

# Implementation of Standards of Good Pharmacy Practice in the World: A Review

Liana Unhurian, Oksana Bielyaieva, Irina Vyshnytska, Natalia Suschuk, Irina Petkova

*Department of Organization and Economics of Pharmacy, Faculty of Pharmacy, Odessa National Medical University, Valihovsky Lane, 2, Odessa - 65026, Ukraine*

## Abstract

The aim of the study is to review the historical stages of development of the requirements of good pharmaceutical practice (GPP), generalization of the normative documents recommended by the International pharmaceutical company (MFP) for use in the world of pharmaceutical practice. Methods of generalization of the information material and system analysis were used in the study. Historical stages of the development of the concept of the GPP in the world and the role of the World Health Organization and the FIP in the process were analyzed. Researches of professional standards of pharmacy practice in developed countries reveal different approaches to the regulation of such activities, however, despite the applicable model standards are developed by the pharmaceutical associations and are used by regulatory bodies, business owners, and professionals to control the quality of pharmacy services that are provided to the population. The study indicates that the development of the GPP standards should be resolved at the level of public professional organizations as the national regulation of pharmacy practice in different countries varies significantly. Prospects of further scientific researches are aimed on using the results of the study while developing and implementing national standards of the GPP in the world.

**Key words:** Guideline, pharmaceutical practice, pharmacies, the good pharmacy practice, the World Health Organization

## INTRODUCTION

The pharmaceutical practice varies in different countries and continents, including developing countries, transitional and developed countries. The standard of quality of pharmacy services, that is the joint guideline of the World Health Organization (WHO)/International Pharmaceutical Federation (FIP) of the Good pharmacy practice (GPP) updated in 2011, is intended to take into account these changes in practice.

The profession of pharmacist is currently growing fast, and new roles are being offered and proclaimed not only by the profession but also by other medical professionals and national and organizations and institutions. The guideline of the GPP is visionary and flexible, and it has to retain its relevance with the emergence of new roles. One of the main methods of quality control of medicines and pharmaceutical services for the population is to standardize various aspects of

pharmacies. Guide of the GPP is an important step toward the improvement of pharmacy services.<sup>[1]</sup>

The WHO and FIP emphasize that the guideline of the GPP is intended for use by national professional pharmaceutical associations as well as by national authorities and other relevant bodies responsible for drawing up the relevant documents and related laws and regulations in their countries. It is not a set national standard, but it provides guidance on specific achievable roles, functions, and activities, which execute the mission of pharmacy practice in the new millennium.

### Address for correspondence:

Liana Unhurian, Department of Organization and Economics of Pharmacy, Faculty of Pharmacy, Odessa National Medical University, Valihovsky Lane, 2, Odessa - 65026, Ukraine. Tel.: +380487779818. E-mail: lianau@ukr.net

**Received:** 02-03-2018

**Revised:** 19-03-2018

**Accepted:** 24-03-2018

Considering the text of the entire guideline, a special importance is given to professional issues and attitudes, and welfare of the patient has a paramount importance. However, it should be noted that it is the first time when legal, economic, and labor framework in the context of the structure of the GPP is introduced, and it is quite in time considering worldwide debates on the economic aspects of medicines, access to quality medicines, access to skilled medical workers, the global failure of the workforce, the increased cost of medical care, and new models of pharmacy practice.<sup>[2]</sup>

The WHO and FIP define the GPP as a pharmacy practice that meets the needs of people who use services of pharmacists to provide optimal medical care on the principles of evidence-based medicine. To support this practice, it is necessary to create a national system of quality standards and guidelines.

The work purpose is the research of historical stages of development of the GPP requirements and examination of modern normative documents, recommended by FIP to use in the global pharmaceutical practice, and study of the current status of this issue in the world.

Methods of generalization of the information material and system analysis were used in the study.

Since the late 80s, the WHO and the FIP have been working toward defining the roles and functions of pharmacists, as well as developing guidelines for the GPP as the framework of pharmaceutical care.

