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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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CRIMINAL LAW PROTECTION OF THE CIRCULATION OF MEDICINAL PRODUCTS ACCORDING TO THE LEGISLATION OF THE FEDERAL REPUBLIC OF GERMANY, THE REPUBLIC OF AUSTRIA AND THE SWISS CONFEDERATION

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Abstract.

Aim: The purpose of the article is to find out the scope of the criminal law protection of the circulation of medicinal products according to the legislation of the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation.

Materials and methods: The materials of the research were the legislation of the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation. Dialectical, axiological, comparative, and legal methods were applied during the research.

Results: Having studied the experience of the scope of criminal law protection of the circulation of medicinal products made it possible to conclude about the importance of having a certain legislative reference point that can help improve the criminal legislation of these and other countries and build a new model of the system of norms that ensure the criminal law protection of circulation of medicinal products.

Conclusions: It has been concluded that in the criminal legislation of the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation there is an "aspiration" of the legislator to ensure the most complete scope of criminal law protection of circulation of medicinal products by creating their own specific systems. It has been proposed to single out separate groups of signs of criminal protection of pharmaceutical activity, since the scope of such protection is not the same in such countries (but has a lot in common). This may be a certain legislative guideline of the systematization of norms that ensure the circulation of medicinal products from the point of view of their criminal law protection.

Key words. Criminal law protection, pharmaceutical activity, acts of criminal legislation, circulation of medicinal products, comparative legal research, criminal offence.

Introduction.

The current state of scientific research related to the analysis of acts of foreign criminal legislation regulating the criminal law protection of pharmaceutical activity (its separate fragments [1,2]) requires increased attention from scientists. Analysis of acts of the criminal legislation of European countries regarding the determination of the scope of criminal protection of the circulation of medicinal products is proposed to be carried out on the example of the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation.

The systematization of the legal provisions of the mechanism of criminal law protection of the circulation of medicinal products is a necessary element for clarifying the peculiarities of the legal regulation of pharmaceutical activity as a whole [3-7]. But this issue has not found its scientific review comprehensively. Although, one way or another, some elements of such systematization and definition of its scope were the subject of research by individual scientists [8-12]. It is proposed to carry out such a systematization according to the types of criminal offences that encroach on the established order of circulation of medicinal products and the scope of such criminal protection.

The purpose of the article is to find out the scope of the criminal law protection of the circulation of medicinal products according to the legislation of the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation. In accordance with the purpose the following objectives have been defined: to work out the criminal legislation of the Federal Republic of Germany, the Republic of Austria and the Swiss Confederation in terms of clarifying the scope of the criminal law protection of the circulation of medicinal products, to identify common and distinctive features, to single out groups within such scope (this structuring will help to typify the features of criminal legal protection of pharmaceutical activity, since it (such protection) is not the same in the Federal Republic of Germany, the Republic of Austria and the Swiss Confederation, but has common features), which can be a certain legislative reference point for improving the criminal legislation of these and other countries.

Materials and methods.

The materials of the research were the criminal legislation of the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation.

The solution of the set objectives is possible on the basis of using the system of general (philosophical) and special methods. The use of the dialectical method made it possible to establish the importance of finding out the scope of the criminal law protection of the circulation of medicinal products in the legislation of this countries. The axiological method provided an opportunity to emphasize the value of distinguishing the types of criminal offences related to the circulation of medicinal products on the example of the above-mentioned countries. The comparative legal method made it possible to compare the scope of criminal legal protection of the circulation of medicinal products in the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation.

Results and Discussion.

