

# The study of pharmaceutical specialists' thoughts concerning self-regulation of pharmaceutical activity in Ukraine

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## Abstract

The aim of our study was to investigate the views of pharmacists on understanding the nature and necessity of implementing the self-regulation of pharmaceutical practice in Ukraine. We conducted an anonymous questionnaire survey among pharmaceutical specialists (n = 827) from the majority (16 out of 25) of the regions controlled by the Ukrainian government during the period from October till December 2018. This survey revealed lack of pharmacists' understanding the concept of self-regulation of pharmaceutical practice. On the one hand, most respondents do not oppose the implementing of self-regulation and don't reject exclusive membership in self-regulated pharmaceutical organizations for only pharmaceutical specialists, but on the other hand the survey showed a low willingness voluntarily to become a member of such organizations and also low level of knowledge of self-regulation process. This indicates the need to update the self-regulation process through providing training activities for pharmacists, the development of legal framework and the government's assistance of self-regulation of pharmaceutical practice.

## Keywords

Self-regulation, pharmaceutical activities, pharmaceutical practice, pharmaceutical societies, public organizations, Ukraine

## Introduction

Globally, the interests of over four million pharmacists, pharmaceutical scientists and pharmaceutical educators are represented by the International Pharmaceutical Federation (FIP), which is an official partner of the WHO and includes 151 national organizations, academic institutions and individual members (IPF 2020).

As for the EU, today the key role here is played by the Pharmaceutical Group of the European Union, (whose members are represented by the national associations and professional bodies of community pharmacists in 31 Eu-

ropean countries including EU Member States, EU candidate countries and EEA/EFTA countries) and European Association of Hospital Pharmacists, which unites more than 23.000 hospital pharmacists in 35 European countries (EAHP 2020; PGEU 2020).

Functioning of the pharmaceutical industry in developed countries is primarily related to the pharmaceutical practice self-regulation (PhPSR) activities, implemented through such self-regulated pharmaceutical organizations (SRPhO) as for example the American Pharmaceutical Society in the US, the Royal Pharmaceutical Society in the UK, the Polish Pharmaceutical Society and the Pharmacy

Chamber in Poland, the Bulgarian Pharmaceutical Union and The Bulgarian Association of Hospital Pharmacists in Bulgaria and others.

There are a number of different trends that indicate how the healthcare system is changing in response to financial and organizational hurdles (Kolasa et al. 2020), but the quality and accessibility of pharmaceutical services to the public is one of the main criteria for the effectiveness of the health care system, this is why about thirty years ago European and US scientists initiated research of the PhPSR development in their countries (Hepler 1988; Van Den Bergh and Faure 1991).

In Ukraine, that relates to developing countries, the question of setting up a SRPhO have arisen just now. The need to implement pharmaceutical self-regulation in Ukraine is conditioned by the range of factors. Ambiguity, instability and controversy of pharmaceutical legislation are the most important of them. European integration processes in Ukraine (Litvinenko and Sobkova 2015) and prospects of voluntary implementation of world standards for the pharmaceutical services (Hala 2014) are also essential preconditions to build PhPSR institution in Ukraine.

The systemic crisis in the pharmaceutical sector of the Ukrainian health-care system is conditioned by a number of factors, but the absence of PhPSR is fundamental. Despite the lack of legislative support for self-regulation of pharmaceutical practice, there are about 120 organizations in Ukraine that, according to the set of functions they perform and their inherent characteristics, can be classified as self-regulated. Non-government organization All Ukrainian Pharmaceutical Chamber is one of such organizations. It is an organizational member of FIP and it has branches in most regions of Ukraine. However, shifting the emphasis to bureaucratization of most of these organizations does not ensure the implementation of proper self-regulation (ie activities, beneficial for their members and consumers of medicines and pharmaceutical services).

Several Ukrainian scientists contributed to the study of this issue in Ukraine, especially Liana Unhuryan (Unhuryan 2014), and a group of scientists including Alla Nemchenko, Iryna Susharyna, Viktoriya Nazarkina and Viktor Khomenko (Nazarkina et al. 2015; Susharina et al. 2017a, b). The authors of this article analyzed PhPSR foundations in foreign countries (Hromovyk and Pankevych 2017), conducted a situational analysis, using SWOT analysis methodology (Hromovyk and Pankevych 2018; Pankevych and Hromovyk 2017), and determined the development strategy of the pharmaceutical self-regulation in Ukraine (Pankevych and Hromovyk 2019). The implementation of PhPSR vitally requires wide support of this idea among pharmaceutical specialists (PhS). However, in order to make a decision, they must at least understand what PhPSR is and why it is so necessary for the proper functioning of the pharmaceutical healthcare sector. That is why **the aim of our study** was to investigate the views of pharmacists about understanding the nature and necessity of PhPSR implementation in Ukraine. The obtained results will allow to determine the main priorities on the way of development of PhPSR institution in Ukraine.

