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Analysis of the legislation of the Republic of Moldova in terms of pharmaceutical security

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Abstract

Background: The pharmaceutical security can only be ensured taking into account its multidimensional and systemic character; the partial or one-sided approach will not ensure the feasibility and the sustainability of such security. A major condition to ensure pharmaceutical safety is the existence of a legislative base. The purpose of the paper is to highlight regulatory gaps affecting the pharmaceutical security of the Republic of Moldova.

Material and methods: Based on a logical analysis, all conditions, the compliance with which would ensure the pharmaceutical security of the state and of each citizen were determined. The existence or absence of legal provisions legalizing the application of various ways, methods, processes, procedures, regulations and other measures that would impose compliance with pharmaceutical security conditions was highlighted. The level of legislative coverage of the requirements for the provision of pharmaceutical security was determined. The quantification scale regarding the level of legislative coverage for the provision of pharmaceutical security was developed.

Results: The research resulted in the development of the methodical toolbox by means of which the legislative coverage level of the pharmaceutical security was identified. The calculations demonstrated that the legislation of the Republic of Moldova does not sufficiently cover the pharmaceutical security. This fact refers mostly to the insufficient regulation of the good quality of pharmaceutical services, of the proper functioning of the entire pharmaceutical system and of ensuring physical and economic availability of drugs.

Conclusions: The impact of the governmental factor in the Republic of Moldova concerning certain aspects of the pharmaceutical security was highlighted. The toolbox of methods for the analysis of the level of legislative coverage of pharmaceutical security was drawn up.

Key words: pharmaceutical system, legislation, security.

Introduction

The notion of pharmaceutical security was addressed for the first time, in the Republic of Moldova, in 2009, in a report by the Ministry of Health [6], but it should be mentioned that, in that case, the Ministry only related the results of activities to:

- Ensuring the access of the population to drugs, pointing out certain procedures (price analysis, drugs compensation, centralized procurement);
- Promotion of reasonable use of drugs;
- Development and promotion of the local drug manufacturer.

The report presented by the Ministry of Health lacked a systemic or, at least, many-sided approach to the pharmaceutical security notion. Consequently, the reports of the Ministry of Health did not include the chapter on "pharmaceutical security".

The issues related to ensuring the pharmaceutical security started being addressed nationwide from the year of 2015 [1].

The Government of the Republic of Moldova regularly started addressing various aspects of the pharmaceutical security [2, 4, 5].

At the same time, it is worthwhile mentioning that government talks are limited to certain aspects of pharmaceutical safety, without taking into account the systemic nature of this area of security [1]. To improve the situation, it is necessary to analyze the legal basis relating to pharmaceutical security of the state and of each citizen. The results of such analysis would create grounds for notifying the state authorities on the need to strengthen, in all of its aspects, and not partially, the pharmaceutical security.

The specialized literature did not offer works on the analysis of the state pharmaceutical security legislation, this fact, in tandem with the aforementioned circumstances, features the topicality of the issue being addressed.

The objective of this article is to highlight the legislative gaps affecting the pharmaceutical security of the Republic of Moldova.

Material and methods

In order to achieve the determined objective, all the legislative and normative acts, directly or indirectly regulating the pharmaceutical security, have been initially selected.

The systematization of legal and normative acts has been performed based on the following two principles:

I – law/legislation: pharmaceutical, medical, and other fields;

II – subsystems of the pharmaceutical safety system [1]: a) effectiveness, harmlessness and quality of drugs, b) availability of drugs, c) quality of pharmaceutical services and the smooth operation of the pharmaceutical system.

The list of all legislative and normative acts defining rules aimed at ensuring the pharmaceutical security includes 112 documents, among which: pharmaceutical – 78, medical – 26, other areas – 8.

