

Z.O. Zhalimova¹, A.R. Shopabaeva¹, K.S. Urazgaliyev², S.L. Tursumatova¹¹Asfendiyarov Kazakh National medical university²West Kazakhstan Medical University named after M. Ospanov

FEATURES OF THE IMPLEMENTATION OF THE INTERNATIONAL STANDARD “GOOD PHARMACY PRACTICE” IN THE WESTERN REGION OF RK

An information analysis of data on the Republic of Kazakhstan (hereinafter referred to as the RK) allowed to assess the status and prospects of the transition of pharmacy organizations to the international standard Good Pharmacy Practice (hereinafter GPP), during which it was revealed that the West Kazakhstan region is in the top three lagging regions.

One of the most pressing problems in the pharmaceutical industry of our republic is the transition of as many pharmacy organizations as possible to the international GPP standard - good pharmacy practice. In accordance with the recommendations of the World Health Organization, in 2006, its own national standard was developed, harmonized with GPP - the State Standard “Good Pharmacy Practice”, and on May 27, 2015, Order No. 392 “On Approving Good Pharmaceutical Practices” was adopted. In the Republic of Kazakhstan, the requirements for the transition of pharmacy organizations to GPP standards by 2020 are legislatively enshrined in the Code of the Republic of Kazakhstan dated September 18, 2009 No. 193-IV “On the Health of the People and the Health Care System” (as amended on 01.01.2020) [1].

Keywords: pharmacy organizations, quality drugs, good pharmacy practice, GXP, GPP, western region of the Republic of Kazakhstan

Introduction

Currently, in Kazakhstan, out of 8887 pharmaceutical license holders, 3% have certificates for good pharmacy practice. In accordance with the Law of the Republic of Kazakhstan dated December 28, 2018 No. 211-VI ЗРК “On Amendments and Additions to Some Legislative Acts of the Republic of Kazakhstan on the Circulation of Medicines and Medical Devices” with Article 69, the transition for pharmaceutical license holders to the international standard GPP extended to 2023

According to the current legislation of the Republic of Kazakhstan, from January 1, 2023, all pharmacy organizations must switch to the international standard of good pharmacy practice. It is also planned to extend the validity of the GDP and GPP certificates from 3 to 5 years after two consecutive confirmations, the third – unlimited [2].

An analysis of the data of holders of certificates of good pharmacy practice in the republic showed that the Western region of Kazakhstan belongs to the top 3 not practicing GPP standard. The leading positions in the implementation of the GPP standard are held by the cities of Almaty, Shymkent and the Karaganda region (Picture 1).



Picture 1 – The number of pharmacy organizations that have implemented the GPP standard from 2018-2019

Purpose of the study

The purpose of this work is to analyze the activities of pharmacies in Aktobe for compliance with the requirements of the international GPP standard.

Materials and methods

In preparing this study, methods of sociological survey (questionnaire) were used, as well as comparison methods, mathematical, statistical methods, a descriptive method, a logical method, etc.

The main materials in the study are the data on regulatory documents governing the assessment of the safety of medicines according to good pharmacy practice. Also, the results of the questionnaire of pharmacy organizations in the Aktobe region such as the Millennium pharmacy chain, Europharma, as well as pharmacy organizations at health facilities. In this study, descriptive statistics methods were used. To analyze the results, the SPSS software package (version 12.0) was used.

Results and discussion

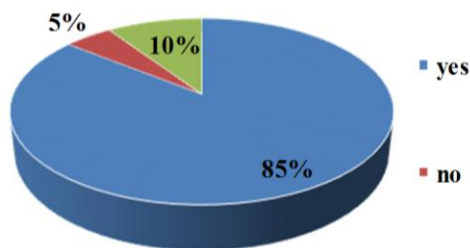
At the end of the 1st quarter of 2020, out of 347 holders of international GPP standard certificates in the republic, the West Kazakhstan region accounts for 12%.

The transition to the international standard in the Republic of Kazakhstan occurred in 2016, but in the Western region, implementation began only in 2017 [3]. In 2017, the number of pharmacy organizations that implemented the standard was 27. In 2018, the situation changed and the number of pharmacies that switched to the standard doubled, which amounted to 3.2%. A sociological survey was conducted in order to identify the main causes and levers that inhibit pharmacy organizations in the transition to an international standard, characteristic of the Western region of Kazakhstan.

As a result of the examination and analysis of the results of the work done as part of the implementation of good pharmacy practice, about 100 pharmacists and heads of pharmacy organizations were interviewed. The survey was conducted among pharmacists and pharmacy managers in the public and commercial sectors. The study involved pharmacists with work experience from 6 months to 35 years [4].