The Criminal Code of the Federal Republic of Germany is the main act of the criminal legislation of this European country [13], but it does not contain typical types of criminal offences in the field of medicinal products. In contrast to additional

acts of German criminal law, namely the Medicinal Products Act (Gesetz über den Verkehr mit Arzneimitteln – germ.) of August 24, 1976 (in the version published on 12 December 2005) [14]. It provides for types of criminal offences related to the illegal circulation of medicinal products. Similar to the German approach, although less "branched", is the criminal law understanding of the illegal circulation of medicinal products according to the Austrian Federal Law on Medicinal Products Act of March 2, 1983 [15] (this Act is also an additional act of Austrian criminal legislation). The model used in the Swiss Confederation includes the Swiss Federal Act on Medicinal Products and Medical Devices of December 15, 2000 [16]. This legislative act, as well as the acts of Germany and Austria, contains criminal law provisions for the protection of the circulation of medicinal products and is an act of additional criminal legislation of Swiss Confederation.

In order to clarify the extent of criminal protection of the circulation of medicinal products according to the legislation of this countries, we will consider in more detail the definition of the concept of medicinal products as the object of such protection. P. 1 Section 2 of Medicinal Products Act (Gesetz über den Verkehr mit Arzneimitteln – germ.) of the Federal Republic of Germany of August 24, 1976 (in the version published on 12 December 2005) provides the following definition of the concept of medicinal products: (1) Medicinal products ... are products that are intended for administration to human beings. These comprise substances or preparations made from substances that: 1. are intended for use in or on the human body and are intended for use as remedies with properties for the curing, alleviating or preventing of human diseases or disease symptoms, or 2. can be used in or on the human body or can be administered to a human being, either: a) to restore, correct or influence the physiological functions through a pharmacological, immunological or metabolic effect, or b) to make a medical diagnosis [14].

In according with p. 1 § 1 of the Austrian Federal Law on Medicinal Products Act of March 2, 1983 [15], the concept of medicinal products covers substances or preparations made from substances that: 1. are intended for use in the human or animal body or on the body of a human or animal and as agents with properties for the treatment, alleviation or prevention of human or animal diseases or medical conditions, or 2. are used in the human or animal body to: a) restore, correct or affect physiological functions by pharmacological, immunological or metabolic action, or b) making a medical diagnosis [15].

According to p. 1 Art. 4 of the Swiss Federal Act on Medicinal Products and Medical Devices of December 15, 2000, medicinal products are defined as products of chemical or biological origin which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products [16].

So, in a meaningful sense, the scope of the concept of "medicinal products" formulated in the legislative acts of the Federal Republic of Germany is significantly different from the approach of other countries, primarily in terms of its biological and chemical "components".

It is proposed to single out the typical types of criminal offences related to the illegal circulation of medicinal products in Federal Republic of Germany according to the Medicinal Products Act of August 24, 1976 (in the version published on 12 December 2005), namely:

- place on the market or use of unsafe (bedenklich – germ.) medicinal products, as well as prohibition of their use on another human being (p. 1 Section 5).
- manufacture, place on the market or administer medicinal products if in manufacturing of this medicinal product substances, preparations from substances or objects that are prohibited has been used (p. 1, 2 Section 6).
- place on the market radiopharmaceuticals or medicinal products in the manufacture of which ionizing radiation has been used (p. 1 Section 7) (unless for the cases when according to p. 1 Section 7 of the Act with the consent of the Federal Ministry of the Environment, Environmental Protection and Nuclear Safety is allowed to place radiopharmaceuticals on the market or the use of ionizing radiation in the manufacture of medicinal products provided that this is not compromise human health. The container in which the medicinal product is located, its outer packaging and the insert sheet must contain relevant information about the radioactivity of the medicinal product).
- manufacture or place on the market medicinal products or their active components or otherwise trade them in violation of p. 1 or 2 Section 8, as well as in combination with p. 4 Section 73 or Section 73a of the Act. Here we are talking about the prohibition of the manufacture or place on the market medicinal products and active substances that have a slight decrease in quality due to non-compliance with the relevant pharmaceutical requirements, and/or those that cause a mistake regarding their name, explanation and appearance, as well as the prohibition of the manufacture or place on the market of falsified medicinal products or falsified active substances, as well as any trade them;
- trade or sale of medicinal products that may only be dispensed by pharmacies upon prescription (p.1, 2 or 3 Section 43). According to Section 43 of the Act, trade in prescription medicinal products can be carried out only in pharmacies, even when they are put into circulation for professional medical purposes or for commercial purposes, and therefore, any forwarding and transportation of them during trade outside pharmacies is prohibited, and the corresponding the activity of sending and transporting medicinal products is carried out only in the presence of the obtained license.
- supply of medicinal products that can be provided to consumers, as well as to persons or organize different from those indicated in p. 2 Section 47 only by prescription.
- dispend or sale medicinal products to institutions other than those specified in p. 1 § 47a. Thus, the Act prohibits "pharmaceutical entrepreneurs" who are allowed to dispense only medicinal products intended for the termination of pregnancy, in special institutions and only with a doctor's prescription; in this case, they must number the packages of medicinal products accordingly, that are intended for their release, ensuring their appropriate accounting).
- set a special requirement for medicinal products for new types of treatment (therapy), dispending of such medicinal products (without a prescription) (p. 1 Section 4b).