Development of the analytical method

As a methodical tool for highlighting the level of legislative and normative coverage of the pharmaceutical security, the following algorithm was developed:

Step I

Determining, based on a logical analysis, all conditions, the compliance with which would ensure the pharmaceutical security of the state and of each citizen. This analysis should take into account the de facto situation of the pharmaceutical system.

Pursuant to the content analysis of the legislation and of the sub-legislative acts, as well as taking into consideration the national and international practice, the advanced experience in the field of pharmaceutical security, the conditions for ensuring this security were systematized and grouped according to the 2nd systematization principle (tab.1).

The total number of conditions necessary to ensure the pharmaceutical security shall be marked by (Cn). The number of necessary conditions can be determined as the total conditions (Cn) or the aggregate of conditions to ensure pharmaceutical security directions:

Cqd – conditions for ensuring the quality, the effectiveness and the harmlessness of drugs;
Cad – conditions for ensuring the (physical and economic) availability of drugs;
Cqa – conditions for ensuring the quality of the pharmaceutical act.

Step II

Highlighting of the existence / absence of legal provisions legalizing the application of various ways, methods, processes, procedures, regulations and other measures that would impose compliance with conditions necessary for pharmaceutical security.

Highlighting of the existence / absence of legal provisions aimed at ensuring the pharmaceutical security was performed by applying the expertise method combined with the Delphi method [3].

For this purpose a panel of experts was created randomly, representing:

– the Parliament of the Republic of Moldova;
– the Government of the Republic of Moldova;
– the Ministry of Health;
– the Medicines and Medical Devices Agency;
– Specialized pharmacy chairs of the SUMPh "Nicolae Testemițanu";
– Pharmacists Association of the Republic of Moldova;
– Local drug manufacturers;
– Pharmaceutical storehouses;
– Drugstores: community (private and network) and hospital drugstores.

Therefore, the panel of experts numbered 15 members, each of which was provided with a questionnaire to assess the compliance with the conditions of ensuring the legislative coverage for pharmaceutical security (tab. 1) [1], as well as the method of assessing the legislative coverage:

– Existence of the necessary legal provision – 1 point;
– Absence of the legal provision – 0 points;
– Existence of the necessary legal provision, but failure to comply with – 0.5 points;
– Inefficiency of the regulation for providing the pharmaceutical security – 0.5 points.

The legislative coverage of conditions for providing the pharmaceutical security shall be marked as:

(Pe) – existing legal provisions aimed at ensuring the compliance with the conditions necessary, in their turn, to provide the pharmaceutical security. Indicator (Pe), as well as (Cqa) may be highlighted for the total number of existing rules or for the directions of pharmaceutical security provision:

Peqd – effective legal provisions covering the conditions of pharmaceutical security provision by ensuring the quality, the efficiency and the harmlessness of drugs.

Pead – effective legal provisions ensuring the physical and economic availability of drugs;

Peqa – effective legal provisions ensuring the quality of the pharmaceutical act.

Step III

Determining the degree of legislative coverage of requirements for pharmaceutical safety provision. This indicator shall be marked as (LCp) – for the total number of existing legal provisions and necessary conditions, and for the three directions for providing pharmaceutical security, accordingly:

LCqd = Peqd / Cqd (1) – indicator of legislative coverage of pharmaceutical security provision by ensuring the quality, efficiency and harmlessness of drugs;

LCad = Pead / Cad (2) – indicator of legislative coverage of pharmaceutical security provision by ensuring the physical and economic availability of drugs;

LCqa = Peqa / Cqa (3) – indicator of legislative coverage of pharmaceutical security provision by ensuring the quality of the pharmaceutical act.

Step IV

Development of the quantification scale for the degree of legislative coverage for the pharmaceutical security provision. Taking into consideration that the value of indicator (ALn) may vary between "zero" and "1", we undertook to develop a clear assessment scale.

