0,76
8	0,66	20	0,83	32	0,2
9	0,66	21	0,76	33	0,6
10	0,66	22	0,66	34	0,83
11	0,76	23	0,66	35	0,66
12	0,93	24	0,66	36	0,66

As in the process of questionnaires should be involved experts – respondents possessing a degree of competence within 0,6-1.0 from the total of 36 questionnaires, two of questionnaires were excluded: questionnaire no. 1 (ki = 0.46) and questionnaire no. 32 (ki = 0.2). Thus, in the analysis of the information on strategic planning in the pharmaceutical system were included 34 questionnaires of pharmacists respondents.

According to domain of activity of the pharmacists respondents, they work in different pharmaceutical fields: 35.29% – Pharmacists, chiefs of pharmaceutical companies (12 respondents); 23.52% – Instructors of the pharmacists

Questionnaire

Dear colleague, the absence in Moldova of a strategy for development of pharmaceutical system very often led to chaotic actions that keep this system in a «feverish» stage.

To redress the situation, please answer the questions of this questionnaire.

1. Do you consider it necessary to have a strategy for development of Moldova's pharmaceutical system?

- Yes
 No

2. Motivate the negative answer (by tick);

- is it sufficient to have a strategic development of the health system;
 is it sufficient the existence of State Policy in the domain of Medicine;
 the main components of the pharmaceutical system are private and they do not need „the state strategy“;
 other reasons (specify them): _____

3. Motivate the positive answer (by tick);

- the strategy and strategic planning is the most effective way of selecting their aims, objectives and development programs;
 the strategy and the strategic plan is a real support for short - term planning and operational phase;
 the strategy of development of the health system does not contain 0,1 part of the strategic issues of the pharmaceutical system;
 other reasons (specify them): _____

4. Set the rank (numbering taking into consideration the priority) for the next 10 points which are planned to be included in the strategy of development of the pharmaceutical system of RM (1-most important... 10 the least important)

- Improving the undergraduate and postgraduate training of pharmacists.
 The quality of pharmaceutical services provided in outpatient clinics and hospitals-based on ethic and professional principles.
 Authorization of pharmaceutical activity (licensing and accreditation).
 Pharmaceutical Assistance in rural areas.
 Ensuring patients with compensated drugs in outpatient departments.
 Improving the mechanism of price formation for drugs.
 Resumption and further development of medicines preparation.
 Improving the mechanisms of ethical promotion of medicines.
 Solving the situation regarding to informational ensuring of pharmaceutical act.
 Promoting the concept of good governance of the pharmaceutical system.

5. From your point of view, please mention additional development directions that deserve to be included in the strategy and determine their priority (points 1 to 10):

- 5.1. _____
5.2. _____
5.3. _____
5.4. _____
5.5. _____

6. From your point of view, please mention at least five of the most important and concrete issues that should be included in the strategy of the development of the pharmaceutical system:

- 6.1. _____
6.2. _____
6.3. _____
6.4. _____
6.5. _____

7. From your point of view, which would be the optimal period of the strategy of the development of the pharmaceutical system?

- 5 years; • 7 years; • 10 years; • 15 years; • 20 years.

8. Please specify some personal data (by tick):

- a) Domain of activity;
• Pharmacist, chief of a pharmaceutical company; • Pharmacist practitioner of a pharmaceutical company;
• Training the pharmacists; • pharmaceutical research;
• coordination and control system; • others
- b) Work experience (tick):
• up to 5 years; • >5-10 years; • >10-15 years; • >15 years;
- c) Professional category that you hold at the moment (tick):
• 2nd; • first; • the highest;
- d) Scientific degree (tick):
• habilitated doctor in pharmaceutical science; • doctor in pharmaceutical science; • no scientific degree;
- e) Have you experience in elaborating of the project of documents (tick)
- | | | |
|------------------------|-------|------|
| • sublegislative | • yes | • no |
| • government decisions | • yes | • no |
| • Orders | • yes | • no |
| • politics | • yes | • no |

Thank you for your support! _____

(sign) - optional

Fig. 1. Questionnaire Cassette 1.

