

SCI-CONF.COM.UA

TOPICAL ISSUES OF THE DEVELOPMENT OF MODERN SCIENCE



**ABSTRACTS OF VIII INTERNATIONAL
SCIENTIFIC AND PRACTICAL CONFERENCE
APRIL 8-10, 2020**

**SOFIA
2020**

TOPICAL ISSUES OF THE DEVELOPMENT OF MODERN SCIENCE

Abstracts of VIII International Scientific and Practical Conference

Sofia, Bulgaria

8-10 April 2020

Sofia, Bulgaria

2020

UDC 001.1
BBK 91

The 8th International scientific and practical conference “Topical issues of the development of modern science” (April 8-10, 2020) Publishing House “ACCENT”, Sofia, Bulgaria. 2020. 577 p.

ISBN 978-619-93537-5-2

The recommended citation for this publication is:

Ivanov I. Analysis of the phaunistic composition of Ukraine // Topical issues of the development of modern science. Abstracts of the 8th International scientific and practical conference. Publishing House “ACCENT”. Sofia, Bulgaria. 2020. Pp. 21-27. URL: <http://sci-conf.com.ua>.

Editor

Komarytskyy M.L.

Ph.D. in Economics, Associate Professor

Editorial board

Dessislava Iosifova, VUZF University, Bulgaria
Aleksander Aristovnik, University of Ljubljana, Slovenia
Efsthios Dimitriadi, Kavala Institute of Technology, Greece
Eva Borszeki, Szent Istvan University, Hungary
Fran Galetic, University of Zagreb, Croatia
Goran Kutnjak, University of Rijeka, Croatia
Janusz Lyko, Wroclaw University of Economics, Poland
Ljerka Cerovic, University of Rijeka, Croatia

Ivane Javakhishvili Tbilisi State University, Georgia
Marian Siminica, University of Craiova, Romania
Mirela Cristea, University of Craiova, Romania
Olga Zaborovskaya, State Institute of Economics, Russia
Peter Joehnk, Helmholtz - Zentrum Dresden, Germany
Zhelio Hristozov, VUZF University, Bulgaria
Toma Sorin, University of Bucharest, Romania
Velizar Pavlov, University of Ruse, Bulgaria
Vladan Holcner, University of Defence, Czech Republic

Collection of scientific articles published is the scientific and practical publication, which contains scientific articles of students, graduate students, Candidates and Doctors of Sciences, research workers and practitioners from Europe, Ukraine, Russia and from neighbouring countries and beyond. The articles contain the study, reflecting the processes and changes in the structure of modern science. The collection of scientific articles is for students, postgraduate students, doctoral candidates, teachers, researchers, practitioners and people interested in the trends of modern science development.