To the question “Do you know in which year the main provisions of the GPP were adopted in our country?”, 85% of respondents said that they were aware, 10% had difficulty answering and 5% were not aware of the international GPP standard, which tells us that 15% of respondents are not aware of the standard of good pharmacy practice.

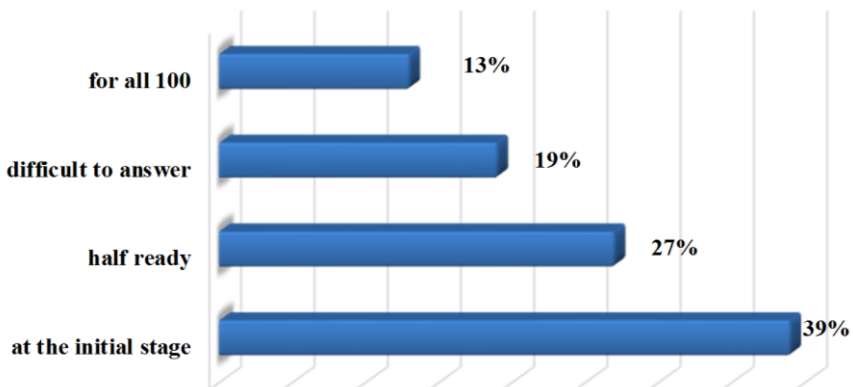
DO YOU KNOW WHAT YEAR WAS THE BASIC PROVISIONS OF THE GPP WERE ACCEPTED IN OUR STATE?



Picture 2

We also asked respondents to evaluate at what stage the implementation of GPP is their pharmacy organization at the moment. The superior number of respondents in pharmacy organizations in the commercial and public sectors, namely 39%, said that their organization was at the initial stage of GPP implementation and 27% said they were half ready (Picture 3).

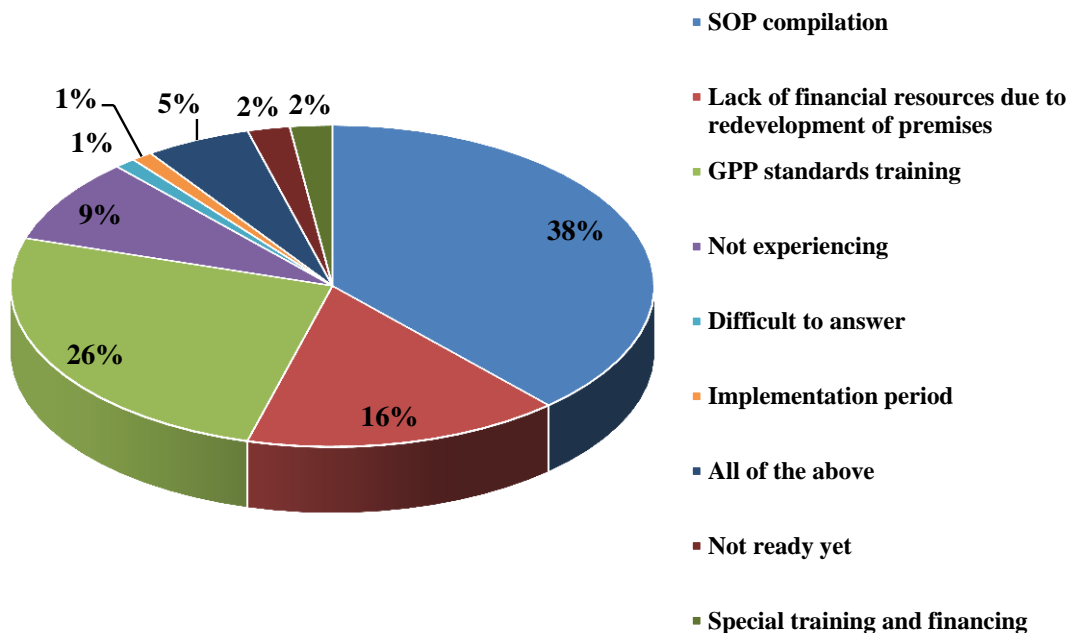
WHAT STAGE OF GPP IMPLEMENTATION IS YOUR PHARMACY ORGANIZATION AT THIS TIME?



Picture 3 - Analysis of the implementation stage of the GPP standard in the western region of Kazakhstan

The diagram below presents the main reasons for the long transition of pharmacy organizations to the GPP standard in the Western region of Kazakhstan. 38% of respondents agreed that the development of standard operating procedures (hereinafter SOPs) makes it difficult, 26% on the need for pharmacists to learn GPP standards (Picture 4).