The Medicines Strategy, adopted by the World Health Assembly in 1986, was revised by the WHO, and according to it, there were two meetings regarding the role of pharmacist organized. The first meeting took place in 1988 in Delhi, India.<sup>[3]</sup>

In 1992, the FIP developed standards for pharmaceutical services - the methodology of good pharmaceutical practice, spread by the WHO Information Centers in March 1993. During the congress in Tokyo, Japan, the standards of pharmacy services entitled "GPP in Public and Hospital Pharmacies" were officially published.<sup>[4]</sup>

The FIP congress adopted the FIP/GPP text under the auspices of the Tokyo declaration on quality standards of pharmacy services. According to this document, the FIP has urged pharmaceutical companies and governments to cooperate to implement standards for the GPPs or to revise existing national standards in countries where they already exist.

Then, in May 1994, a resolution of the World Health Assembly WHA47.12 on the role of the pharmacist in support of the revised strategy of the WHO for medicines was adopted.

A text of the GPP was also submitted to the Expert Committee of the WHO on specifications of pharmaceutical medicines in 1994 in Geneva.

According to recommendations of the WHO Expert Committee and the approval of the Board of the FIP in 1997, a joint document of the WHO/FIP of the GPP was published in 1999 in a series of technical reports of the WHO Expert Committee on questions of the specification of pharmaceutical medicines. This provided recommendations of the GPP, a more formal status, and ensured its wide distribution in the world.<sup>[5]</sup>

Soon the WHO organized two more meetings on the role of the pharmacist in 1997 in Vancouver, Canada, and in 1998 in Hague, the Netherlands. These meetings confirmed the need to reform the pharmaceutical education programs and noted the role of the pharmacist in self-help and self-healing.

Pharmaceutical group of the European Union (the EU) in 1998 developed a document with the GPP for Europe in which particular attention was paid to the EU countries - "the GPP in Europe."<sup>[6]</sup>

In 2001, the "GPP in the New Independent States. Guidelines for the development and implementation of standards" was developed in Denmark by the Copenhagen center of drug policy and development of pharmaceutical practice. The document analyzed the state of practice of pharmacies and focused attention on issues of education of responsibility for own health and prevention of morbidity, the provision of prescription drugs and their use, self-treatment, the effect from prescription and use of drugs, as well as the method of step-by-step implementation of proper pharmacy practices in developing countries and countries in transition. The WHO experts suggested to implement European standards for pharmacies on the level of existing national standards to regulate various aspects of pharmaceutical activity, in particular the quality of the prescription data received by the pharmacist; development of medical forms; building contacts with doctors according to individual recipes; evaluation of data on the use of medical products in medical and pharmaceutical practice; construction and implementation of educational programs for health-care workers; conducting of advertising campaigns and spreading of information; and the question of a building of a privacy policy for information about individual patients.<sup>[7]</sup>

According to FIP recommendations, there is a strategy for implementing of national standards of GPP. First of all, basic pharmaceutical services are set up, for which the regulatory framework and relevant standards should be developed. After that, the system of secondary and higher education in pharmacy should be changed, since pharmacists will need more in-depth knowledge of pharmacotherapy, pharmacopeia, and communicative skills. The final stage is the provision of more complex professional pharmaceutical services.

The FIP highlights such GPP elements that demonstrate that the pharmacy provides qualitative assistance and works according to high standards: Availability of pharmacist on

change; availability of a pharmacy for people with disabilities and elderly patients; availability of a comfortable waiting area; the possibility of a private conversation between a pharmacist and a patient, including those with disabilities; and presence in the pharmacy of a zone with information about healthy lifestyle.

According to FIP's recommendations, the role of the pharmacist in providing effective drug therapy is as follows: Management of therapy, monitoring the effectiveness of treatment, and providing information on the rational use of medicines. The pharmacist should assess the health and needs of the client, taking into account his individual characteristics.

An important aspect of GPP is the professional collaboration between the pharmacist and the doctor. The first one should have the necessary medical and pharmaceutical information (diagnosis and laboratory data) for each patient.

It is also important to monitor the compliance with GPP standards. It can be internal and/or external; it also may be mandatory or only for the purpose of accreditation/certification. This will reveal the disadvantages of fulfilling GPP requirements, as well as provide recommendations for their elimination. One of the simplest methods of controlling the quality of a pharmacy's work is to evaluate customer's satisfaction with the service.

In cooperation, FIP and WHO published the handbook "*developing of the pharmacy practice - a focus on the patient*" in 2006. This handbook describes the new paradigm of the pharmacy practice, and the approach to pharmaceutical help is introduced.

