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Problems Of Legal Regulation Of Trade Of Veterinary Drugs Through The Example Of "Trifuzol".

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ABSTRACT

In this article, the issues of legal regulation of veterinary pharmacy were covered based on the actual Ukrainian law, management of similar issues in foreign countries and international guidelines were analyzed, problems of trade of veterinary drugs on the market were studied through the example of veterinary medicine "Trifuzol," new suggestions regarding the amendments in laws that control the sales of veterinary drugs were developed.

Keywords: trifuzol, veterinary drugs.

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INTRODUCTION

The current stage of development of all branches of human society is characterized by significant modifications and, along with that, emphasizes on new achievements and issues, resolution of which is urgent for further progressive development of international community in general and the entire state of Ukraine in particular. However, priorities in this pursue must remain unchanged: humanity, its health and wellbeing, honor and dignity, safety and integrity. Constitution of Ukraine defines these as the utmost social values and considers the establishment and implementation of human rights and freedoms as the main responsibility of the state (art. 3) [1].

Veterinary pharmacy is directly related to this responsibility and is included in the integration process to the world economic space along with other branches of domestic entrepreneurship. Such factors as the development of the world veterinary drugs market, availability of a wide array of foreign veterinary pharmaceutical products, and intensification of animal husbandry together demand making significant changes in Ukrainian industry of veterinary pharmacy and market of veterinary drugs. Its relevancy has been increased since Ukraine entered World Trade Organization that requires absolutely new approaches to risk assessment of unreasonable application of pharmaceuticals in terms of their impact on safety and quality of animal products and indirectly on human health through the consumption of animal products. According to experts, market of veterinary drugs is a part of a bigger market of animal health protection means. Apart from that, its segments that are targeted at farm animals are parts of a resource market for agro-industrial complex, whereas those that are dedicated to domestic animals and pets are parts of a consumer goods market [2, p. 70].

Such Ukrainian and foreign researchers as Dukhnytskyi, Bushuieva, Dovhan, Nemchenko, Palytsia, Havryliuk, Bogdan, Palamar, Horoshko, Troshyn, Danylevska, Duran, Bruskiewitz and others have been researching legal issues of veterinary pharmacy. However, since there is a scarce knowledge on legal issues of the branch as well as relationships in this sphere develop rapidly nowadays, further research on this topic is of great importance.

Purpose of the article: study the problem that has risen during the enforcement of intellectual property rights and trades of “Trifuzol” veterinary drug on the market, normative legal acts of Ukraine and foreign countries, international acts that regulate registration procedures and the introduction of veterinary pharmaceuticals to the market, development of suggestions on betterment of laws in the mentioned branch.

MATERIALS AND METHODS OF RESEARCH

Regulatory basis, method of analysis and synthesis, law comparison method, structural-functional method, and formal-legal method.

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MAIN BODY

It is worth noting that many laws have been introduced into Ukrainian legal system that regulate the development, production, and practical application of veterinary drugs as well as their safety and quality as a part of the organization and implementation of sanitary examination and inspection in veterinary and so on. A system of institutions has been created with power to enforce the related laws. Main regulative basis for veterinary pharmacy includes: Law of Ukraine "On veterinary medicine" from 25.06.1992 [3], Law of Ukraine "On state control of adherence to legal norms for foods, feeds, secondary animal-derived products, health and wellbeing of animals" from 18.05.2017 [4] and other.

Among main goals of the state with regard to veterinary medicine, art. 3 of Law of Ukraine "On veterinary medicine" highlights the appropriate, due, effective, and safe application of veterinary drugs. In order to achieve these and other goals, Cabinet of Ministers of Ukraine, central institution of the executive branch in agrarian policy, State Department of Veterinary Medicine together with state inspection of veterinary medicine and local authorities that represent it hold a government control over the branch (art. 4 of Law of Ukraine "On veterinary medicine"). As of today, Ministry of Agrarian Policy and Food is a central institution of the executive branch in agrarian policy according to The Resolution of Cabinet of Ministers of Ukraine from 25.11.2015 [5].

The Minister of agrarian policy and food directs and coordinates the operation of the central institution of the executive branch State Service of Ukraine for Food Safety and Consumer Protection (Derzhspozhyvsluzhba), which enforces state policy regarding the veterinary medicine according to the Resolution… [6].

The operation of State Pharmacological Commission of Veterinary Medicine is controlled by Derzhspozhyvsluzhba; the Resolution declares the service as an expert advisory board for registration and regulation of safe and effective application of veterinary drugs, feed additives, premixes and ready feeds [7]. The main tasks of the Commission include the provision of scientifically approved estimations and suggestions on drug development, efficiency and safety of medicines for animals, evaluation of appropriateness of use of new drugs in animal farming and veterinary medicine based on the results of pre-clinical and clinical studies (par. 3 of the Resolution).

In addition, the Resolution of Cabinet of Ministers of Ukraine approved the Procedure of registration of veterinary drugs, feed additives, premixes and ready feeds [8], whereas the decrees of State Committee of Veterinary Medicine of Ukraine from 14.07.2008 and Ministry of Agrarian Policy and Food of Ukraine from 20.11.2015 regulate the procedure (scheme) of the state registration after the pre-expertise of the files of new drug application, which is conducted by State Scientific-Research Control Institute of Veterinary Medicinal Products and Feed Additives (SSRCI VMPFA) [9]. These documents establish the List of files in new drug application for veterinary drugs and the procedure of its formation, application form that is provided by the applicant for the registration, re-registretion, or amending to the new drug application for veterinary drugs, text information for packaging (labelling).