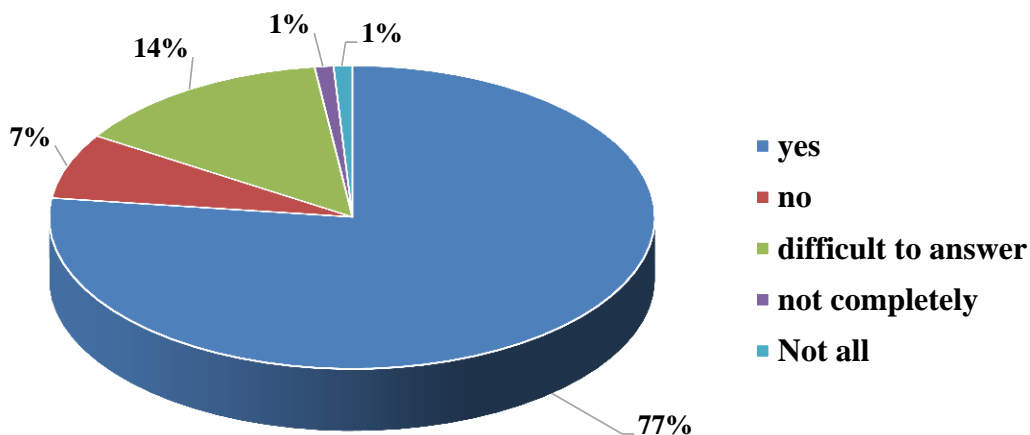
WHAT DIFFICULTIES DO YOUR PHARMACEUTICAL ORGANIZATION TESTED OR TESTING AT THE IMPLEMENTATION OF NAP?



Picture 4 - The main difficulties in the transition to the international standard GPP

We also asked managers and pharmacists themselves to assess awareness of the main provisions of the international GPP standard. In most cases, managers and heads of pharmacy organizations replied that pharmacists were partially aware of the international standard NAP. Although 77% of pharmacists themselves are confident that they are aware of all aspects of the standard, in spite of the fact that they do not practice international standards of good pharmacy practice.

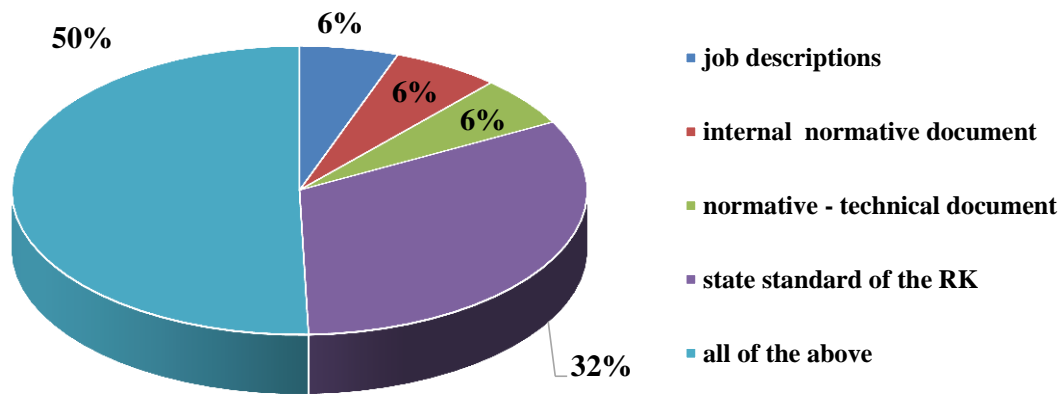
ARE YOU AWARE OF THE BASIC PROVISIONS OF THE GPP INTERNATIONAL STANDARD?



Picture 5 - Awareness of pharmaceutical workers on the main provisions of the international GPP standard

For a more detailed study of the knowledge of pharmacy employees about NAP standards, we asked to answer the question: What can be taken as a documentary basis for the development of standard operating procedures? 50% of respondents say that the basis of the document is to take job descriptions.

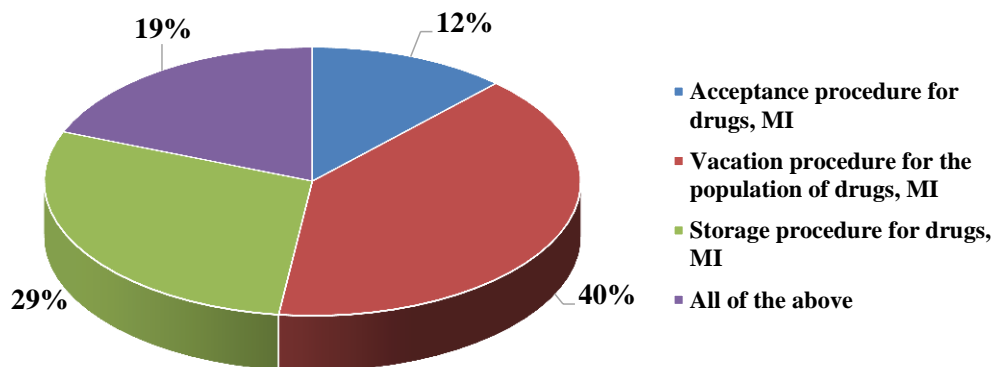
WHAT CAN BE TAKEN AS THE BASIS FOR THE DEVELOPMENT OF SOP DOCUMENT?