To improve standards and practice of distribution and use of medicines with the help of the setting of the WHO/FIP with the GPP as the framework, the FIP has taken the initiative to explore the possibilities of providing technical assistance to its member organizations in Cambodia, Moldova, Mongolia, Paraguay, Thailand, Uruguay, and Vietnam in developing of national standards of the GPP in a pilot study from 2005 to 2007.

In 2007, in Southeast Asia, the "Bangkok declaration of the GPP in public pharmacies" was adopted, and commitments of member associations for improving the quality of pharmacy services and professional practice were introduced.<sup>[8]</sup>

After accepting the guideline of the GPP in community and hospital settings, significant changes have occurred in the practice, applied science and technology, and pharmaceutical policy. Despite changes that have occurred since the adoption of the previous guidance of the GPP in the pharmaceutical policy, practice, and applied science in 2007, FIP was initiated to investigate the problem of updating the guiding principles of the GPP taking into account the modern standards of the present time and peculiarities of professional thinking.<sup>[9]</sup>

For this purpose in 2008, the FIP organized expert consultations in Basel, Switzerland, during the 68<sup>th</sup> World Congress. The meeting was attended by 50 participants, including the working group (WG), FIP of the GPP, the WHO staff from headquarters, representatives of the WHO regional office for the Eastern Mediterranean countries, the medicines advisers from Ghana, Nigeria, and the United Republic of Tanzania, presidents and secretaries of six Regional Pharmaceutical Forums, member organizations of FIP, and several invited international experts.<sup>[10]</sup>

After these consultations, the WG of FIP of the GPP has conducted an extensive investigation of the existing national standards for GPP in at least 37 countries and established a time frame that may allow carrying out adequate consultations with all 120 National Associations - members of FIP, relevant experts, and the WHO. The proposal concerning this initiative was presented at the 43<sup>rd</sup> meeting of the WHO expert Committee on questions of the specification of pharmaceutical medicines in October 2008 and an updated report was presented to the Committee of Experts at its 44<sup>th</sup> meeting in October 2009.

At the same time, in the end of 2008, the Pan-American health organization with the support of a group of experts from different pharmaceutical organizations was prepared "the guide for pharmaceutical services in primary health care" with the aim of underlining the role of pharmaceutical experts in the health system of Latin America.

Taking into consideration the consultations with 120 national members of the FIP in 2011 and changes in the pharmaceutical market, guidelines of the GPP through the adoption of a joint guideline FIP/WHO "the GPP: Standards of the quality of pharmacy services" were adopted and updated. This general guideline was published in the 45<sup>th</sup> report of the WHO Expert Committee as new standards of the quality of pharmacy services. Furthermore, this document calls national pharmacy professional organizations to adopt these guidelines and develop some special rules for the GPP.<sup>[11]</sup>

The GPP sets the standards that are usually higher than the requirements of the pharmaceutical legislation of the given country. There are several roles of pharmacists in the updated version of the GPP:

1. Manufacture, receipt, storage, security, distribution, use, release, and disposal of medical products.
2. Ensuring the effective management of the drug therapy.
3. Maintaining and improving of professional activity.
4. Promoting the increasing of the effectiveness of the system of medical care and health.<sup>[9]</sup>

These roles may vary for each pharmacist depending on duties they perform. Specific standards of the GPP can be developed only within national pharmacy professional organizations.

This guideline is recommended in the form of a set of professional goals that must meet the interests of patients and other stakeholders in the pharmaceutical sector.

Thus, in comparison with the previously approved concept of the GPP, the current updated version strengthens the requirements for the already known main elements of the GPP and highlights certain functions in each pharmacist's role for which minimum national standards should be set.

In different countries, the rules of the GPP exist in different forms. In some countries, there are holistic documents, where both requirements of material-technical base, facilities, personnel, and standards for the provision of pharmaceutical care are included. In other countries, these standards and requirements are set out in various documents. For example, in France, the standards for pharmacists are outlined in numerous guidelines. In Austria, on the contrary, almost all the requirements for pharmacists are joined in one law. There is also a guideline about the work of pharmacies, in which despite usual requirements for premises, equipment and staff there are also requirements for quality management system. In developed countries, the GPP standards have a recommended character. Hence, standards of pharmacy practice of Norway developed by the Norwegian pharmaceutical association in collaboration with other professional bodies contain requirements for activities of pharmacies that are used by the owners of the pharmacy business to conduct the internal quality control of pharmacy services. The minimum requirements for the operation of pharmacies are approved in legal acts that are adopted by the government.<sup>[12]</sup>

Pharmaceutical Society of Ireland issued Guideline on pharmacy practice to assist pharmacists in fulfilling legislative and regulatory requirements in providing pharmacy services.<sup>[13]</sup>

Furthermore, the GPP is implemented in countries of the CIS. Thus, in particular, Belarus has introduced a categorization of pharmacies. In Kazakhstan, the GPP was adopted in 2006, and in the Russian federation, rules of the GPP of the customs union were currently accepted.