(8 respondents); 23.52% – Pharmacist practitioners of pharmaceutical companies (8 respondents); 11.76% – coordination and control system (4 respondents); 5.88% – pharmaceutical research (2 respondents);

According to work experience in the domain there were obtained the following data: 5 to 10 years – 5.88% (2 respondents); > 10 to 15 years – 14.7% (5 respondents); > more than 15 years – 79.41%.

Regarding the professional category, most of the specialists have the highest category – 79.41%, the 1st category – 14.7% and 5.88% have the 2nd category.

According to scientific degree the pharmacists are classified as follows: 17.64% are doctors in pharmaceutical sciences and 2.94% – pharmacists with habilitated doctor in Pharmaceutical Sciences, the rest of the respondents (79.41%) have no scientific degree.

Experience of elaborating normative legal acts possess 12 respondents (35.29%), including trainers of pharmacists – 17.64%, specialists of coordination and control system – 11.76% and pharmaceutical research – 5.88%.

Analysis of answers

When asked whether there is a need to create a strategy for the development of the pharmaceutical system in Moldova all 34 pharmacists – respondents gave an affirmative answer. As a motivation for their positive response were ticked the following: 41.37% – mentioned p. a) – the strategy and strategic planning is the most effective way of selecting their aims, objectives and development programs; 31,03% – mentioned p.b) – the strategy and the strategic plan is a real support for short - term planning and operational phase; the last place 27,58% – ticked p.c) – the strategy of development of the health system does not contain 0,1 part of the strategic issues of the pharmaceutical system.

As a result of quantifying the strategic directions by establishing of the rank, it was determined the importance of each direction and it was highlighted the priority of the stra-

tegic directions in relation to the deadline needed to achieve the stipulated plan for the strategy (tab. 2).

All the experts added to the proposed directions in the 4th question considered to indicate some other directions that might also be included in the strategy for the development of the pharmaceutical system. Totally they proposed 21 more directions, including: 5 more directions were proposed by one expert; the other expert came with 4 more proposals; the other 5 experts came with 3 proposals; 13 experts came with 2 proposals and 4 experts gave one proposal each (tab. 3).

In conclusion, it was obtained that the first three strategic direction proposals were formulated by five experts; the following five proposals were submitted by four experts; next 5 - by 3 experts, following six proposals were formulated by 2 experts and the last two directions were formulated only by one expert. Thus, the degree of repeatability of other strategic directions which were proposed by the pharmacists-experts is 90.5%.

To integrate the responses of the experts to question 5 taking into consideration the directions formulated in question 4, it was proposed to formulate question 6 – to mention at least 5 of the most pressing and important issues that should be included in the strategy of the development of the pharmaceutical system. The answers to the 6th question are shown in table 4.

From the total number of respondents – experts, 32 of them mentioned 5 important issues, and 2 experts mentioned 4 issues each. Thus, all pharmacists-experts have mentioned 168 issues, which are oriented in two directions. The medium repeatability degree is 8, maximum – 16 and minimum – 2. From the total number of urgent issues, 3 of them were proposed by 16 respondents, 5 – by 14 respondents, 12 – by 4 respondents and only one issue was proposed by 2 experts.

On the 7th question (the optimal period for the strategy),

Table 2

Ranking according to priorities of strategic directions of the development of the Republic of Moldova pharmaceutical system

Rank	Strategic direction	Accumulated amount
1	Authorization of pharmaceutical activity (licensing and accreditation)	103
2	The quality of pharmaceutical services provided in outpatient clinics and hospitals-based ethic and professional principles	105
3	Improving the mechanism of price formation for drugs	146
4	Pharmaceutical assistance in rural areas	156
5	Promoting the concept of good governance of the pharmaceutical system	164
6	Ensuring patients with compensated drugs in outpatient departments.	183
7	Improving the undergraduate and postgraduate training of pharmacists	197
8	Improving the mechanisms of ethical promotion of medicines	214
9	Resumption and further development of medicines preparation	220
10	Solving the situation regarding informational ensuring of pharmaceutical act	267

the answers of the pharmacists-respondents were: 5years – 11 (32.35%); 7 years – 4 (11.77%); 10 years – 17 (50%); 20 years 2 (5.88%). The 15 year period was not mentioned by any expert. Thus, it is recommended the period of 10 years (2017-2027) for the strategy of the development of the pharmaceutical system in Moldova.

