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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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DRUG POLICY IN GEORGIA AND ASPECTS OF PHARMACEUTICAL BUSINESS REGULATION

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Abstract.

In the context of global health challenges in the 21st century, against the background of a fundamentally changed pharmaceutical landscape, pharmaceutical sector needs to be newly understood and regulated. To assess how effective, the state is in managing pharmaceutical risks, how ready it is to curb the expansion of substandard drugs on the market, to ensure access to high quality and effective drugs.

The aim of the preparation of above article was to analyze the legislative and legal norms of the Georgian pharmaceuticals market, their comparison with corresponding international standards. Identifying the main challenges in the sector and proposing recommendations. Legislations, Laws, and government orders for improving the supply of medicine to the population served as information bases for the study. During the work, reports from the Agency of the Regulation for Medical and Pharmaceutical Activities, Georgian Representatives of International organizations, the State Statistical Service, and industry experts were used.

High prices for medicines, their irrational consumption and direct (out-of-pocket) payments, along with quality, safety, and efficiency, have been and remain the main challenge of the Georgian healthcare system.

Georgia's population spends an average of 3% of GDP annually on drugs each year, twice as much as the Organization for Economic Co-operation and Development (OECD) member states. It varies within.

Thus, due to the urgency of the issue, we have made it a priority to work on drug policy issues in terms of containment of financial expenditures, both in terms of reducing the total cost of medicines and in terms of direct payments made by the population.

To consider all the above, it can be said that the research of the pharmaceutical business policy was selected due to the high public interest, the challenges of the field and the scarcity of study in this regard. In order to highlight the shortcomings and deficits in the regulation, to suggest ways to correct them.

Key words. Generic medicines, essential drugs, polypragmasia, side effects, pharmacovigilance.

Introduction.

The products of the pharmaceutical industry are essential for wellbeing of all human beings. The importance of the comprehensive research on the economic aspects of the development in the pharmaceutical business is a matter of national security as well, because as one of the most important sectors of the world's economy, the pharmaceutical industry has a serious impact on political, economic, or social situations of the world. The COVID-19 pandemic situation, during recent years, is an apparent example of Pharma Business complexity and multi-influentially factors.

Georgian healthcare and pharmaceutical environment are not an exception. In the present article, on the example of the Georgian pharmaceutical market, we will provide you with answers to the questions regarding how important the state regulation of the pharmaceutical market is and whether it is enough to trust the rules of a completely "free market" economy.

In Georgia, the state policy in the field of pharmaceutical activity provides for the existence of effective, safe, and quality pharmaceutical products.

The Implementer of the drug and pharmaceutical activity is the "LEPL Regulation Agency for Medical and Pharmaceutical Activities" (hereafter referred to as the "Agency") within the system of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health, and Social Affairs of Georgia".

The Agency, depending on the field of activity, is a controlling body. In accordance with the procedure established by the legislation of Georgia, the Agency, within its competence, carries out state regulation of medical, medical-social expertise drug and pharmaceutical activities of individuals and legal entities in the entire territory of Georgia. As well as other powers provided by the legislative and sub-legal acts and regulations of Georgia.

Bellow we discuss chronologically the challenges identified and ways for problem solving in the system of pharmaceutical activities in more detail manner.

Materials and methods.

During the preparation of the article, a thematic desk research was held, a comparative analysis of the relevant local legislation in relation to international standards. The content analysis of historical, comparative, and statistical analysis and synthesis research tactics. The information base of the analysis was data on the legislative norms of the pharmaceutical market, business environment, government policy and decisions. We took into usage the following whilst working on separate topic issues: the data of state statistics, recent media, non-governmental sector reports in recent years actively discusses the issues of regulatory effectiveness, quality management and control effectiveness of medical activities.

Review of issue.