## Materials and methods

Questionnaire method, mathematical and statistical methods, method of generalization and interpretation of results were used in this scientific research. The respondents were PhS from the majority (16 out of 25) of the regions controlled by the Government of Ukraine. The study was conducted in the period from October till December 2018. Paper questionnaires were distributed anonymously among participants in regional pharmaceutical conferences, through pharmacy chains, regional branches of existing pharmaceutical non-government organizations and through the system of obligatory continuing pharmaceutical education.

As there were no samples of questionnaires on the researched question, we developed the questionnaire according to recommendations (Meadows 2003). The questionnaire consisted of two blocks of questions. In the first we revealed the educational level of the respondents, age, gender, region, work experience in the specialty and membership in pharmaceutical public organizations (PO). In the second block of questions, we studied the opinion of the respondents about thoughts concerning self-regulation of pharmaceutical activity in Ukraine. 1000 questionnaires were sent, 894 questionnaires were received, from which 827 (92.5%) qualitatively completed questionnaires were selected and processed.

The majority of respondents (67.1%) were pharmacists with university degree, all the rest were pharmaceutical college graduates. Women significantly prevailed (90.9%) among the respondents. The youngest respondent was 21 years old and the oldest – 74. The age distribution showed that the majority of respondents (41.4%) represent the age range of 26–35 years.

The PhS working experience of the surveyed people is characterized as follows: 1) up to 5 years – 30.6%; 2) from 6 to 10 years – 20.7%; 3) from 11 to 15 years – 19.9%; 4) from 16 to 20 years – 7.3%; 5) over 21 years – 21.5%. It is important to summarize that the majority of participants (69.4%) were PhS with 6 years or more working experience, which gives reason to believe that the information received in this survey is reliable, since this group of respondents is quite professionally experienced.

In the study we used a simplified formula for calculating a probability sample in a public opinion poll ( $P = 0.954$ ) (Savka et al. 2008), which is recommended if the population is greater than 5,000 persons (the total number of PhS is 48,200 (Practical pharmacy 2020)):

$$n = 1 / \Delta^2,$$

where  $n$  – sample size,  $\Delta$  – the fraction of the specified sampling error.

The sampling error in the case of 827 participants is  $\pm 0.034$  or  $\pm 3.4\%$ , so the obtained survey results show the investigated reality within the usual measure of reliability ( $\Delta = 3\text{--}10\%$ ) (Marketing-Helping 2020).

To determine the statistical significance, we used Kendall concordance coefficient, which was calculated with the formula:

$$W = \frac{12S}{m^2(n^3 - n)}$$

where  $S$  is the sum of squared deviations of total ranks of each factor from mean value of total ranks;  $m$  is the number of factors;  $n$  is the number of observation units.

Respondents were divided into two groups depending on their membership in PO, related to the pharmacy. It was found that Kendall concordance coefficient indicates minor differences of agreement among raters in these groups: in the group “non-members of PO” (NMPO) – 0.399 ( $n = 730$  or 88.2%), and in the group “members of PO” (MPO) – 0.332 ( $n = 97$  or 11.8%).

## Ethics approval

All procedures were performed following ethical standards of the Helsinki declaration and its amendments.

## Results and discussion

According to the results of the sociological survey (Table 1), the level of respondents’ awareness with the basic principles of self-regulation of the certain markets is extremely low: almost one-third among MPO and 14.8% among NMPO. Despite this, nearly two-fifths of MPO respondents and over a third NMPO are positive about the possibility of PhPSR. It is worth to note that only 16.7% of MPO and 14.5% of NMPO fully support PhPSR being mandatory for all market players. According to the majority of respondents (76.3% and 62.3% respectively), only PhS can become members of the self-regulated organizations. At the same time, over a third of the MPO and over a fifth of the NMPO are ready to become members of the SRPhO themselves.