- manufacture of medicinal products (according to Section 6 of the Act, manufacture the medicinal product, place it on the market and use, if in the process of such manufacturing the corresponding requirements for the use of certain substances or preparation from substance has been violated).

- manufacture or place on the market medicinal products or active substances (p. 1 Section 8).

- manufacture of medicinal products or their substances, without a corresponding permit (p. 1 Section 13, p. 1 Section 72). In p. 1 Section 13 of the Act has been established the obligation to obtain a permit by the competent authority for professional and commercial activities with: medicinal products; active substances of human, animal, or microbiological origin, and genetically produced active substances; other active substances of human origin intended for the manufacture of medicinal products.

- obtaining tissue in the process of laboratory tests or carrying out laboratory tests without the permission provided for in p. 1 Section 20c of the Act, or implementation in the process of laboratory tests of processing, preservation, testing, storage or place on the market tissues or active substances used in the preparation of tissues, without the permission required according to p. 1 Section 20 of the Act.

- distribution of finished medicinal products (p. 1 Section 21).

- transfer of active substances used in the preparation of tissue, placed in manufacture without the permission required according to p. 9 Section 21a of the Act for the first time.

- not providing complete information or providing inaccurate information, which is required according to Section 22 of the Act, as well as not providing the document referred to in Section 28 of the Act, or not filling in or not providing their correct content.

- place on the market medicinal products in violation of the relevant provisions of Sections 30, 35 of the Act, when the permit issued for the distribution of medicinal products can be revoked, cancelled, or suspended (that is, a violation from the prohibition to refrain from place on the market medicinal products, if the permit issued to it is revoked, cancelled or suspended).

- place a batch of medicinal products on the market without the necessary permission (Sections 32, 35).

- place on the market finished medicinal products as homeopathic or traditional herbal medicinal products without required registration (Sections 38, 39a).

- start of clinical trials without the approval of the authorized federal body of such a clinical trial (Section 40).

- conduct of clinical trials in violation of established requirements for conducting such clinical trials (Sections 40a, 40b).

- dispend without a prescription of a medicinal product contrary to the requirements of Section 48 of the Act, which contains a list of medicinal products, which are allowed to be dispensed only with the prescription of physicians, dentists, or veterinarians.

- carrying out wholesale trade without a permit, which is required according to Section 52a of the Act.

- accept of medicinal products by an intermediary who trades in them (Section 52c).

- import of stem cells and their tissues or active substances uses in the preparation of such tissues, without a permit, which is necessary according to Sections 72, 72b, 72c of the Act.

- import of medicinal products, their active substances or other substances (Section 72a).

- import of tissues or active substances that can be used in the preparation of tissues (Section 72b).

- falsification of medicinal products or their active substances (Section 73).

- place on the market medicinal products, despite the fact that liability insurance, indemnification or guarantee obligation required in accordance with Section 94 of the Act no longer exists.

