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Distribution Is an Important Link in Providing High–Quality Medicines

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Abstract

The paper considers the issue of development of distribution of pharmaceutical medicines in the Republic of Uzbekistan based on the international standard GDP (Good Distribution Practice) for providing the population with high-quality medicines. The issues of implementing modern requirements in the development of the pharmaceutical industry are analyzed.

Keywords: *Medicines; Quality Management; Personnel; Transportation; Storage; Distribution*

Introduction

The pharmaceutical industry of Uzbekistan is developing successfully from year to year. Domestic pharmaceutical products were produced in the amount of 1.4 trillion sums in 2017. In 2021, this figure increased to 3.2 trillion sums that was 228.6 percent growth.

At the same time, the import of medicines and medical devices tends to grow. So, if in 2017 imports amounted to 1.4 billion US dollars, then in 2021 this figure was equal to 1.6 billion US dollars, or an increase of 14.3 percent.

The work carried out on the implementation of international GMP standards at manufacturing enterprises allows increasing the export of medicines and medical devices. So, in 2017, products worth $ 18.3 million were exported, while in 2021, exports amounted to $ 70.2 million, or an increase of 3.8 times.

Thanks to the favorable conditions created for the pharmaceutical industry, progressive development is planned in 2022–2026. So, in 2022, the forecast of pharmaceutical production is 3.6 trillion sums, which is 12.5 percent more than in 2021. In 2024, it is planned to issue in the amount of 4.2 trillion sums and in 2026–8.2 trillion sums providing an increase of 2.6 times compared to 2021.

An important indicator that characterizes the industry is the number of mastered products. As of the beginning of 2021, 3,350 units of pharmaceutical products were mastered, and it is expected that the mastered products will reach 3,450 units in 2022, 4,150 units in 2024, and 5,100 units in 2026, providing an increase of 1.5 times compared to 2021.

The state of the pharmaceutical industry is also characterized by the ratio of manufactured and imported international nonproprietary names (INN). In 2021, 462 items were produced in Uzbekistan, and 1,126 were imported. At the same time, in Kazakhstan, the ratio of these indicators was 799 and 925, and in Russia – 14115 and 260.

The industry is developing, and it is planned to implement 99 investment projects worth $ 545.5 million in 2022–2024. At the same time, the projects' own funds amount to $ 168.3 million, while foreign investments amount to $ 289.2 million.

As of January 1, 2022, 102 enterprises engaged in the production of medicines, 367 enterprises in the wholesale trade of pharmaceutical products and 14.8 thousand pharmacy institutions were registered in Uzbekistan. 22 industrial enterprises are certified according to GMP standards and 4 wholesale enterprises are certified according to GDP standards.

Role of Distribution

Distribution of medicines plays an important role in providing high–quality medicines for the population, as through distribution organizations, medicines are delivered from the manufacturer to pharmacies. Pharmaceutical distribution companies are responsible for high-quality transportation and storage of medicines, since in the life cycle of medicines, most of drugs are stored by distribution organizations. During all distribution processes, there are many risks of drug damage, and therefore all participants in the distribution chain must take a responsible approach to maintaining the quality of medicines. Depending on the origin of drugs, distribution channels can be expanded and organizations must comply with all requirements for maintaining the temperature regime of drugs.

In Uzbekistan, 189 enterprises have a license for the production of pharmaceutical products, each of which specializes in the production of several to hundreds of names of medicines and medical devices. Moreover, medicines are produced in large batches, sometimes one name of a medicine is released for several days, after which, according to the production regulations, there will be preparation and transition to the production of another medicine. At the same time, the pharmacy chain needs to purchase a large range of medicines and medical devices in small batches. Successful pharmacies offer the maximum range of pharmaceutical products for rational use of financial resources and to ensure sales within the expiration date.

Consequently, pharmacies need an intermediary in the face of distribution wholesale supplier who purchases batches of drugs from different manufacturers, ensures proper storage and sells them in small batches to pharmacies and medical institutions.

Thus, distribution is an important and integral link in the path of pharmaceutical products from the manufacturer to pharmacy and medical institutions.