An independent Georgian pharmaceutical market was established and developed after the collapse of the unified soviet

pharmacy system, after the abolition of the state-generated ordering, production, and delivery model. Georgia, as an independent country, adopted the first country specific law on pharmaceuticals “Law on Drugs and Pharmaceutical Activities” in 1997. "The purpose of this law is to promote the increase of the population's access to reliable pharmaceutical products, which provides a basis, rights and responsibilities of individuals and legal entities in this field. This law is the main guideline defining the state policy and role in the field of pharmaceutical product circulation” [1].

Based of those new regulations, the first pharmaceutical business entities started to form, their number gradually increased, the market leading companies emerged, which were able to successfully overcome many challenges over a period of 20-25 years and become leader market players. Later, they successfully invested in expanding into adjacent segments as following - building their own strong sales network, setting up their own manufacturing facilities, then privatizing / building hospitals, and entering the insurance business. And this integration into adjacent segments components of healthcare chain, raises serious questions today, in terms of the transparency of the pharmaceutical business environment.

A number of liberal changes in legislation, which have been implemented several times since 2009, has further facilitated above-mentioned processes. We will highlight some key changes, the introduction of parallel import regime in the market - many regulatory barriers to imports have been removed and companies involved in the pharmaceutical business, as well as individuals interested in this business, have been given more opportunities. As a result, imports and physical availability of pharmaceutical products have increased significantly. The number of medicines allowed on the market in Georgia has doubled, but this has not improved their financial availability, as we see from various sources and as discussed further in the article.

Amendments to the Law on Medicines and Pharmaceuticals were also made in 2010-2015, although it should be noted that they were administrative in nature, focusing mainly on market control levers and addressing the raising of administrative fines (for example: fines increased from 500 GEL to 6000 GEL, from 1000 GEL to 12000 GEL). In addition, the prescription regulations as a multi-component regulatory tool were introduced. As of today, prescription regulation is not fully implemented, and state body announced about further amendments to the law in terms of liberalization...

The second important regulatory document is the Law of Georgia on Licensing and Permits (2005) which defines the procedure for issuing licenses for licensed medical and pharmaceutical activities, which are closely related to the preparation, sale, export, import, re-export, wholesale and sale of medicines, quality control of whole process.

"This Law also regulates the field regulated by licenses and permits, defines a comprehensive list of types of licenses and permits, sets out the rules for issuing licenses and permits, making changes to them and revoking them" [2].

Analyzing of all above mentioned amendments of Law it can be said that these changes did not have a direct impact on the financial and physical availability of medicines either.

After the short overview, now let analyze in more detail some aspects of the existing Georgian regulatory industry standards and their status in relation to international standards, defining scientifically the stages of development of managerial system of the Georgian Pharmaceutical sector, drug regulation policy. Further, we will provide:

- Analysis of local regulatory data bases and regulatory norms and their familiarization with internationally accepted practices, guidelines, and standards.
- Analysis of data basis and officially published statistics from Ministry of Health and Geostat.
- Analysis of reports of independent non-governmental international organizations in regards of pharma business.

As the market research shows, state regulation is characterized by a high degree of liberalization in the sector. Weak or even more formal barriers to gain marketing authorization, market entry and further operation are evident, leading to high market concentrations. At the stage of drug registration, no local laboratory quality examinations, no local clinical data required by the Law. National registration is a relatively simple procedure, there are even more simplified modes for recognition registration procedure and addition of different make-up, they can be used any an interested person without medical background and authorization from the direct manufacturer or Marketing Authorization Holder. During recognition procedures, documentations are not sent from the first source and their authenticity is also questionable.

Analysis of data from the last decade reveals that the annual number of registered medicines has doubled. During last two years about 4000 products were registered under national regimen 2321 under recognition regimen [3]. It is interesting here to do an in-depth study to determine how much of this nomenclature is really demanded, then when we have up to ten different medicines for one active ingredient registered. As the research shows, most of those products after registration on the market were imported only once, and some of them were not imported at all. Which indicates that registration takes place spontaneously without any preliminary marketing research and proper planning.

