

ОРГАНІЗАЦІЙНІ ТА СОЦІАЛЬНО-ЕКОНОМІЧНІ ЗАСАДИ ФАРМАЦЕВТИЧНОЇ ДІЯЛЬНОСТІ

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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.

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ФАРМАЦЕВТИЧНА РЕФОРМА В РЕСПУБЛІЦІ МОЛДОВА У ПЕРІОД НЕЗАЛЕЖНОСТІ

За останні два десятиліття Республіка Молдова пройшла складний і суперечливий шлях свого розвитку. З метою визначення вектору свого розвитку, виходячи з демократичних цінностей західної культури, практично повністю була переглянута і створена нормативно-правова база. Концепція реформи Молдови полягала у лібералізації цін і відмові від планової системи управління економікою під час створення необхідних механізмів для функціонування ринкової економіки: створення банківської системи, ринку капіталу, інших установ, введення національної валюти, а також тривалий процес створення нової правової бази.

Мета: аналіз основних реформ, проведених у Республіці Молдова у сфері фармації за період незалежності: виділення їх впливу на очікувані ефекти і розроблення рекомендацій щодо поліпшення сучасної фармацевтичної допомоги.

Матеріали та методи: як інструменти дослідження використовувалися аналітичні та соціологічні методи (анкетування).

Результати дослідження. В анкетуванні були задіяні працівники практичної фармації зі стажем роботи не менше 25 років, що володіють певними професійними компетенціями: мають високу професійну категорію, опубліковані наукові статті або науковий ступінь, досвід роботи у системі

координації і контролю, а також досвід роботи керівником фармацевтичного підприємства / організації. Як експерти обрано 93 фахівця, зокрема і фармацевти, з яких: 7 докторів медичних наук, 5 фахівців, що опублікували наукові статті, 78 мають вищу професійну категорію, 3 є колишніми і діючими посадовими особами з досвідом роботи в системі координації і контролю. Після анкетування експерти проаналізували головні реформи у галузі фармації, які відбулися в Молдові за 25 років (1990-2015 рр.).

Висновки. Було показано, що негативний вплив цих реформ перевищує позитивний в 1,46 разу. Розроблено та запропоновано рекомендації щодо усунення / усунення негативних наслідків реформ у галузі фармації; вивчення / можливості ініціювання низки фармацевтичних реформ / нормативних актів, запропонованих експертами, які брали участь у дослідженні.

Ключові слова: фармацевтична реформа; фармацевтична система; фармацевтичні послуги; компетентність; ступінь досягнення реформи; споживач ліків.

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ФАРМАЦЕВТИЧЕСКАЯ РЕФОРМА В РЕСПУБЛИКЕ МОЛДОВА В ПЕРИОД НЕЗАВИСИМОСТИ

За последние два десятилетия Республика Молдова прошла сложный и противоречивый путь своего развития. С целью определения вектора своего развития, исходя из демократических ценностей западной культуры, практически полностью была пересмотрена и создана нормативно-правовая база. Концепция реформы Республики Молдова включала либерализацию цен и отказ от плановой системы управления экономикой при создании необходимых механизмов для функционирования рыночной экономики: создание банковской системы, рынка капитала и других учреждений, введение национальной валюты, а также длительный процесс создания новой правовой базы.

Цель: анализ основных реформ, проведенных в Молдове в области фармации за период независимости; выделение их влияния на ожидаемые эффекты и разработка рекомендаций по улучшению фармацевтической помощи.

Материалы и методы: инструментами исследования были аналитические и социологические методы (анкетирование).

Результаты исследования. В процессе анкетирования были задействованы сотрудники со стажем работы не менее 25 лет, обладающие определенными профессиональными компетенциями: имеющие высокую профессиональную категорию, опубликованные научные статьи или ученую степень, опыт работы в системе координации и контроля, а также опыт работы руководителем фармацевтического предприятия / организации. В качестве экспертов выбрано 93 специалиста, в том числе фармацевтов: 7 докторов медицинских наук, 5 специалистов, опубликовавших научные статьи, 78 обладателей высшей профессиональной категории, 3 являются бывшими и действующими должностными лицами с опытом работы в системе координации и контроля. После анкетирования эксперты проанализировали главные реформы в области фармации, которые произошли в Молдове за 25 лет (1990-2015 гг.).

Выводы. Было показано, что отрицательное влияние этих реформ превышает положительное в 1,46 раза. Разработаны и предложены рекомендации по устранению / устранению негативных последствий реформ в области фармации; изучению / возможности инициирования ряда фармацевтических реформ / нормативных актов, предложенных экспертами, участвовавшими в исследовании.

