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PHARMACEUTICAL BUSINESS REGULATION IN GEORGIA ACCORDING TO THE EUROPEAN UNION STANDARDS

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Abstract

International regulations are intensively introduced in the pharmaceutical activity of Georgia, which is the tendency of the world pharmaceutical business. The pharmaceutical market of Georgia is growing at a fast pace every year and is a very profitable field.

The European Union's pharmaceutical strategy is the development of the pharmaceutical industry and business operations, also reducing the prices of medicines and their availability is of great importance.

The GMP/GDP standards ensure the high quality of pharmaceutical products in circulation and, at the same time, increase the country's export potential. According to the international standards of the European Union, GMP – Good Manufacturing Practice is a system that outlines the production and quality control of pharmaceutical products under standards. Georgia has recently begun implementing Good Distribution Practice (GDP) in pharmaceutical activities. In Georgia, the transition to the GMP/GDP standard is mandatory for all pharmaceutical enterprises and wholesale distributors.

Keywords: *GMP, GDP, GLP, European Union, Pharmaceutical affairs*

Introduction

The pharmaceutical sector in Georgia accounts for approximately 60% of healthcare expenses, a notably high proportion. This issue arises from elevated drug prices and the common practice of physicians prescribing unnecessary medications.

In Georgia, the pharmaceutical industry is entirely private, lacking state regulation to ensure the quality of available drugs. The government should prioritize strengthening the healthcare system and ensuring access to high-quality, effective, and safe medications and medical services for all residents.

There are international standards set by the European Union with the primary aim of ensuring the provision of high-quality medicines to citizens. In Georgia, one of the methods for importing and registering medicines is through **recognition registration**, which applies to medicines manufactured in EU countries. This means that if a drug is produced in an EU country, the Ministry of Health of Georgia acknowledges it without requiring additional documentation to confirm its quality.

Despite the wide range of medicinal products available and the significant presence of European medicines in the pharmaceutical market, the cost of medicines in Georgia remains high. Accordingly, many vital drugs are out of reach for the patient due to high cost.

International regulations are intensively introduced in the pharmaceutical activity of Georgia, which is the trend in the world pharmaceutical business. The pharmaceutical market of Georgia is growing at a fast pace every year and is a very profitable field. The demand for pharmaceutical products grew by an average of 17% per year in 2005–2010.

Pharmaceutical production in Georgia amounted to 48 million USD in 2011, and the export of medicines made in Georgia increased by about 47% (this is indicated by Maridashvili M., 2017).

Discussion of pharmaceutical activity regulations

Georgia is linked with the European Union through the trade regime DCFTA, providing the right to export 9,600 products with zero customs tariff. This was officially implemented on September 1, 2014.

With the implementation of DCFTA, goods and services produced in Georgia, if certain conditions are met, will be opened to the world's largest market, which at this stage unites 27 countries and more than 500 million consumers.

Through this trade agreement, Georgia has the opportunity to attract more investors, leading to increased investment flows and the creation of new jobs. The implementation of the DCFTA will also foster the establishment of new enterprises and the export of products, including safe medicines and consumer goods, benefiting the people of Georgia. Ultimately, this will positively impact the country's economic growth and development.

Within 16 months of the launch of the Deep and Comprehensive Trade Area, the total volume of foreign trade (export-import) with the EU reached almost $4 billion.

The European Union's pharmaceutical strategy, calls for increased preparedness for any crisis and stable provision of the necessary medicines to the population. In 2020, the new program "European Union for Health" (EU4Health) entered into force, the volume of which is 5.1 billion euros.

It should be noted that the economic situation of the country's population, constant stresses, deterioration of human health due to high prices for medicines, and insufficient financing of pharmaceutical scientific research are directly related to the development of the pharmaceutical industry and business operations. Reducing the prices of medicines and their availability is of great importance.

The basic requirements of EU regulations in the pharmaceutical business are known in Georgia as well. The pharmaceutical industry is highly regulated, therefore following regulatory requirements is mandatory (noted in Guidelines on GDP 2013, also Rules and Guidance for Pharmaceutical Distributors 2022).

By implementing the GMP/GDP standards, Georgia recognizes the European Union standards in the direction of quality control of pharmaceutical products. The GMP/GDP standards ensure the high quality of pharmaceutical products in circulation and, at the same time, increase the country's export potential.

The European Union Directive EU GMP (EU Good Manufacturing Practice) represents a set of requirements: the management of pharmaceutical enterprises' personnel, infrastructure, documentation, production, and quality control work, as well as work performed by external resources. The EU GMP standard text consists of 9 chapters: pharmaceutical quality management, personnel, premises and equipment, documentation, quality control, outsourced work, complaints, and self-inspection (noted in The Rules Governing Medic. Prod. in the EU. GMP for Medicinal Products for Human and Veterinary Use. 2014 and 2017).

Pharmaceutical Quality Management – this chapter covers the management of quality system external resources, monitoring and management review, as well as quality risk management. The company must ensure continuity of product quality and distribution.

Personnel section – there are requirements for the person responsible for the quality, the education of the personnel, and compliance with the rules of hygiene. The organization must have an adequate number of personnel, and the standard of education requires that personnel receive appropriate training to ensure quality and to prevent falsification of medicines.