Meanwhile the internationally used is Electronic registration of medicines through eCTD - interface, it means the transfer of registration material from the pharmaceutical industry to the regulator in a formalized manner, which allows objective evaluation of the safety, efficacy and quality of medicines and is considered to be the highest standard in the world. It is used by the most developed and advanced regulatory systems. The eCTD format dossier provides not only sufficient information to draw conclusions about safety and efficacy, but also systematization and placement of material in databases, archiving, and involvement of authorized persons in processes, and most importantly, for their monitoring. The introduction of this component is strongly recommended for the recovery of the local pharmaceutical market.

Analysis of the regulatory policy system in line with internationally recognized norms of “good practices”, shows shortcoming in regards of ensuring the quality, safety and

efficacy of medicine imported in the country is not a priority, according to both pre-marketing and post-marketing regulations. Specifically, from internationally recognized "good practices" - GMP, GDP, GLP, GCP, GVP only two of them - GMP and GDP are going to work on national level at the moment. However, so far, only a few of the 47 facilities inspected in 2019-2020 have met the requirements for GMP and only one unit from 40 facilities was certified of GDP certificate [4].

The lack of good distribution practices, standards, quality of medicine is put at risk in circulation of the country. Especially, when parallel import is allowed on the market. Traceability of distribution chain from manufacturer to final destination mostly non-transparent during these regimen and GDP and GPV requirements are also in question. It is crucially important more to actively implement internationally recognized practices and GDP standards.

One more recommendation for an objective assessment of physical and financial access to medicines, is to examine the relevance of the list of Essential medicines, the marketing status of the formulas included in the list, and compliance with clinical guidelines.

As it turned out that 40% of the surveyed doctors never use this list, the possible reasons are considered to be that of the surveyed doctors

- 53% have not heard of the list of essential medicines.
- 64% are not satisfied with this list because they believe that it does not contain the necessary medicines (?!)
- 41% do not use it because this list is not covered by insurance schemes (?!)

These answers raise many other questions, and it is advisable to study the generic in addition, although these data also indicate non-compliance of pharmaceutical benefit policies with insurance coverage schemes [5].

Another challenge is ethical aspects, as a pharmaceutical industry seeks and sees opportunities to intervene and influence clinical decisions, clinical trials, the continuing health education system. The way of impact is direct and indirect transfers, and the forms are various: salary, honorarium, sponsorship, gifts, entertainment, travel and hotel financing, dinners, continuing education, royalties, etc. The industry uses both individual and corporate practices of cooperation.

The Sunshine Act, passed in the United States in 2010, establishes the transparency of interactions between the pharmaceutical industry and healthcare providers to enable these interactions to monitor the impact of professional decisions. The regulation is committed to transparency in the relationships between pharmaceutical and medical system staff, to support professional impartiality, and to restore patients' trust in the health care system. Promotional spending is also mandatory in France and Denmark, the process began in the UK in 2014, and the Sunshine-type regulations were introduced in 2013 in Portugal. The rest of Europe introduced regulations under the European Federation for Pharmaceutical Industry and Associations Openness Code in June 2016 [6].

The "Law of Georgia on Health Care" [7] qualifies a transaction with the pharmaceutical industry as a) "conflict of interest" and obliges the medical institution and the healthcare staff not to enter into such a transaction. We consider that transparent business relationships among healthcare professionals should be regulated strongly.

One of the biggest problems that the modern world cannot solve is the high cost of healthcare. The increase in its funding significantly precedes the development of the countries' economies. The world is looking for ways to make healthcare more cost-effective. Medication is precisely the component whose cost-effectiveness study has shown that keeping costs balanced in this segment so as not to hurt the creation of innovations is one of the most effective solutions.

According to the World Health Organization and IMS Health, annual global health spending was $ 6.5 trillion in 2012, including $ 965 billion in drug spending. From 2011 to 2016, this expenditure was expected to increase by US $ 220-250 billion and, therefore, drug expenditures were expected to exceed US $ 1.2 trillion in 2016. In 2020 approximately US $1.27trillion and that number is expected to increase to 1,7billion by the year 2025.