For a clearer perception of the indicator ALn, it was proposed to multiply its value by 10, thus, the indicator amplitude will fall in the range of 1-10. For the quantification, the following appreciation scale was suggested:

LCp = 0 - null;
LCp = > 0 … 2 – vulnerable;
LCp = > 2 ... 5 – insufficient;
LCp = > 5 ... 8 – moderate;
LCp = > 8 …< 10 – good;
LCp = 10 – total.

Therefore, the final formula for computing the degree

of legislative coverage for the state pharmaceutical security provision (LCp) is as follows:

$$LCp = \frac{P_e}{C_n} \times 10 \quad (4),$$

in which:

Pe – the number of existing legal provisions aimed at pharmaceutical security provision;

Cn – the number of necessary conditions aimed at pharmaceutical security provision.

Results

Experts expressed their opinions, assessing the existence / absence of the respective legal provision and / or the existence and failure or inefficiency of the existing provision. The opinions of all the experts coincided for 39 conditions (90.7%). The opinions of three experts (20%) were different for four legislative conditions of pharmaceutical security provision (1.5, 2.12, 3.8 and 3.9). Following the application of the Delphi method, a consensus was reached and the as-

Table 1

Conditions for pharmaceutical security provision

No	Conditions for pharmaceutical security provision	Legislative coverage
1	2	3
I.	**Ensuring efficiency, harmlessness and good quality of drugs**	
1.1.	Conducting drug development research on ethical principles aimed at achieving health benefits;	0,5
1.2.	Consistent and efficient operation of the authorisation procedure for drugs manufacturing in domestic enterprises;	1
1.3.	Compliance with Good Practice Rules: GLP (good laboratory practice), GCP (good clinical practice), GMP (good manufacturing practice) for drugs;	0,5
1.4.	Ensuring quality of drug substances and excipients used in the manufacture and preparation of drugs;	1
1.5.	Consistent and efficient operation of the service of pharmacovigilance;	1
1.6.	Ensuring transparency in the R&D process in the development of new drugs;	0
1.7.	Ensuring the efficiency of the licensing process (expertise, approval, registration) of drugs marketing;	1
1.8.	Ensuring the consistency and efficiency of the process of licensing drug imports;	1
1.9.	Prevention of placing drugs not subject to quality control on the pharmaceutical market	1
1.10.	Availability and continued application of measures to prevent the placement on the pharmaceutical market of counterfeit drugs	0
1.11.	Ensuring consistent storage (GDP, GSP) and consistent transportation (GTP) of drugs.	0
II.	**Ensuring physical and economic availability of drugs**	
2.1.	Uniform location of community drugstores throughout the country according to demographic and geographic rules;	0
2.2.	Ensuring the presence of essential drugs, including compensated drugs in/at: • State drug nomenclature; • National Catalogue of manufacturer prices; • Drug storehouses; • Community drugstores; • Healthcare institutions (according to the Institutional Pharmaco-therapeutical Form and national clinical protocols).	0,5
2.3.	Establishing accountability for the availability /lack of essential drugs in the pharmaceutical market;	0
2.4.	Development and implementation of the orphan drugs concept;	0
2.5.	Providing assistance with medications for people during the day and 24 hour-emergency assistance;	0
2.6.	Providing full information regarding the availability /lack of drugs at community drugstores /drug storehouses;	0,5
2.7.	Existence of the rule regarding the minimum required range of drugs within community drugstores and drug storehouses;	0,5
2.8.	Establishing a legal provision prohibiting unjustified refusal of drug delivery from the pharmaceutical storehouse to drugstores and medical institutions;	0