e-mail: sofia@sci-conf.com.ua

homepage: <http://sci-conf.com.ua>

©2020 Scientific Publishing Center “Sci-conf.com.ua” ®

©2020 Publishing House “ACCENT” ®

©2020 Authors of the articles

12.	<i>Voskoboynikova H., Dovzhuk V., Konovalova L., Zavertalyuk K.</i> DEFINITIONS OF FORMATION AND DEVELOPMENT FACTORS OF THE WHOLESALE PHARMACEUTICAL MARKET OF BULGARIA.	78
13.	<i>Абабина Н. В.</i> НЕРАВНОВЕСНЫЕ КРИТИЧЕСКИЕ СОСТОЯНИЯ В ТВОРЧЕСКОЙ ДЕЯТЕЛЬНОСТИ ПИСАТЕЛЯ.	84
14.	<i>Ананьян Е. Л.</i> СУСПІЛЬНО-ПОЛІТИЧНА ЛЕКСИКА ТА ЇЇ ФУНКЦІОНАЛЬНИЙ ПОТЕНЦІАЛ У ПРОЦЕСІ МАРКУВАННЯ РЕАЛІЙ СУЧАСНОСТІ (НА МАТЕРІАЛІ АНГЛІЙСЬКОЇ МОВИ).	92
15.	<i>Андрієнко М. М., Павлова М. Ю.</i> ПРИЧИНЫ ДВИЖЕНИЯ КАПИТАЛА И ДИНАМИКА ПОСТУПЛЕНИЯ ПРЯМЫХ ИНОСТРАННЫХ ИНВЕСТИЦИЙ В ЭКОНОМИКУ УКРАИНЫ.	95
16.	<i>Антіпов А. О., Величко С. П., Лопаткін Р. Ю.</i> РОЗВИТОК ДОСЛІДНИЦЬКОЇ ДІЯЛЬНОСТІ ШКОЛЯРІВ ЦИФРОВИМИ ВИМІРЮВАЛЬНИМИ КОМПЛЕКСАМИ.	102
17.	<i>Альбеценко О. С.</i> ТЕОРЕТИЧНІ ЗАСАБИ ФОРМУВАННЯ ТУРИСТИЧНО- ГОТЕЛЬНОГО ПІДПРИЄМНИЦТВА НА СУЧАСНОМУ ЕТАПІ РОЗВИТКУ ГАЛУЗІ.	113
18.	<i>Атаманчук П. С., Мендерецький В. В., Панчук О. П.</i> ЦІЛЕОРІЄНТОВАНЕ ФОРМУВАННЯ ПРИРОДНИЧО- НАУКОВИХ КОМПЕТЕНТНОСТЕЙ МАЙБУТНЬОГО ВЧИТЕЛЯ.	121
19.	<i>Бакун О. В., Скидан Т.</i> ВПЛИВ ПЛАЗМАФЕРЕЗУ НА ІМУНОЛОГІЧНІ ПОКАЗНИКИ У ЖІНОК З БЕЗПЛІДДЯМ АСОЦІЙОВАНИМ З ЕНДОМЕТРІОЗОМ ПРИ ЗАПЛІДНЕННІ IN VITRO.	132
20.	<i>Баленко О. І., Тоберт О. Ю.</i> РОЗРОБКА СТРУКТУРИ КОМП'ЮТЕРНИХ КОМПОНЕНТІВ, ЩО ДОЗВОЛЯЮТЬ АВТОМАТИЗУВАТИ ПРОЦЕС РОЗСИЛКИ ПОВІДОМЛЕНЬ МІЖ КОРИСТУВАЧАМИ ПОШТОВИХ СЕРВІСІВ.	141
21.	<i>Березовська Л. І.</i> ОСОБЛИВОСТІ ДІЛОВОГО СПІЛКУВАННЯ У ПРОФЕСІЙНІЙ ДІЯЛЬНОСТІ СОЦІАЛЬНОГО ПРАЦІВНИКА.	149
22.	<i>Бразалій Л. П.</i> З ДОСВІДУ ВИКЛАДАННЯ ВИБІРКОВОЇ НАВЧАЛЬНОЇ ДИСЦИПЛІНИ.	156
23.	<i>Вергеліс В. І.</i> ВПЛИВ ТЕМПЕРАТУРИ НА ПОКАЗНИКИ ЛАБОРАТОРНОЇ СХОЖОСТІ РІЗНИХ ВИДІВ САСТАСЕАЕ.	162

UDC: 378:615: 658.8

DEFINITIONS OF FORMATION AND DEVELOPMENT FACTORS OF THE WHOLESALE PHARMACEUTICAL MARKET OF BULGARIA

КОПІЯ
БІРНА



Voskoboynikova Halyna

Professor, Doctor of Pedagogical Sciences

Dovzhuk Viktoriya

Associate Professor, Candidate of Pharmaceutical Sciences

Konovalova Lyudmila

Associate Professor, Candidate of Pedagogical Sciences

Zavertalyuk Kateryna

student

National Medical University

named after OO Bogomolets

Kyiv, Ukraine

In the pharmaceutical sector of the European Union countries, the functioning of wholesale companies is directly dependent on the policies pursued in the field of health care and the main problems of the health care system in the countries of Eastern Europe.