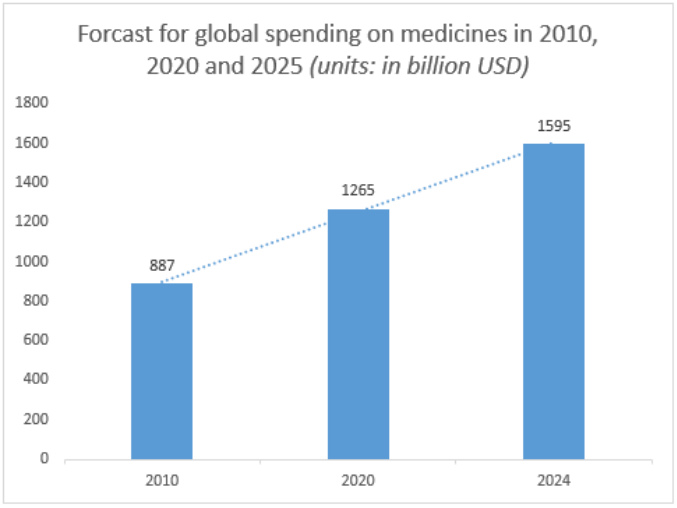

Figure 1. *Global spending on medicines in 2010,2020 and forecast for 2025 (in billion USD); source www.statista.com.*

Spending on medicines has increased everywhere globally. Despite such high expenses, about a third of the population, about 2 billion people, are unable to purchase vital medicines on a regular basis, resulting in millions of deaths each year.

A large part of the population, due to financial problems, refused to receive planned medical services and applied to the medical institution only in cases of failure, and often even delayed a visit to the doctor; Consequently, the overall outpatient and inpatient visit rate is low (Figure 2).

Figure 2. *State and household expenditures on health care (share rate in %); source www.WHO.com.*

Table 1. *Conceptual framework for drug availability and quality assessment Source: www.WHO.com.*

Assessment	Component for Assessment	Sub-component for Assessment	Indicator
Drug	Pharmaceutical expenses	Price	a) index of consumer price
Availability			b)cost plus level
		Irrational use	a) therapeutically equivalence of generics
			b) clinical guidelines
			c) good prescription practice
			d) unethical polypragmasia
			e) correction of side effects
	Direct expenses	Drug expenses ratio in total healthcare	a)ambulatory drugs
			b)other program co-payment
Quality	Drug safety	Efficacy of regulation system	a)assessment system for generics
	Efficacy Standards	a) premarketing control	b)traceability of problematic drugs
		b) post marketing control	c) post marketing quality control system

Pharmaceutical spending has been steadily rising over the years, accounting for almost half of the money spent by families on healthcare. With a 40-57% share of spending on medicines in private healthcare, Georgia ranks first among European countries, where the figure ranges from 16-17% on average.

Significant shortcomings of the healthcare system in Georgia today are that out-of-pocket payments (70% and more) in total healthcare expenditures have not changed significantly in recent years; A large share of the financial burden still falls on medicines; quality problems remain unresolved.

Data of reports from the international research institutions about the local pharmaceutical market are also noteworthy. According to numerous studies, we found that one of the highest price-tags in the region for medicine is in Georgia and reaches about 89% for original brands and about 210% for non-original generics [8].

Looking over the history of prices from recent years, they are the highest in region and equally rising. According to Geostat in 2021, with the six-month data of Geostat, comparing last year's prices to a similar period of time this year, prices of drugs have risen up to 6% [9].

The National Statistics Office monitors the group of drugs that are included in the consumer basket, these are the most widely used drugs: vasodilators, analgesics, antibiotics, vitamins, digestive system, anti-inflammatory; And uses the methodology for calculating the consumer price index to determine the percentage change in prices for medicines; This methodology involves monitoring the prices of goods and services. Consumer price registration is carried out monthly in five cities of Georgia (Tbilisi, Batumi, Kutaisi, Gori, Telavi).