Based on the survey results, only 16.8% of all respondents are aware of the essence of self-regulation. Nevertheless, it is worth to note that the level of awareness of the basic principles of work of self-regulated organizations among MPO is twice bigger – 32.0%, than among other respondents – 14.8%. This situation is caused by many factors, including small PO membership experience among PhS, generally limited financial resources and the lack of adequate grant support for the PO in Ukraine.

Three-quarters of the respondents do not have any warnings concerning the possibility of PhPSR implementation. Obviously, the current state of national pharmacy does not satisfy them and implementation of PhPSR may be considered as an option to improve current situation. Almost a quarter of respondents cannot judge this issue. In our opinion, this is due to the indifferent professional outlook, fear of being used, and

**Table 1.** Results of sociological survey.

Answer option	MPO, %	NMPO, %	Total, %	p-level
<b>Do you know the basic principles of self-regulation of certain markets (work of self-regulated organizations)?</b>				
Yes	32.0	14.8	16.8	$p < 0.05$
No	27.8	50.8	48.1	
I do not know	40.2	34.4	35.1	
<b>How do you treat the opportunity of PhPSR?</b>				
Positively	39.2	37.5	37.7	$p > 0.05$
Neutrally	37.1	37.7	37.6	
I do not know	23.7	24.8	24.7	
<b>Do you support the statement that PhPSR should be mandatory for all market players?</b>				
Fully support	16.7	14.5	14.8	$p > 0.05$
Preferably support	40.6	35.1	35.7	
Neutrally	30.2	36.8	36.1	
Mostly I do not support	5.2	8.5	8.1	
I totally do not support	7.3	5.1	5.3	
<b>Who should be a member of the SRPhO?</b>				
PhS only	76.3	62.3	64.0	$p < 0.05$
All employees of the pharmaceutical organization, regardless of education	17.5	22.3	21.8	
I do not know	6.2	15.1	14.2	
<b>Would you join a SRPhO?</b>				
Ready to join voluntarily	35.0	22.6	24.1	$p < 0.05$
Only when the membership will be mandatory	29.9	34.0	33.5	
I do not know	35.0	43.4	42.4	

widespread skepticism among PhS. It should be noted that the results of the answers to this question indicate the absence of significant difference between MPO and NMPO answers.

We found that only 16.7% of MPO and 14.5% of NMPO fully support the obligatoriness of PhPSR for all market entities, two-fifths and over a third of the representatives of the relevant groups mostly support it. About a third of respondents expressed hesitation about this issue. In return, 12.5% of the MPO and 13.6% of the NMPO mostly or completely do not support this position. The above indicates a lack of understanding the need for implementation of PhPSR among PhS.

According to the majority of respondents (three-fourths of the MPO and almost two-thirds of the NMPO) only PhS can be members of the SRPhO. The presence of pharmaceutical education among all participants of the PhPSR process is a key to the skilled and professional approach to solve urgent problems of the pharmaceutical activity.

Only about a third of the MPO and more than a fifth of the NMPO stated for willingness to voluntarily become a SRPhO member. Instead, less than a third of the MPO and over a third of the NMPO are ready for membership only when it will become mandatory. Sadly, that almost a third of the MPO and more than two-fifths of NMPO were not able to decide their answers to this question.

Based on the results of the survey, as well as on the mission of PhPSR (which we mean in the protection / support of interests, rights and freedoms of pharmaceutical specialists and consumers of medicines and pharmaceutical services) we believe that the main strategic directions of PhPSR in Ukraine should be:

- popularization of the idea of PhPSR among pharmacists, as well as contact audiences with control functions (President of Ukraine, Verkhovna Rada of Ukraine, Cabinet of Ministers of Ukraine, Ministry of Health of Ukraine) or without such ones (pharmaceutical non-government organizations, media networks, general public);
- ensuring the development of a national model of PhPSR by the adoption of the Framework Law “On Self-Regulation” and the Law “On Pharmaceutical Self-Government” by Verkhovna Rada of Ukraine.

## Conclusion

Our results show that the pharmacists’ support of the prospects of PhPSR in Ukraine is insufficient. On the one

hand most respondents do not oppose the implementing of self-regulation and don’t reject exclusive membership in self-regulatory pharmaceutical organizations for only PhS, but on the other hand we revealed low willingness to become a member of such organizations voluntarily and low level of knowledge about self-regulation process among PhS.

This indicates the need to update the self-regulation process through providing training activities for pharmacists, the development the appropriate legal framework and the government’s assistance of self-regulation of pharmaceutical practice.

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