Ключевые слова: фармацевтическая реформа; фармацевтическая система; фармацевтические услуги; компетентность; степень достижения реформы; потребитель лекарств.

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

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 of 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

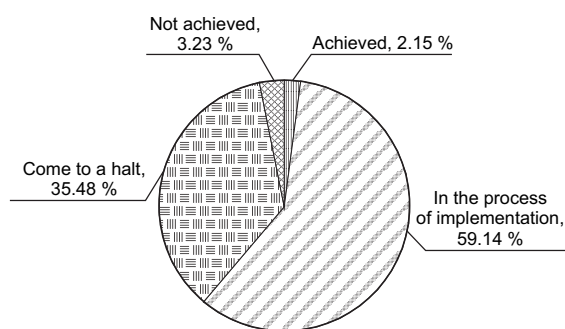


Fig. 1. The introduction of basic pharmaceutical services in community pharmacies

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;

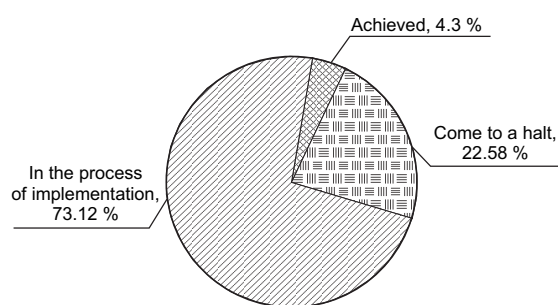


Fig. 2. Changing the pricing system for medicines

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.

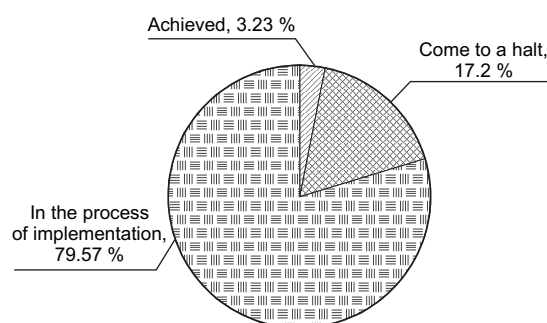


Fig. 3. Implementation of good practice rules (GMP, GDP)

Table 1

THE IMPACT OF THE PHARMACEUTICAL REFORMS ON DRUG CONSUMERS

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

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

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 82.8 %. 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 2

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

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

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

Pharmaceutical Reforms	The assessment of indicators (%)					
	S	M	Z	D	PI	NC
a) Privatization of pharmacies and liquidation of the state pharmaceutical sector	79.57	20.43				
b) The permission to create a community pharmacy for people without a pharmacy qualification	82.8			12.2		
c) A warehouse permit for a pharmacy chain	37.63	32.26		30.11		
d) The transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber		37.63	35.48	21.51		5.38
e) Application of accreditation of pharmaceutical companies		24.73	59.14	16.13		
f) Reorganization of INF into AM (AMDM)	30.11	32.26	10.75	26.88		
g) Provision of basic pharmaceutical services	73.12	26.88				
h) Application of the CTD format in the process of drug authorization	55.91			3.23	40.86	
i) Changing the pricing system for medicines	72.04		27.56			
j) Implementation of good practice rules (GMP, GDP)	55.91			3.23	40.86	

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

Table 4

THE IMPACT ON THE EFFICIENCY OF THE ENTIRE PHARMACEUTICAL SYSTEM

Pharmaceutical Reforms	The assessment of indicators (%)					
	S	M	Z	D	PI	NC
a) Privatization of pharmacies and liquidation of the state pharmaceutical sector	80.65			19.35		
b) The permission to create a community pharmacy for people without a pharmacy qualification				100		
c) A warehouse permit for a pharmacy chain	18.6			91.4		
d) The transfer of licensing of the pharmaceutical activities under the jurisdiction of MS RM to the Licensing Chamber				100		
e) Application of accreditation of pharmaceutical companies	12.9	19.36	67.74			
f) Reorganization of INF into AM (AMDM)	37.73	40.86	21.51			
g) Provision of basic pharmaceutical services	6.45	64.52	29.03			
h) Application of the CTD format in the process of drug authorization		75.27	4.3		20.43	
i) Changing the pricing system for medicines			51.61	48.39		
j) Implementation of good practice rules (GMP, GDP)	78.49				21.51	

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;

- 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.

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