This unfortunate reality can be fixed. It is a fact that, various countries worldwide have experienced successful models of drug price regulations to avoid such an issue.

We would like to briefly address a few most significant:

Regulation of mark-ups in the pharmaceutical supply and distribution chain - this particular approach is used in many countries, in wholesale and retail trading chains, or in both in parallel, mostly in regulation of prices on the essential medicine [9]. This approach is a great way to regulate extra costs on drugs. From the point of regulation politics, it is also simple and easily accomplishable [9].

Use of external reference pricing - which means using prices of similar economic-social countries as ours, for a standard price. According to the World Health Organization (WHO) data more than 40 countries are successfully using this "standard price" model, for the success of the model, it is crucial to accurately select a country for comparison and establish mutual cooperation with country policy makers for data sharing [10-13].

Promotion of the use of generic medicine – it is a fact that generic medicine is well experienced and time-trusted, therefore, promotion of this particular group is not risky, is ethical, and gives the opportunity to decrease prices on general medical care. It's comparatively easy to gain permission on entrance of generics on the market. It is also easy to work out different treatment guidelines and schemes due to the interchangeability of generics. Without a doubt, treatment with generic medicine significantly decreases public healthcare expenses on drug segment. Promotion of generic medicines, on regulatory level is a route to the better accessibility, cost efficiency, stimulates growth of local manufactures, and overall, gives a multi-faced economic effect [9].

Health insurance systems have great potential to improve the cost-effective use of medicine by leveraging better provider prescribing, more cost-effective use by consumers, and lower prices from pharmaceutical companies.

Noteworthy that, insurance systems have several key features that give them a unique advantage in influencing the cost-effective use of medicines:

1.Product selection strategies

Medicine lists (formularies)- implementation of a formulary can decrease medicines expenditures and reduce utilization of medicines that are less cost effective.

Consumer cost-sharing schemes can provide incentives for appropriate, cost-effective use of medicines and potentially reduce total medicine expenditures.

Generic substitution policy increase prescribing of generics rather than originator products, it has mix results in terms of providing the most cost-effective medicines treatment.

2. Product purchasing strategies

Generic reference pricing strategy can successfully reduce medicine prices and encourage patients to choose more cost-effective medicines.

Negotiated prices- insurance programs, can use their potential leverage as large purchasers (i.e., market power) to negotiate with the pharmaceutical industry to obtain lower medicines prices.

3. Reimbursement design and contracting strategies

The use of economic incentives to influence provider (e.g., doctor, hospital, pharmacist, etc.) behavior is the most common strategy.

The evidence on the effects of policies separating prescribing and dispensing and reducing the reimbursement rates for medicines suggests that these strategies have a mix impact in low- and middle-income countries.

4. Utilization management strategies includes educational strategies and disease management which ensure that patients receive optimal care.

There are categories of policies and management strategies that health insurance systems can use to balance the competing goals of outcomes, encouraging appropriate use, and keeping costs affordable.

Reducing or eliminating out-of-pocket medicines payment through insurance coverage in low-income country such as Georgia should translate into greater access to medicines, improved health outcomes and increased satisfaction with the health care system.

Insurance is used as a safeguard in many types of financial relationships and at the same time it can be flexible enough to suit any individual. It has the opportunity to become a protective mechanism for the interests of both legal entities and individuals in case of material or non-material damage [5].

The changes in the legislation are positive as the access to the pharmaceutical market is facilitated by the existing mechanisms in the legislation, but it is important to have control mechanisms that do not create an artificial barrier to the entry and subsequent circulation of the pharmaceutical product in the Georgian market [14].