Characteristics of the Wholesale Chain in the Republic of Uzbekistan

Distribution organizations play an important role in maintaining the quality of medicines, as they are responsible for transportation from the manufacturer and storage of medicines in warehouses, as well as for distributing medicines to pharmacies. In this regard, distribution organizations make a significant contribution to ensuring the availability of high–quality medicines to the population. Moreover, thanks to the development of wholesale organizations, the distribution of counterfeit drugs on the market is

prevented to protect the population from non–certified medicines. For these purposes, the state pays great attention to the development of the entire distribution chain to ensure that the population is confident in the effectiveness and quality of medicines.

According to statistics of the Agency for the Development of the Pharmaceutical Industry, 367 wholesale pharmaceutical companies operate in the Republic of Uzbekistan, of which 24 organizations have received the GDPR certificate "Good Distribution Practice". As for manufacturers of medicines, 22 manufacturers work in the Republic of Uzbekistan, as well as 24 organizations prepare documents for licensing the production of medicines according to the GMP (Good Manufacturing Practice) standard.

Every year, the Republic consumes $1.6 billion worth of pharmaceutical products, of which $1.2 billion is imported medicines, which is 75% of the total volume. The import rate is the highest since 2000. The export volume is $22.4,4 million. In this regard, the President of the Republic of Uzbekistan instructed to implement a program for accelerated development of the pharmaceutical industry for 2022–2026. According to the decree of the President of the Republic of Uzbekistan on the development of the pharmaceutical industry, all areas of distribution of medicines are moving to the international level of drug storage to distribute high–quality medicines to the population. For these purposes, a program has been created to introduce international standards for all pharmaceutical companies.

The Logistics of Medicines from the Manufacturer

The life cycle of medicines starts from the manufacturer and ends in pharmacies, which directly sell drugs to end users and patients. In this regard, the formation of medicines begins in industrial premises, then it is transported to distribution companies, which store the drugs in warehouses and distribute them to pharmacies. According to the drug traffic scheme, the manufacturer can use outsourced transport services to deliver drugs to distribution organizations. It is necessary to pay attention to the fact that all organizations that are participants in distribution, starting from the manufacturer and ending with pharmacies, are responsible for proper storage of medicines. Moreover, companies must take a responsible approach to the transportation of medicines, since trucks are "mobile storage facilities", so maintaining the temperature regime during transportation is critical to prevent spoilage of medicines.

Regarding the import of medicines, a foreign manufacturer is responsible for delivering medicines to a logistics center (air, seaport, railway), from where imported distribution companies deliver medicines to their destination through logistics companies. After customs procedures, the drugs are delivered to the warehouse of distribution organizations, which then transport the drugs to pharmacies. When importing medicines, it is critical to take into account the risks of transportation from distant foreign countries, since companies can use the services of different types of transport (air, sea, railway, auto) and logistics companies. During transportation, it is necessary to consider the temperature regime of preparations, if these are thermolabile preparations with a temperature regime of +2°C/+8°C, then transportation must be carried out exclusively in cold storage rooms and containers with a controlled temperature regime. In this regard, the risk of damage to imported drugs is high and distribution companies should consider all the details of receiving, storing and transporting drugs.

Distribution Functions

The main functions of drug distribution are to ensure that proper storage, transportation, and distribution conditions are in place to ensure the quality, safety and effectiveness of medicines throughout the supply chain, as well as to prevent the risk of counterfeit medicines entering the supply chain.

Maintaining proper storage conditions in warehouses is critical, as medicines are stored in warehouses for most of the entire distribution chain. In this regard, distribution companies must comply with all the requirements of the GDP standard for storing medicines in warehouses, considering the

temperature regime, humidity and sanitary standards. To control these parameters, pharmaceutical companies conduct daily monitoring through paper media, as well as information technology.

Transportation of medicines is also one of the key functions of distribution, as the risk of damage to medicines during transportation is very high, depending on the distance of manufacturers and pharmacies. In this regard, companies are responsible for providing the necessary equipment and proper transport during the transportation of medicines. Moreover, great attention is paid to the knowledge and health of drivers who are responsible for delivering medicines to pharmacies in compliance with all transportation conditions. It is critical to observe the temperature regime during transportation, as well as compliance with measures to protect vehicles from possible theft and substitution of drugs during transportation.