- change of information, incorrect indication of information or content of the relevant document, which is submitted contrary to the requirements of Art. 6 Regulation No. 726/2004 of the European Parliament and of the Council of Europe of March 31, 2004 [17] laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

- violate of Regulation No. 536/2014 of the European Parliament and the Council of Europe of April 16, 2014, on clinical trials of medicinal products for human use [18] and repeals Directive 2001/20/EC [19], in particular, by incorrect or incomplete prepare and submissions of an application, or conducts a clinical trial contrary to Sections 28, 29, 32, 33 of the Act.

In p. 1 Section 95 “Penal Provisions” of the Act imposed a punishment in the form of imprisonment for a term of up to three years or a fine for such acts [20]. Therefore, determining the signs of the specified elements and the content of the illegality of these violations, the unifying element here is the “properties” of activities with medicinal products and/or their active substances. Taking into account the properties defined in the “non-criminal” provisions of the Act, the German legislator forms prohibitions and corresponding types (forms) of their violation.

The analysis of these provisions provides grounds for asserting that the objective and subjective features of the elements of criminal offences and the illegality of the violation of the prohibitions defined in the Medicinal Products Act of Federal Republic of Germany of August 24, 1976 (in the version published on 12 December 2005) are formed by the legislator on the basis of:

a) determination of the scope of activities with medicinal products and/or active substances that are subject to legal regulation by establishing appropriate permits and prohibitions on their implementation and are included in the content of circulation of medicinal products as its constituent components: manufacturing medicinal products, their use in treatment; release for by prescription; place on the market of medicinal products or active substances; use of active substances in the manufacturing process of medicinal products; laboratory tests and clinical trials; transfer; release (in particular, without a prescription); acceptance; trade and import;

b) determination of prohibited types of activities with information and documents related to medicinal products and/or active substances and providing relevant components of the circulation of medicinal products or the entire circulation as a whole.

c) determination of the scope of activities with medicinal products and/or active substances, which are subject to legal regulation by establishing certain prohibitions and are included in the content of circulation of medicinal products as its constituent components: falsification of medicinal products or their active substances.

The approach of the legislator under the criminal law of the Republic of Austria is similar but has its differences. Thus, according to § 82b of the Austrian Federal Law on Medicinal Products Act of March 2, 1983, the following types of criminal offences are defined:

1) a person who falsifies medicinal products, active or auxiliary substance with the intention (p. 25, 26 § 1) that they be transferred to another person shall be punished by imprisonment for a term of up to three years for intentional falsification, and if they are left to another person, then they are punished by imprisonment for a term of up to three years (p. 1 § 1).

2) a person who offers, purchases or transfers counterfeit medicinal products, active or auxiliary substances to another person or keeps them in a warehouse, exports or imports them with the intention of transferring them to another person, is also subject to punishment (p. 2 § 1).

3) a person who commits a criminal offence in accordance with p. 1 or 2 above, as a doctor, dentist (Zahnarzt – germ.), veterinarian, pharmacist, dentist (Dentist – germ.) or obstetrician, shall be punished by imprisonment for up to five years (p. 3 § 1).

4) a similarly determined punishment for any person who commits a criminal offence in accordance with p. 1 or 2 with the intention of regularly receiving income and who has already been convicted of such an act (p. 4 § 1).

5) a person who also commits a criminal offence provided for in p. 4, as a doctor, dentist (Zahnarzt – germ.), veterinarian, pharmacist, dentist (Dentist – germ.) or obstetrician, shall be punished by imprisonment for a term of up to ten years (p. 5 § 1).

6) if the criminal offence provided for in p. 1 or 2 resulted in the death of a person or serious bodily injury (p. 1 § 84 of the Criminal Code of Austria) of a large number of people, then the person who commits this act will be punished by imprisonment for a period of five to fifteen years (p. 6) (it is important to note that p. 1 § 84 of the Criminal Code of Austria [15] establishes a punishment in the form of imprisonment for a term of up to three years for a person who commits physical violence against another person and thereby negligently causes damage to health or disability for a period of more than twenty-four days or severe mutilation or health damage).