Picture 6 - Documentary basis for the development of standard operating procedures as part of the transition to the international GPP standard

Despite the fact that pharmacists are aware of the main provisions of the international GPP standard, they still do not understand the basic mechanism for writing standard operating procedures, and, therefore, will not be able to provide the population with proper pharmaceutical assistance to the population and qualitatively implement medicines, as modern pharmaceutical development trends are required our state's market as part of the transition to the international GPP standard.

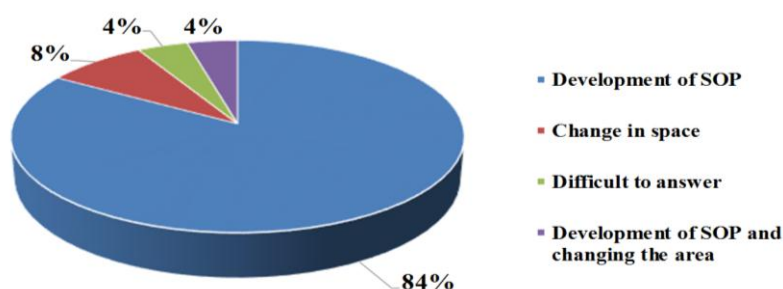
WHICH OF SOP NEED TO BE DESCRIBED IN YOUR PHARMACY ORGANIZATION?



Picture 7 - Standard operating procedures that need to be described according to respondents in their pharmacy organizations

To the question, "What standard operating procedures do you need to describe in your pharmacy organization?", 30% of the respondents answered the procedure for storing drugs, MI and MT, and about 40% answered the procedure for dispensing drugs, MI and MT to the population. An analysis of the data showed that one of the main factors in the long transition is the lack of on-site training of employees in the modern requirements for the provision of pharmaceutical care according to GPP standards. Although according to 63% of respondents, pharmacy organizations have a person in charge of compiling SOPs.

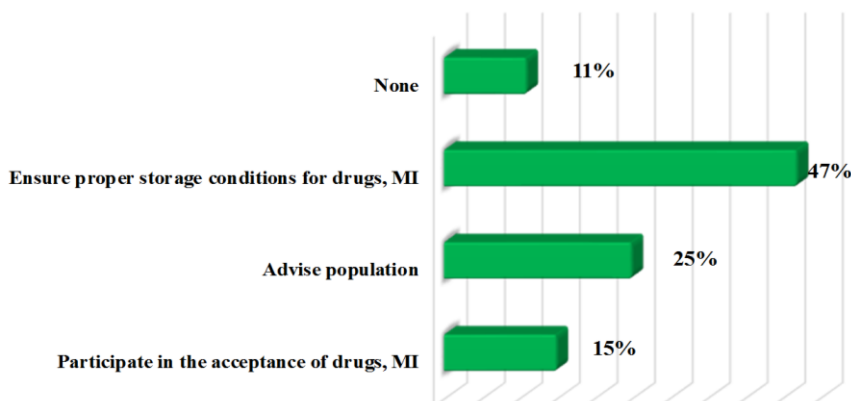
**MAIN OBJECTIVES OF THE PHARMACY ORGANIZATION
IMPLEMENTING THE GPP STANDARD IN 2020?**



Picture 8 - The objectives of the pharmacy organization that introduced the international GPP standard in 2020

Many employees of the pharmacy organization have difficulty in additional types of pharmaceutical assistance to the population within the framework of the GPP standard. One of them, the presence of a separate office for consultation on certain issues with the consumer.