Based on the recommendations of The WHO (World Health Organization) efficiency of the public healthcare system in the pharmaceutical segment, is evaluated with the following indicators: Quality of medicinal products, their safety and efficiency. Accessibility and social justice are also important, social justice conceptualizes availability of high medical standards for every citizen, despite of their social, ethnical, or other differences, with the basis of need, not the ability of payment.

As mentioned in the introduction, the importance of the drug component in restraining healthcare costs is widely acknowledged. That is why market generation is relevant all over the world today, this gives insurance companies and states the opportunity to save significantly on health care budgets, it is very effective for markets where the share of original brands is high in the market, i.e., developed markets. But when it comes to third-tier countries and direct payment, market generation is not enough for access, and it is necessary to include pay schemes. However, in this part we will talk about the quality and safety of generic copies.

The quality of generic copies in circulation in developed markets is comparable to the originals, and the price is much lower, so state support for them is high. Georgia is facing a serious challenge of aggressive expansion of generic copies from emerging markets (India, China, Russia, Ukraine, Turkey ...), and market growth is also expected at the expense of subsidizing cheap generics. The main documents used for this desk review are National Health System Reports, System Performance Assessment Reports, Reliable Statistics and Analytics, Reliable Surveys, Academic Literature, In-Depth Interviews with Key Health Ministry Representatives, Physicians, Insurance and Non-Pharmaceutical Experts, with patients ...)

The review focuses on two components: drug availability and quality. Accordingly, the methodology was modeled on quality and accessibility indicators.

As for quality assurance of medicine, also there is need for one more mechanism on the ground, such as the national quality control unit for example, in order to constantly control the quality in the required volume, in accordance with their specifications for the imported and local products from the chains. Because the number of quality control tests performed annually requires improvement e.g., only 252 names of medicines to be purchased as a testing sample for analysis, while several thousands of medicines regularly are circulated in the market [3]. In this regard, it is desirable to establish local state quality control laboratory and implement GLP standard requirements.

Analyzing GVP standard implementation, we are thrilled that in 2021 a Pharmacovigilance annual report was first published [3]. However, it is very important to further develop a national pharmacovigilance system with active communication with whole medical sector, NCDC, manufacturers, patients, license holders and develop communication channels. Awareness-raising activities for the patient as well as healthcare professionals to provide information flow about drug adverse events, which will enable the regulatory body to implement a risk assessment system to control the pharmaceutical product safe turnover on the market.

Based on analysis of the annual regulatory report of competent authority in Georgia, currently 132 clinical trials (both international and local) are conducted while the country does not have a national GCP Good Clinical Practice standards [3]. This number is high for the population of Georgia, and we welcome the success, but there is a benefit of the doubt whether the lack of a local legal framework stimulates this process. We believe that this requires an urgent correction of the legislative gap [15-17].

Conclusions.

As we discussed above from the Good Practices (GP) of the international standards, only two out of six have been implemented in national level – GMP Good Manufacturing Standards and GDP Good Distribution Standards. Also important challenges of the healthcare system: financial accessibility and rational use, monitoring of the quality of medicine and safety; Regulation this is a state intervention to alleviate market difficulties, which is aimed at preventing risks or correcting the consequences, if no result is achieved, then the problem is in the regulation system itself. It is either incorrectly modeled, or poorly administered, or both.

These days, it's not difficult to analyze governmental attitude towards giving out a helping hand to the public healthcare system, enlargement of the healthcare budget, improved healthcare programs and readiness ensures better care for public welfare, but it's obvious, that still noteworthy challenges exist:

The safety, efficacy, quality, rational consumption and availability of medicines have been and remain the challenge of the Georgian healthcare system.

Quality of pharmaceutical market simulation (through Georgian practice of generic copy authorization, comparative analysis with advanced practices and targeted audit of the departmental register of medicines).

Oligopoly in the pharmaceutical market.

High price on medicines.

Week pharmacovigilance system

Ethics of clinical trials.

Unethical marketing relations and polypragmasia.