According to the survey, the data from the tables 2-4 were grouped into the following five complex strategic directions, in which are elucidated all the problems and issues:

- I – Promoting an ethical pharmacy;
- II – Strengthening the quality of the pharmaceutical activity;
- III – Ensuring of the accessibility to the medicines;
- IV – Ensuring good conditions for the development of pharmaceuticals units;
- V – Reviewing the pharmaceutical legislation by harmonization with the EU acquis.

Table 3

Other directions that deserve to be included in the strategy according to the respondents' opinion

Nr. d/r	Proposed directions	Nr. of the experts
1	Promoting of an ethical pharmacy	5
2	Rational use of medicines	5
3	Compliance with the regulation regarding expansion of the pharmacies	5
4	Licensing of the pharmaceutical activity by the Ministry of Health	4
5	Establishing a more drastic legislative regulating framework of the pharmaceutical activity and improving the legal framework	4
6	Extending the number of pharmacies with medicines preparation	4
7	Pharmacies should belong only to pharmacists	4
8	Excluding the commercial interest in pharmacies	4
9	To revise the regulations and standards that directly and indirectly affect the pharmaceutical system in the Republic of Moldova	3
10	Managing the pharmacies and pharmaceutical warehouses only by specialists with pharmaceutical education	3
11	The development and implementation of best practice rules (the ones that are not elaborated yet)	3
12	Strict compliance with occupied positions in the institutions according to education and skills of the pharmacists.	3
13	To restore the collaboration between the physician and pharmacist	3
14	More active promotion of healthy lifestyle oriented towards disease prevention	2
15	To create and promote the concept of the pharmacy "model" by establishing advanced standards to all aspects of pharmaceutical activity	2
16	Reforming of the former central pharmacies into multifunctional units, including coordination and control.	2
17	Restoring a pharmacy chain with public capital	2
18	Taking over Romanian legislation in regulating pharmaceutical activity	2
19	Implementing informational system regarding patients files records	2
20	Improving the situation regarding human resources in pharmaceutical system (recording, migration, education recognition, equivalence of diplomas)	1
21	Creating database for pharmacists and their subsequent record, in order to prevent practicing pharmaceutical activity by non-professional people	1

Table 4

The most pressing and important issues that should be included in the strategy of the development of the pharmaceutical system

Nr. d/r	Most pressing and important issues	Nr. of the experts
1	Licensing and accreditation	16
2	Compliance with regulation on pharmacies location	16
3	Taking concrete and effective measures that would not allow practicing pharmaceutical activity by non-specialists	16
4	Perfecting pricing system for medicines	14
5	Preventing the pharmaceutical warehouses from holding pharmacies (important factor in the exaggerated development of pharmaceutical chains)	14

Nr. d/r	Most pressing and important issues	Nr. of the experts
6	Reorganizing of Pharmacists Association activity with an orientation to College of Pharmacists from Romania	14
7	Returning to actuality presence and functionality of automated information system of recording the movement of drugs	14
8	Approving the plan of the development of the pharmaceutical system	14
9	Pharmacists technician should not be allowed to dispense Rx products	4
10	Ensuring physical accessibility of medicines	4
11	Reviewing the right of existence of pharmacy chains	4
12	Orientation to recognized providers of medicines and exclusion of dubious suppliers	4
13	Liquidation of community pharmacy chains	4
14	Restoring the legislative framework regarding the statistics in the pharmaceutical domain	4
15	Proper hospitals supply with necessary qualitative and harmless medicines	4
16	Development of best practice rules	4
17	Correct prescribing the medicines by the doctors	4
18	Fight against abuse of drug advertising	4
19	Excluding the corruption in the process of centralized drug acquisitions	4
20	The development of domestic pharmaceutical industry	4
21	Changes / completing of the Administrative Code	2

Conclusions

1. It has been highlighted the absence of the strategy of the development of Moldovan pharmaceutical system, which would take care systemically of the full range of pending issues.

2. It has been developed a special method of questionnaires in which were involved specialists-experts with a quantified by three – factor degree of competence: theoretical and practical confidence, work experience and experience in elaborating of legislative and normative regulations in the domain of medicines and pharmaceutical activity.

3. There were highlighted five strategic directions for the development of Moldovan pharmaceutical system, which include about 50 issues, some of them are more general, others – are concrete, but all of them are oriented towards achieving a single goal – providing benefits to public and individual health.

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