7) a person who falsifies a commercial package or any other document related to a medicinal product, active or auxiliary substance, with the intention of using this document to transfer counterfeit medicinal products, active or auxiliary substances to someone else, shall be punished by imprisonment for a term of up to one year, if the person who committed this act is not punished in accordance with p. 1 or 2, which are given above (p. 7).

8) a person who induces or otherwise helps another person to purchase counterfeit medicines for himself or his relative (§ 72 of the Austrian Criminal Code) so that they can be used for him or a relative shall not be punished in accordance with parts 1-7 (p. 8) [21]. Falsified medicinal products are subject to confiscation (§ 82c of the Act).

According to p. 1 Art. 86 “Serious and Less Serious Criminal Offences” of the Swiss Federal Law on Medicinal Products and Medical Devices of December 15, 2000, the types of criminal offenses that encroach on the established procedure for the circulation of medicinal products are:

1) manufacture, place on the market, use, prescribe, import, or export, or trade in a foreign country medicinal product without the required marketing authorisation or licence, or contrary to the due diligence requirements stipulated in Articles 3, 7, 21, 22, 26, 29 and 42 (“a”).

2) use antibiotic substances contrary to the restrictions or prohibitions laid down in Article 42a paragraph 2 (“b”).

3) violation, when handling blood or blood products, the provisions on the fitness of the donor to give blood, on the obligation to test, on the obligation to record or archive or due diligence requirements in accordance with Article 37 or fails to take the necessary protections and safeguards (“c”).

4) place on the market, export or use medical devices which do not satisfy the requirements of the Act or use medical devices without the necessary technical or operational requirements being fulfilled (“d”).

5) violation the due diligence requirement pursuant to Article 48 or the obligation to maintain medical devices (“e”).

6) perform a clinical trial on a human being which does not satisfy the requirements of the Act or allow the same to be performed (“f”).

7) unlawfully copy, falsifies, or incorrectly name medicinal products or medical devices, or place on the market, use, import or export, or trade in a foreign country, unlawfully copied, falsified, or incorrectly named medicinal products or medical devices (“g”).

8) violation a prohibition under Article 55 (“h”).

9) place on the market products which do not meet the requirements specified by the Federal Council in accordance with Article 2a (“i”).

10) offer, grant, demand or accept a financial gain or other advantage for human tissue or human cells or use such tissues or cell for the manufacture of products as specified in Article 2a (“j”).

11) remove or use human tissue or human cells for the manufacture of products as specified in Article 2a in the absence of consent for removal (“k”) [16].

In Swiss Confederation, the punishment for the listed intentional acts is a custodial sentence for a term of up to three years or a monetary penalty. However, it is envisaged to increase the punishment by a custodial sentence for up to ten years in combination with a monetary penalty, if in the cases provided for in the above-mentioned letters “a”-“g” and “i”-“k” paragraph 1 Art. 86 of the Act, a person: 1) knows or should

assume that the violations specifically endangers human health; health (“a”); 2) achieves a high turnover or makes substantial profits through commercial activity (“b”). Paragraph 3 of the same article of the Act establishes a penalty of a custodial sentence for a term of up to ten years or a monetary penalty for a person who acts as a member of a gang involved in the illicit trade in therapeutic products in the cases referred for letters “a”, “c”, “d”, “f”, “g” and “i”-“k” paragraph 1 Art. 86 of the Law. In paragraph 4 stipulates the punishment of a monetary penalty if the person concerned acts through negligence [16].