2.9.	Existence of an efficient mechanism of drug pricing;	0,5
2.10.	Providing professional negotiation of manufacturer prices;	0,5
2.11.	Ensuring effective functioning of the mechanism of drug public procurement for the needs of public medical institutions;	0,5
2.12.	Ensuring total transparency and excluding the conflict of interest from the process of public procurement of drugs;	0
2.13.	Continuous extension of the list of compensated drugs;	0,5
2.14.	Creation of incentive mechanisms for ensuring the availability of generic drugs on the pharmaceutical market.	0
III	**Ensuring good quality of pharmaceutical services and of good operation of the pharmaceutical system**	
3.1.	Ensuring compliance with essential pharmaceutical services (consistency with the accreditation standards and standard operating procedures)	0,5
3.2.	Combating unfair competition in the pharmaceutical market, banning monopoly	
3.3.	Establishing enhancers for the implementation of advanced pharmaceutical services	0
3.4.	Providing uninterrupted/timely information on the pharmaceutical act	0,5
3.5.	Ensuring the compliance with the requirements related to the professional level of specialists engaged in pharmaceutical activity	0
3.6.	Compliance with standards of good pharmacy practice (GPP) and standards of good distribution practice (GDP)	0,5
3.7.	Strengthening the functionality and efficiency of the Pharmaceutical Inspectorate	0,5
3.8.	Regulating the principles of reasonable use of drugs	0
3.9.	Streamlining the concept and the procedures for the accreditation of pharmaceutical enterprises;	0
3.10.	Amending the procedure for authorising (licensing) the pharmaceutical activity and its professional strengthening;	0
3.11.	Ensuring the compliance with the rules for the ethical promoting of drugs;	0
3.12.	Ensuring the prevention of conflicts of interest and of corruptibility in all processes, procedures and functions comprised in the notion of pharmaceutical activity;	0
3.13.	Strengthening the procedures for the safe disposal of expired, refuse or deteriorated drugs;	1
3.14.	Due exercise of the professions of pharmacist and assistant pharmacist;	0,5
3.15.	Strengthening the role of professional organisations of pharmacists in order to ensure the high quality of pharmaceutical services and the smooth functioning of the entire pharmaceutical system;	0
3.16.	Establishing and promoting the principles for the collaboration between doctors and pharmacists to the benefit of the patient;	0
3.17.	Effective contributions to the prevention and combating of drug abuse and drug dealing;	0,5
3.18.	Interaction regarding the development of all the dimensions of the clinical pharmacy concept.	0

sessment results coincided for the whole panel of experts (tab. 1, section 3).

The data provided at point 3, table 1 show the degree of legislative coverage of the conditions necessary for ensuring pharmaceutical security in the Republic of Moldova (tab. 2).

The data in table 2 indicate that the legislative coverage of the pharmaceutical security of the Republic of Moldova is insufficient. All the sectors need to be completed and require new legal provisions, but the most poorly regulated is the quality of pharmaceutical services and the functioning of the pharmaceutical system as well as the ensuring the availability of drugs. The results obtained point to legislative gaps that affect the pharmaceutical security and may serve as benchmarks in the legislative activity regarding the pharmaceutical field.

Table 2

Level of legislative coverage of the pharmaceutical security of the Republic of Moldova

Sectors	Legislative coverage				Level of coverage
	Existence of rules	Lack of rules	"Non-compliance", "insufficiency"	Points accumulated	
1. Ensuring efficiency, harmlessness and high quality of drugs	6	3	2	7	6,63 moderate
2. Ensuring physical and economical availability of drugs	-	7	7	3,5	2,50 insufficient
3. Ensuring the high quality of pharmaceutical services and the smooth functioning of the pharmaceutical system	1	10	6	4	2,22 insufficient
The entire system	7	20	15	14,5	3,37 insufficient

Conclusions

1. The impact of the governmental factor in the Republic of Moldova concerning certain aspects of the pharmaceutical security was highlighted;

2. The toolbox of methods for the analysis of the level of legislative coverage of pharmaceutical security was drawn up;

3. The insufficient legislative coverage of pharmaceutical security was proven and the legislative gaps related to pharmaceutical security and, namely, the conditions necessary for its ensuring were pointed out: lacking – 20 rules; inefficient or not complied with – 15 rules.

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