**WHAT ADDITIONAL PHARMACEUTICAL ASSISTANCE TO
POPULATION MAKE YOU DIFFICULT WHEN IMPLEMENTING
THE INTERNATIONAL GPP STANDARD?**



Picture 9 - Analysis of the types of pharmaceutical assistance to the population that cause difficulties for pharmacists

According to changes in the resolution of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 27, 2015 No. 392 "On the Approval of Good Pharmaceutical Practice", mandatory diagnostic tests and other provisions on medical services performed in accordance with the requirements of the Standard of Good Pharmaceutical Practice (GPP) were excluded. Despite the fact that the date of mandatory compliance with the GPP standard has been postponed to a later date, pharmacy motivation tools are being introduced in the Ministry of Health of the Republic of Kazakhstan. For example, the European Bank for Reconstruction and Development (hereinafter EBRD), together with the Government of the Republic of Kazakhstan, provides grants of up to 10 thousand euros for a partial reimbursement of the company for the implementation of international standards (GxP) [5]. This shows that our state provides pharmacy organizations with the opportunity to solve the financial component as part of the transition to international standards of good pharmacy practice.

Conclusion

Thus, having studied and analyzed the process of introducing the GPP standard by drug users, it can be concluded that the main reasons for the West Region of the Republic of Kazakhstan in the top 3 lagging areas are, firstly, the lack of awareness of pharmacists in the provisions of the GPP standard, the most knowledgeable are the administrative and managerial personnel. Secondly, the compilation of SOPs causes difficulty, despite the fact that there are responsible persons in pharmacy organizations. Thirdly, the lack of monetary resources for redevelopment of premises according to the requirements of the GPP standard.

REFERENCES

1. The state standard of the Republic of Kazakhstan "Good pharmacy practice". 1615-2006.
2. A.R. Shopabaeva, O.N. Evtushenko, A.R. Tulegenova Analysis of the readiness of the transition of Kazakhstan pharmacies to GPP standards // Bulletin of KazNMU. - 2014. - №5 - P. 165-167.
3. Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 27, 2015 No. 392 "On approval of good pharmaceutical practices". URL: <http://adilet.zan.kz>
4. No. 193-IV 3PK "On the health of the people and the healthcare system" with add. and rev. for 2020 // The Code of the Republic of Kazakhstan dated. – 2009. – P. 2-6.

5. Kaydar E.K., Kenesova A.A., Yurchenko I.V., Sabyrov The health of the population of the Republic of Kazakhstan and the activities of healthcare organizations in 2017. - 2018: Statistical collection. - Astana: Ministry of Health of the Republic of Kazakhstan, 2018. – 353 p.

З.О. Жалимова¹, А.Р.Шопабаева¹, К.Ш. Уразғалиев², Ш.Л. Турсұматова¹

¹*Қазақстанның ұлттық медицина университетінің атындағы С.Д. Асфендияров университеті, Қазақстан
Кафедра ұйымдастыру, экономика және клиникалық фармацевтика*

²*Западно-Қазақстанның медицина университетінің атындағы М.Оспанов*

ОСОБЕННОСТИ ВНЕДРЕНИЯ МЕЖДУНАРОДНОГО СТАНДАРТА GOOD PHARMACY PRACTICE В ЗАПАДНОМ РЕГИОНЕ РК

Резюме: Информационный анализ данных по Республике Казахстан (далее РК) позволил оценить состояние и перспективы перехода аптечных организации на международный стандарт Good Pharmacy Practice (далее GPP), в ходе которого было выявлено, что в топ трёх отстающих областей входит Западно-Казахстанский регион.

Ключевые слова: аптечные организации, качественные ЛС, надлежащая аптечная практика, GXP, GPP, западный регион РК

З.О. Жалимова¹, А.Р.Шопабаева¹, К.Ш. Уразғалиев², Ш.Л. Турсұматова¹

¹*С.Д. Асфендияров атындағы Қазақ Ұлттық медицина университеті, Қазақстан
Фармацевтика және клиникалық фармацевтика ұйымдастыру, басқару бөлімі*

²*Марат Оспанов атындағы Батыс Қазақстан медицина университеті*

ХАЛЫҚАРАЛЫҚ СТАНДАРТТЫ ЖҮЗЕГЕ ТИІМДІЛІК ҚАЗАҚСТАН РЕСПУБЛИКАСЫНЫҢ БАТЫС АЙМАҒЫНДА GOOD PHARMACY PRACTICE

Түйін: Қазақстан Республикасы (бұдан әрі – ҚР) бойынша ақпараттық мәліметтерді талдау фармацевтикалық ұйымдардың Good Pharmacy Practice (бұдан әрі - GPP) халықаралық стандартына көшуінің қазіргі жағдайы мен болашағын бағалауға мүмкіндік берді, осы зерттеу барысында Батыс Қазақстан облысы артта қалған үш аймақтың қатарында екендігі анықталды.

Түйінді сөздер: дәріхана ұйымдары, сапалы дәрі-дәрмектер, жақсы дәріхана практикасы, GXP, GPP, Қазақстан Республикасының батыс аймағы