Transparency and rationality of public administration in the pharmaceutical sector

Lack of properly qualified specialists (pharmacologists, clinical pharmacists, pharmaco-economists), Due to the above mentioned the institutions are not able to rationalize the lots to be purchased, they also have operational difficulties. Individual work is required with the patient to receive each medication.

The existing system was also assessed as unsatisfactory by the recent state audit report of the State Pharmaceutical Regulatory System Efficiency Assessment Report, the audit described the system's shortcomings, system formality, irrationality and improper administration; retail sales, quality control, pharmacovigilance.

The regulatory system of the Georgian state is unable to carry out such supervision due to formal regulations and irrational administration, and the market is self-sustaining.

Regulation (prohibition, restriction, incentive, etc ...) is an intervention in the ongoing processes in the economic field and is provided to correct the behavior of the economic stakeholder, so the expected risks and benefits should be well considered in advance. Regulation should not become a goal, it is just a means to an end, which should be planned not for short-term effects, but to ensure the sustainable development of the system.

Recommendations.

The model of regulation should be constructed according to innovative management standards, rational bureaucracy and maximum transparency.

Analysis of the pharmaceutical business sector shows, that existing regulations are not sufficient and not quite enough. It is important to effectively implement spread of updates and amendments in line with recommendations by the guidelines of World Health Organization (WHO). Also adopt successful worldwide experience and implement harmonized existing law accordingly. It is also important to set right communication ways towards the medical staff and clients, for the sake of fundament and popularization of generic medicine, increase awareness and helping out companies, on the regulation level.

Therefore, it is an essential arrangement of negotiations within of policy makers and business to compose a consensus and stimulate establishment of innovative regulations.

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Reziume

saTauri: wamlis politika saqarTveloSi da farmacevtuli biznesis regulirebis aspeqtebi

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medikamentebze maRali fasebi, maTi araracionaluri moxmareba da pirdapiri (jibidan) gadaxda, xarisxTan, usafrTxoebasTan da efeqturobasTan erTad, iyo da rCeba saqarTvelos jandacvis sistemis mTavar gamowvevad.

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gavaanalizeT ra sakanonmdeblo baza da regulaciebi mivediT im daskvnamde, rom arsebobs sakmarisi mtkicebuleba imisa, rom aucilebelia saxelmwifos meti CarTuloba da sakanonmdeblo bazis reformireba.

Резюме

Политика Лекарств в Грузии и Регуляторные Аспекты Фармацевтического Бизнеса

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В 21 веке в контексте проблем здравоохранения, на фоне фундаментально изменившегося фармацевтического ландшафта, фармацевтический сектор нуждается в новом понимании и регулировании. Оценить, насколько эффективно государство управляет фармацевтическими рисками, насколько оно готово обеспечивать доступ к качественным и эффективным препаратам, и параллельно сдерживать экспансию на рынок некачественных препаратов.

Целью исследования, во время работы над статьей, явилось анализ законодательных и правовых норм Грузинского фармацевтического рынка, сравнение с международными стандартами. Идентификация основных сложностей фармацевтического бизнеса и предложение рекомендаций. Законодательные акты, законы и решения правительства для улучшения снабжения населения лекарственными средствами послужили основной информационной базой для исследования. Во время работы также использованы отчеты от Агентства регулирования медицинской и фармацевтической деятельности, Государственной статистической службы, отраслевых экспертов и Грузинских представительств международных организации.

Население Грузии ежегодно тратит в среднем 3% ВВП на лекарства, что в два раза больше, чем в странах-членах Организации Экономического Сотрудничества и Развития (OECD).

Высокие цены на лекарства, их нерациональное потребление и прямые (наличные) платежи, наряду с качеством, безопасностью и эффективностью, были и остаются главной проблемой системы здравоохранения Грузии.

С учетом всего вышеизложенного можно сказать, что выбор исследования политики фармацевтического бизнеса обусловлен высоким общественным интересом, проблемами отрасли и недостаточностью исследований в этой области, желанием выявить вызовы и предложить пути их решения.