Ethical Pharm Marketing

Ethical marketing is a marketing concept that focuses not only on the benefits of a product or service to the consumer, but also on the positive impact of the product on society and the environment. Ethical marketing plays an important role in the promotion of drugs, as through presentations, trainings, seminars, conferences, doctors learn about new effective drugs that can help in the treatment of the patient. During the seminars, doctors can share knowledge in the treatment of certain diseases and find the right solution in the rapid treatment of patients. Moreover, a link is established between pharmaceutical companies and doctors, who can directly interact in finding the necessary information for treatment. To provide timely information about medicines to doctors, pharmaceutical companies use medical representatives who are responsible for distributing leaflets, booklets, and articles to doctors. To speed up the process of communication between pharmaceutical companies and doctors, online platforms are gaining popularity, through which doctors can exchange information and ask questions. Moreover, social networks also play an important role in providing information about medicines to doctors. The advantage of online platforms is that there are no time constraints in communication.

In ethical marketing, pharmacists who work directly in pharmacies play an important role, as they can advise patients on the choice of medications. In this regard, pharmaceutical companies pay more attention to the knowledge of pharmacy pharmacists through training and seminars for pharmacists. Given the workload of pharmacists and time constraints, companies are increasingly using online platforms to transmit important information about medicines. In this case, social networks play an important role, as they are convenient to use and share information.

The Development of Distribution Activities

To improve distribution operations, it is necessary to pay great attention to human resources, as well as equipment that is used throughout the distribution chain. Employees of the company must take a responsible approach to maintaining the quality of medicines during transportation and storage, as any deviation from the norm can lead to serious consequences. In this regard, first, managers of pharmaceutical companies should focus on maintaining the quality of medicines and provide the necessary resources. In this case, cyclical internal and external training helps employees maintain and improve their knowledge.

To improve the timely delivery of medicines to pharmacies, it is necessary to improve the relationship between wholesale and pharmacy institutions. To speed up the time of ordering drugs, there are currently various online programs through which pharmacies can place orders and wholesale companies can monitor the balances of pharmacies. Moreover, for the transportation of drugs, wholesale companies can use both their own transport and use the services of outsourced transport companies.

Introduction of Good Distribution Practice – the Way to Ensure the Quality of Medicines Entering the Market

Description of Good Distribution Practices

GDP (Good Distribution Practice) was adopted in the Republic of Uzbekistan on October 8, 2018, to improve the activities of drug distributors at the level of developed countries. The main goal of the GDP is to maintain the quality of medicines throughout the distribution chain to ensure that patients receive high–quality medicines. According to the decree, all distribution companies must receive the GDP certificate by January 1, 2024. The GDP standard regulates the proper storage, transportation, and distribution of medicines throughout the distribution chain in order to preserve the quality of medicines and prevent the sale of counterfeit medicines. The GDP standard consists of the following 9 elements:

1. Quality management;
2. Staff;
3. Premises and equipment;
4. Documentation;
5. The process of distribution of medicines;
6. Transportation;
7. Claims, refunds, suspected falsifications, and recalls of medicines;
8. Oursourcing;
9. Self–inspection of distributors.

These elements are interrelated and should be described in detail in all documents of the organization. The main documents that describe all the organization's processes are SOPs (Standard Operating Procedures). The SOPs describe in detail all processes related to the storage, transportation, and distribution of drugs. Thanks to SOPs, employees of the company must perform their functions and be responsible for the correct execution of processes. Moreover, the SOPs indicate which forms, logs, and tools should be used by responsible warehouse employees during the execution of processes. All GDP quality related documents must be approved and monitored by a Responsible Person who is appointed by the Company's Director. The main responsibility of Responsible Person in distribution is to monitor compliance with all processes related to maintaining the quality of drugs described in the SOPs. In this regard, the Responsible Person in the organizational structure takes a position on the same line with the Director of the company. During the audit and inspection, the Responsible Person is responsible for organizing all necessary conditions and provides all information about the organization's processes.

Regulatory Documents for Implementing Good Distribution Practices

According to the Decree of the President of the Republic of Uzbekistan NUP–55 dated 2022 "On additional measures for accelerated development of the pharmaceutical industry of the Republic of Uzbekistan in 2022-2026", from April 1, 2022, new wholesale organizations in the pharmaceutical industry are created in accordance with the requirements of the Good Distribution Practice (GDP). The deadline for mandatory certification of pharmaceutical organizations for compliance with the requirements of good practices (GxP) is set until January 1, 2014.