As Bulgaria is a relatively small European country located in the eastern part of the Balkan Peninsula with a population of more than 7 million people, it has been a member of the European Union (EU) since 2007, which has given a strong impetus to the development of the country's economy. The Bulgarian pharmaceutical market is one of the smallest in Europe, but it is the sector of economy showing the fastest growth in Bulgaria [1].

Since 2012 the Bulgarian pharmaceutical legislation has been harmonized with the relevant European legislation and regulates the following fields: production, import and distribution of active substances and trade in pharmaceuticals. According to the amendments to the Law on Medicinal Products in the field of human medicine 2007,

the production, export and distribution of active substances must comply with the EU Directives on Good Manufacturing Practice and Good Distribution Practice. The BDA is the responsible regulatory authority that licenses the manufacture and trade of active substances and oversees compliance with these regulatory requirements. This change was justified in order to combat the widespread abuse of counterfeit pharmaceuticals and to strengthen the control over the production and quality of medicines [2].

Pharmaceutical companies, particularly those that do so without physically storing medicinal products (considered wholesale), must be licensed by the BDA and meet the requirements of the Good Distribution Practice Directive [3].

Drug distribution is an important activity in integrated supply chain management. Today, the drug distribution network is becoming more complex and demanding. Wholesale pharmaceutical corporations are obliged to keep the quality of distributed medicines unchanged throughout the supply chain, since any departure from the requirements may impair the quality of the medicines and therefore their efficacy and even safety.

According to the European Commission Recommendations on Good Practice for the Distribution of Medicinal Products for Human Use (2013). GDP - the part that ensures the preservation of the quality of medicines at all stages of the supply chain from the place of manufacture to the pharmacy or to a person authorized or granted the right to supply medicines to the general public.

The EU Distribution Good Practices guidelines apply to manufacturers, wholesalers, and other entities involved in the distribution of medicinal products. The current European Union Guidelines for Good Distribution Practice were published on 8 March 2013 and entered into force 6 months later. The revised guidelines have made the necessary changes to the requirements for better display of complex distribution networks in the supply chains and are in line with Directive 2011/62 / EC on preventing counterfeit medicinal products from entering the legal supply chain. These guidelines were later superseded by the 2013 / C 343/01 guidelines of 5 November 2013 in order to correct two important errors. They establish appropriate

tools to assist distributors in maintaining the quality of medicines and preventing counterfeit medicines from entering the regulated pharmaceutical supply market [4–6].

Compliance with good distribution practices ensures control over the supply chain and, therefore, preserves the quality and integrity of medicines. Regulators regularly check this compliance. Directive 2011/62 / EC, which amends Directive 2001/83 / EC, states that "manufacturers located in the European Union or in third countries and distributors of medicinal products shall be subject to re-inspection by the competent authority of the EU Member State concerned.

In Bulgaria, such competent authority is the Bulgarian Medicines Agency (BDA), which conducts these inspections to check that distributors are in compliance with Directive 2001/83 / EC as amended; EU Guidelines on Good Distribution Practice 2013 / C 343/01 and the Medicinal Products Act (2007) with appropriate regulation - Regulation 39 / 13.09.2007 on principles and requirements for Good Distribution Practice [4].

Failure to comply with Good Distribution Practices may endanger the quality of medicines and potentially their effectiveness and safety. Any deviation from the requirements of Good Distribution Practice is recorded as a non-compliance, for example, temperature deviations outside the established standards. Nonconformities must be documented and investigated and distributors must take appropriate corrective action.

Pharmaceutical distributors are part of the drug and medical supply chain and are responsible for the effective storage and distribution of medicines. Distributors must also maintain the continued availability of prescription and over-the-counter medicines required by the Bulgarian society to ensure that medicines are available on the Bulgarian market in a timely manner. Enterprises that have been licensed to wholesale medicinal products or a certificate of registration of wholesale trade in the territory of the Republic of Bulgaria under the Law on Medicinal Products in Human Medicine may carry out wholesale trade in medicinal products of all medicinal groups in accordance with the anatomical and therapeutic classification.