Premises and equipment – requirements for building temperature and environmental control, computer systems, and equipment qualifications are given. Buildings must be protected, lighting level regulated, and temperature, humidity, and cleanliness must be maintained when storing medical products. Instruments must be calibrated following the standard. The accuracy of computer data entry is important, it must be carried out by an authorized person. Data must be protected electronically and physically. Data is stored for at least 5 years. Features of the enterprise, equipment, and engineering systems should be determined by documentation. A comprehensive document is being developed to demonstrate how the design complies with "good practice" requirements. It is crucial to review the technologies and installation processes used in the enterprise to ensure that each detail is installed according to standards before being put into operation. Manufacturing equipment, engineering systems, and computerized systems must undergo regular testing.

Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements. The various types of documents and media used should be fully defined in the manufacturer's Quality Management System. Documentation may exist in a variety of forms, including paper-based, electronic or photographic media. The main objective of the system of documentation utilized must be to establish, control, monitor and record all activities which directly or indirectly impact on allaspects of the quality of medicinal products.

Production operations must follow clearly defined procedures; they must comply with the principles of Good Manufacturing Practice in order to obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorisations.

Quality control is concerned with sampling, specifications and testing as well as the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carriedout, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory.

Outsourced activities – any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. The Quality Management System of the Contract Giver must clearly state the way that the Qualified Person certifying each batch of product for release exercises his full responsibility.

Complaints include recalls of suspected falsified medical products, complaints, and product returns. All complaints and information (relating to defective products) must be considered. The information should be provided to the local regulatory authority, and a detailed study of the alleged counterfeit products should be conducted. This product should be isolated from other medications.

The self-inspection should be performed periodically by the distribution company of medical products, for this, the self-inspection team should have the appropriate competence, there must be no conflict of interest in the team, and they should have the appropriate objectivity.

Thus, **GMP** – Good Manufacturing Practice is a system that outlines the production and quality control of pharmaceutical products under standards. Additionally, Georgia has recently begun implementing Good Distribution Practice (**GDP**) in pharmaceutical activities. The aim is to store and transport

products in line with EU standards – that need to be stored under specific conditions, including appropriate packaging, labeling, and transportation methods. Specific Provisions for Brokers – this is also unique to GDP and covers the activity of buying and selling products without physically handling them (confirmed by European GDP Association (GDPA)).

In Georgia, the transition to the GMP/GDP standard is mandatory for all pharmaceutical enterprises and wholesale distributors. There are also EU international standards:

- GCP – good clinical practice is a system of international ethical and scientific quality standards, which includes the design, documentation, and reporting of clinical trials.
- GLP – good laboratory practice, quality management control of the research laboratory;
- GPP – good pharmacy practice, which takes into account the pharmacist's obligation to provide high-quality service.

Within the framework of close cooperation with the European Union, Georgia is trying to develop the pharmaceutical industry and effectively implement the abovementioned standards in practical activities (noted in PIC/S guideline "Good Practices for Data Management and the Integrity in Regulated GMP/GDP Environments, 2021).

The support of the European Union for the development of the Georgian pharmaceutical business is great. For example, the company **"Biochemfarm"** received a grant of 17.5 million GEL within the framework of two EU programs – EU4Business-EBRD Credit Line. It aimed to comply with international production standards (GMP – good manufacturing practice), which is mandatory for access to the European Union and other international markets. **Phage** will become available to millions of patients around the world in the fight against resistant infections to eliminate the global threat of antibiotic resistance. Phages are planned to be exported to 80 countries. With the support and financing of the European Union, Phage, an innovative product, will become an alternative to antibiotics not only in Georgia but all over the world.

The primary objective of the pharmaceutical reform in the European Union is to lower drug prices, avoid shortages of specific medications, and encourage the development of new antibiotics. Also bringing more generic drugs to the market. The European Union and the United Nations summarized the results of the five-year program worth 5.1 million euros "EU Innovative Project for the Competitiveness of the Private Sector in Georgia". This important initiative, which was implemented in 2019–2023, had a noticeable impact on the Georgian business space. With the help of the European Union, the United Nations Industrial Development Organization (UNIDO) planned an interactive event for the representatives of the Georgian pharmaceutical cluster. In the field of Good Manufacturing Practices (GMP), UNIDO conducted a series of quality improvement trainings for members of the Georgian pharmaceutical cluster. The pharmaceutical cluster of Georgia unites manufacturers of bacteriophages and herbal pharmaceuticals and supporting organizations. It aims to increase manufacturers' competitiveness and sales and improve their access to new markets by introducing internationally recognized quality standards (is indicated by Good Practice Guide on Validation, European Compliance, Academy 2012).

Conclusion

Thus, the European Union supports Georgia in developing its economic potential through international cooperation. This includes helping to comply with EU legal standards.

The European Union supports Georgia with specific investments for the development of various areas of medicine, including pharmacy, in order to promote the production and distribution of high-quality medicinal products, so that after the pandemic, the country can quickly improve the standard of living of its citizens, access to medical services and safe medicines.

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