The Good Distribution Practice (GDP) standards were developed in 2018 by the "State Center for Expertise and Standardization of Medicines, Medical Equipment and Medical Products" Minister of Healthcare of Republic of Uzbekistan. Registered and put into effect by the Resolution of the Uzbek Agency for Standardization, Metrology and Certification ("Uzstandart Agency") No. 05–987 dated 2018. This standard GDP O'z DSt 2764:2018 is developed in accordance with the recommendations of the World Health Organization, EC Guide to good manufacturing practice for medical products (GMP), replacing O'z DSt 2764:2013.

The standard Good Distribution Practices (GDP) does not cancel local sanitary rules and regulations for the operation of warehouses for storing medicines. The main document on the organization of storage facilities management is SanPiN of the Republic of Uzbekistan No. 0319–15 "Sanitary rules and regulations for the design, equipment and operation of storage facilities for storing medicines and medical devices", approved on April 7, 2014, by the Research Institute of Sanitation, Hygiene and Occupational Diseases of the Ministry of Health of the Republic of Uzbekistan. To strengthen the standards for the proper storage of drugs in warehouses, the following orders and regulations are available:

– Order on "Approval of the rules on labor protection in the storage of medicines" (registered by the Ministry of Justice of the Republic of Uzbekistan on June 26, 2009, Registration No. 1976).
– Decree of the President of the Republic of Uzbekistan "On measures for further development of the system of medical and pharmaceutical education and science" (registered on 2019).

Importance of Implementing Good Distribution Practices

The main problem among pharmaceutical distribution companies was to maintain the quality of drugs throughout the distribution chain, so that pharmacies could sell high–quality drugs to patients. At the implementation stage, there were counterfeit and defective medicines from pharmacies, and there were no regulations for working with returned and recalled medicines. Following the implementation of the GDP "Good Distribution Practices" from April 1, 2022, distribution pharmaceutical companies have become responsible for maintaining the quality of medicines throughout the distribution stage. In this regard, pharmacies began to receive medicines that were properly stored and transported. As a result, patients will receive high–quality and effective medicines. In connection with the introduction of the GDP Good Distribution Practices, the status of distribution companies that are involved in the import of medicines increases, since foreign partners must ensure that the storage of medicines in the territory of the Republic of Uzbekistan is reliable before entering into long–term contracts. Moreover, vital thermolabile medicines are sold on the market, which have a special storage temperature of +2°C/+15°C, and there are also immunobiological preparations with a subzero temperature regime. To store such drugs, you must have the appropriate equipment and storage conditions in warehouses, which are described in the SOPs of each organization.

Staff training plays a special role in the GDP (Good Distribution Practices), as it depends on the staff to properly perform all the processes regulated in the organization's SOPs. Staff should receive periodic internal and external training prior to taking office. Special attention should be paid to training warehouse personnel who are directly involved in the storage, transportation, and distribution of medicines. In this regard, the Responsible Person approves the annual training plan and evaluates the effectiveness of the acquired knowledge after the trainings. As a result, thanks to the GDP "Good Distribution Practices", distribution companies receive qualified employees who contribute to maintaining the quality of medicines throughout the distribution chain.

Recommendations for Streamlining the Implementation of Good Distribution Practices

Implementing the GDP "Good Distribution Practices" standards in a distribution company is not a quick process that requires step–by–step actions. This process should primarily involve the Director and all managers of the organization who directly manage all processes. First, it is necessary to participate in trainings on GDP, which are organized by foreign specialists from Ukraine, Russia, and Kazakhstan, in whose country the GDP standard has been successfully implemented. Before implementing the GDP in an organization, you need to prepare the necessary documents such as SOPs, Forms, Logs, and Instructions that employees will follow to complete all processes. These documents can be compiled by an employee of the company, but if there are no qualified employees in the organization, it is better to contact external experts and consulting companies that have experience and knowledge in developing documents. After developing the documents, it is necessary to conduct internal staff training, after which employees will

begin to perform all the processes according to the approved SOPs. At the initial stage, it is recommended to conduct training more often, once a month, so that employees can adapt to new requirements. Moreover, it is necessary that managers monitor and evaluate the activities of departments, so that all processes are carried out properly.

In the process of implementing the GDP, it is recommended to conduct a regular assessment of processes. If deviations from the norm are detected in the processes, then it is necessary to take corrective and preventive actions to eliminate comments. At the initial stage, there will be a lot of deviations, so the organization's managers should be responsible for adapting employees to the new requirements in accordance with the GDP and create the necessary conditions for this.

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