Therefore, pharmaceutical drug distribution companies ensure that their activities are carried out properly. Responsibility for implementation and control rests with the responsible chief specialist and the head of the staff.

Functions of the wholesale sector of the Bulgarian pharmaceutical market:

- ensure the storage of medicinal products in accordance with the marketing authorization or the registration certificate of the medicinal product, follow the expiry date;
- monitoring of the promotion of pharmaceuticals on the pharmaceutical market, which must be accompanied by the manufacturing authorization;
- import, registration certificate for distributors in whom the medicinal products are bought and sold, verification of dosage, quantity, expiration date, batch certificate;
- storage of medicines according to anatomical and therapeutic classification;
- storage of lots in accordance with the order of expiration date;
- when purchasing medicines, require supporting documentation confirming the quality and origin of the batch; and if it is for drugs containing narcotic substances, they require a license to operate drugs containing narcotic substances;
- not allow medicinal products of inadequate quality, with damaged primary or primary packaging, expired medicinal products of dubious origin;
- daily monitoring of environmental parameters (temperature, relative humidity, etc.) in the premises where lots of medicines are stored, data are entered into a special log;
- monitor compliance with sanitary standards, ensure compliance with the sanitary program;
- prepare and ensure that standard work procedures are followed and followed for the work carried out at the warehouse: receiving, distributing, organizing, storing and dispatching batches of medicines;
- to check and keep documents relating to the quality, purchase and sale of each batch of medicines;

- to control the reception, storage and reporting of returned medicines without deviation in quantity, efficacy and safety;
- organize the blocking, withdrawal and storage of medicinal products that have shown non-compliance with the requirements for quality, effectiveness and safety;
- organize the disposal of identified poor quality medicines;
- fixing the movement of each batch with a view to timely detection of gaps, blocking and withdrawal of medicines from the market.

Bulgarian pharmaceutical market wholesale staff – warehouse managers, pharmacists, pharmacist assistants and other warehouse staff should have the appropriate qualifications and experience to ensure the proper quality, storage and distribution of medicines and medical devices.

Thus, drug distributors record the arrivals and movements of each batch in order to promptly identify gaps, blockage and withdrawal of medicinal products from the market and keep all documentation on them. They have approved standard operating procedures for stock-taking activities – receiving, distributing, ordering, storing and dispatching batches of medicines, including in the presence of damaged packages, and ensuring that they are updated promptly.

Drug wholesalers use and maintain a special storage conditions monitoring system and ensure that all drugs are stored according to the specific requirements of the manufacturers.

REFERENCE:

1. Medicinal products in human medicine Act. Promulgated, State Gazette No. 31/13.04.2007, In force from 13.04.2007, subsequent amendments and complements, SG No. 102/11.12.2018 [in Bulgarian].
2. Dimova A., Moutafova E., Rogova M., Etanasova E. (2012) Bulgaria Health system review. *Health systems in transition* 14(3):1-186.
3. Good Manufacturing and Distribution Practices.(2020)URL: https://ec.europa.eu/health/human-use/good_manufacturing_distribution_practices_en

4. Stoimenova A., Zaykova K., Kirilov B. (2019). Analysis of good distribution practice inspection deficiency data of pharmaceutical wholesalers in Bulgaria. *Farmatsiia* . Vol. 66(3):85-89.
5. Zaykova K. Zhelyazkova D., Balgarinova N., Stoimenova A. (2019). A look into medical innovations & medical devices in 2013-2017. *Scripta Scientifica*. Vox Studentium 2, 29.
6. Stoimenova A., Kirilov B., Gueorguiev S., Petkova-Gueorguieva E., Ognianov S. (2020). Good Manufacturing Practice for Medicinal Products in Bulgaria: an Analysis of Regulatory Inspection Findings. *Folia Medica* 62(1): 165-171.