In paragraph 1 Art. 87 “Other offences” of the Swiss Federal Law on Medicinal Products and Medical Devices imposes a fine not exceeding 50,000 Swiss francs for anyone who wilfully: 1) manufactures, places on the market, imports or exports, or trades in a foreign country therapeutic products or excipients which do not conform to the requirements stated in the Pharmacopoeia (“a”); 2) contravenes the regulations on the advertising of medicinal products (“b”); 3) violates an obligation under this Act to notify, register or disclose (“c”); 4) violates the obligations to label, keep records, to archive or to cooperate (“d”); 5) violates the obligation of secrecy, unless there is a violation of Article 162, 320 or 321 of the Criminal Code of Switzerland (“e”) [22]; 6) commits an offence referred to in Article 86 paragraph 1 letters a–g where the therapeutic product is intended exclusively for personal use or involves an over-the-counter medicinal product or a Class I medical device in accordance with Annex IX to Directive 93/42/EEC [23] concerning medical devices (“f”); 7) fails to comply with a ruling against him or her which refers to the penalties provided for in this article of the Law (“g”); 8) infringes the obligation of transparency laid down in Article 56 (“h”) [16].

In addition, in Art. 87 of this Act contains a provision according to which: 1) punishment with a monetary penalty is provided if a person concerned acts in a professional capacity in the cases referred to in paragraph 1 letter “a”, “b”, “e” or “f” paragraph 1 of this Article of the Act, on a commercial basis (paragraph 2); 2) a fine of up to 20,000 Swiss francs is provided if the person concerned acts through negligence (paragraph 3); 3) the fact that an attempts to commit the above-mentioned types of criminal offences and aiding and abetting are also offences (paragraph 4); 5) a five-year statute of limitations is established for the right to prosecute contraventions and execute the penalties for contraventions (paragraph 5); 6) the fact that in particularly minor cases, prosecution and sentencing may be waived (paragraph 6) [16].

Conclusion.

The level of legislative technique in the issue of criminal protection of pharmaceutical activity in the criminal legislation of the Federal Republic of Germany, the Republic of Austria and the Swiss Confederation is extremely high. Thanks to the comparative legal method of research, it was established that the criminal legislation of the characterized countries "aims" to provide the most complete amount of criminal legal protection of the circulation of medicinal products through the formation of its own specific systems.

2. We believe that within the scope of the criminal law protection of the circulation of medicinal products of this countries, and contrary to the relevant legislative requirements, it is expedient to single out such groups of it (that can be certain legislative guidelines for the improvement of the criminal legislation of these and other countries and the construction of a new models of the system of norms that provide criminal law protection of the circulation of medicinal products):

a) creation of medicinal products (the first group of elements of circulation of medicinal products): manufacturing; making; production; laboratory tests and clinical trials; preparation; processing; canning; testing; purpose (for example, for the treatment, relief or prevention of diseases); falsification; falsification of trade packaging; forgery; imitation; name.

b) actions with already created medicinal products that are not related to receiving commercial benefit (the second group of elements of circulation of medicinal products):

- placement (for example, placement in circulation of radioactive medicinal products or medicinal products, manufacture which ionizing radiation was used); application (for example, in the human or animal body); use (for example, to treat another person); provision to other persons (people or legal entities); issuance; transfer; release (for example, to another person without a prescription); receiving; storage (for example, in a warehouse); recipe; requirement; confidentiality obligations; removal; “registration” in a document that ensures circulation (for example, when a person unreasonably changes, incorrectly or completely defines the information or content of the relevant document);

c) actions with already created medicinal products, related to obtaining a commercial benefit (the third group of elements of circulation of medicinal products):

- trade; selling; offer; supply (for example, to consumers for prescription treatment); acceptance (for example, by an intermediary for trade); purchase (for example, when a doctor induces another person to purchase a counterfeit medical products); import; export; delivery; obtaining a commercial benefit; advertising.

3. It can be seen that despite the “desire” of the legislator in the Federal Republic of Germany, the Republic of Austria, and the Swiss Confederation to ensure the greatest possible amount of criminal law protection of circulation of medicinal products, certain “fragments” of such circulation still “fall out” from the content of criminal law protection under the legislation these states. For example, a violation of the order of state regulation of the circulation of medicinal products is not separated into an independent “fragment” of the object of criminal law protection. Therefore, we consider it necessary to carry out further scientific research in the chosen direction. This will make it possible to provide better criminal law protection in the field of pharmaceutical activity.

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