It should be noted that the GPP standard and guidance on the implementation of proper pharmacy practices are the basis for implementing the concept of the total quality management (TQM), which has been operating in the world for more than 30 years, and the international standard of ISO quality management at pharmaceutical companies. The basis of the TQM is the understanding of the existence of an inextricable link between the quality management system and the management system of the organization, as well as the understanding that this is an essential tool for continuous improvement and increasing the competitiveness of the pharmacy organization in any market.<sup>[14]</sup>

## CONCLUSION

Hence, the GPP standards are an important step toward the expansion and improvement of activities of pharmacies

by raising the requirements to ensure the quality of public services.

Development and implementation of the GPP requirements into the practical activity of pharmacies are a long-term and continuous process, despite changes in pharmaceutical science and practice.

In guides of the GPP of editions of all years, the big attention is paid on standardization of work of pharmacists of the provision of the population with medicines and medical products. The development of the GPP standards should be resolved at the level of public professional organizations as the national regulation of pharmacy practice in different countries varies significantly.

The prospects of further scientific researches are aimed on using the results of the study while developing and implementing national standards of the GPP in the world.

## REFERENCES

1. The Order of MOH of Ukraine of 30.05.2013 № 455. On Approval of the Guidelines Good Pharmacy Practice: Quality Standards Pharmacy Services. *Weekly Pharm* 2013;27:18-20.
2. Vetutneva NO, editor. Modern concept of quality assurance of medicinal products. Vinnitsa: Nilan LTD.; 2018. p. 69-75.
3. General Pharmaceutical Council of Spain. Good Pharmacy Practice in Spanish Community Pharmacy. Madrid: General Pharmaceutical Council of Spain; 2013. p. 15.
4. Good Pharmacy Practice (GPP) in developing Countries. Recommendations for Step-Wise Implementation: FIP; 1998. p. 16.
5. Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. Forty-fifth Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. WHO Technical Report Series; 2011;961:310-23.
6. The Patient in Focus: A Strategy for Pharmaceutical Sector Reform in Newly Independent States//EUR/ICP/QCPH062202WHO/DAP/98/8. 1998. p. 38.
7. Good Pharmacy Practice in the Newly Independent States. Guide the Development and Implementation of Standards. Provisor; 2002. p. 17: 3-8, 18: 3-13, 21: 8-14.
8. FIP Reference Guide on Good Pharmacy Practice in Community and Hospital Settings. First edition 2009/ Approved by FIP Council in Istanbul in September 2009. The Hague, Netherlands: International Pharmaceutical Federation Internationale Pharmaceutique; 2009. p. 62.
9. Forty-fifth Report of the WNO Expert COMMITTEE on Specifications for Pharmaceutical Preparations (WHO Technical Report Series; No 961). 2011. p. 310-23.
10. Joint FIP/WHO Guidelines on Good Pharmacy Practice:

- Standards for Quality of Pharmacy Services. Working Document QAS/10.352/.; 2010;1:19.
11. Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services from the WHO Technical Report Series, No. 961, 45<sup>th</sup> Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations © World Health Organization; 2011. p. 20.
  12. Standards of Pharmacy Practice, Norway; 2003. Available from: <http://www.apotek.no/home/standards-for-pharmacy-practice.aspx?sessionstyleid=14733/>.
  13. Pharmacy Practice Guidance Manual. A Self-Audit Tool for Pharmacists and Pharmacy Owners. Ireland: Pharmacy Practice Guidance Manual; 2008. p. 62.
  14. Shanmugasundaram P, Prathyusha V. Total quality management, process analytical technology, five basic principles and pharmaceutical industry: An overview. *Int J PharmTech Res* 2015;8:178-85.

**Source of Support:** Nil. **Conflict of Interest:** None declared.