The decree of Ministry of Agrarian Policy and Food "On enactment of rules of trade for veterinary medicinal products and drugs" from 23.07.2001 plays an important role in Ukrainian veterinary policy [10]. These rules define the procedure of retail and wholesale trade of veterinary medicinal products and major requirements for activity of pharmacies, their departments, and warehouses regarding the provision of drugs that contain animal protection agents (immunobiological, biological, herbal, chemical, pharmaceutical and other veterinary medicines), feeds, feed additives, veterinary equipment (supplies, instruments, etc.) that are intended for veterinary use to animal owners, veterinary clinics, enterprises, institutions and organizations.

The licensing of specific business entities regulates business activities related to the production of veterinary medicinal products, their retail and wholesale trade, which is controlled by Derzhspozhyvsluzhba according to Law of Ukraine "On licensing of business activities" [11].

The introduction procedure for veterinary drugs from their creation to consumption is formed based on the above-mentioned legal normative acts. That said, according to art. 63 of Law of Ukraine "On veterinary

medicine," veterinary medicinal products must undergo state registration before being allowed for trade and use. The registration may be valid for up to 5 years. In order to initiate state registration of veterinary drug, entity must submit an application along with supportive documents, list of which is defined by State Department of Veterinary Medicine, to one of the authorized state scientific-research control institutes.

National Agency of Veterinary Medicinal Products and Feed Additives and/or National Agency of Veterinary Immunobiological Products are responsible for assessment (expertise) of the submitted documents, carrying out all necessary studies, and taking other actions to check the information and data specified in the documents, and also making scientific conclusions with further submission of the latter to State Pharmacological Commission of Veterinary Medicine within no longer than 210 days from date when the application, complete package of documents, and the corresponding payment for fee have been received.

State Pharmacological Commission of Veterinary Medicine reviews scientific conclusions and issues suggestions to the Department regarding the state registration of the respective veterinary drugs. On reliance of the application submitted by the applicant, the conclusion of State Pharmacological Commission of Veterinary Medicine, and the assessment (expertise) of National Agency of Veterinary Medicinal Products and Feed Additives and/or National Agency of Veterinary Immuno biological Products, the Department renders a decision on approval or rejection of state registration for a given veterinary drug. Business entities that have been licensed in accordance with the actual law, may initiate serial production as well as trades, both retail and wholesale, of only registered drugs (art. 66-69) [3].

Veterinary drug "Trifuzol 1% solution for injection" has undergone the described procedure before entering the market. Active ingredient of the drug is piperidinium [5-(furan-2-yl)-4-phenyl-1,2,4-triazol-3-ylthio]acetate (10.0 mg). The drug belongs to synthetic immune modulators and is intended for complex treatment for dogs, cats that have pyo-inflammatory diseases (wounds, abscesses, etc.) to enhance reparative processes, for recovery of animals, and to enable natural body protection mechanisms. Based on the results of the expertise and registration tests, State Scientific-Research Control Institute of Veterinary Medicinal Products and Feed Additives and National Agency of Veterinary Medicinal Products and Feed Additives have issued scientific conclusion with recommendation for State Veterinary and Phytosanitary Service of Ukraine to register the drug "Trifuzol 1% solution for injection" in the country (no. 3835-K/06 from 24.09.2014). The medicine was registered and received registration certificate no. AB-05486-01-14 from 01.10.2014. In this way, Limited Liability Company "Research and Production Enterprise Luhfarma" was claimed as an owner of the registration certificate, while Kharkiv State Biological Factory was assigned as a manufacturer. The drug has found its practical application, showed good performance and has been acclaimed by agrarians and physicians [12].

However, there was another sort of a problem. One of the developers of the drug (Licensor), which also are joint holders of property rights for Verbal Trademark (a sign for goods and services) "TRIFUZOL" under ICGS-10 class 5, for which the Certificate of Ukraine no. 176997 from 10.10.2013 had been received, has signed a license agreement concerning transfer of rights to use the Trademark (a sign for goods and services) with LLC "Research and Production Enterprise Luhfarma" (Licensee) from behalf of all joint holders on 17.02.2014. According to the agreement, Licensor granted the rights for the term of the agreement and was being rewarded, whereas Licensee received an exclusive license (exclusive right) for the use of the Trademark "TRIFUZOL" with regard to all commodities and services listed in the Certificate of Ukraine no. 176997 from 10.10.2013 under class 5 of the International Classification of Goods and Services, which extends to the entire territory of Ukraine. Other commodities, including pharmaceutical, medical, and veterinary products, are listed in class 5 of the International Classification.

The agreement says that the exclusive rights cover production, use, import, trade offers and other ways of realization of goods under that specific Trademark.

In the Appendix, the Parties set the amount, procedure and terms of payment of the reward (lump sum and current deductions – royalties) as well as the rights and obligations of Licensor in case of non-fulfillment or improper fulfillment of conditions regarding the reward. However, Licensee went unfair towards Licensor by not paying reward, which was specified in the agreement, to the party. On the other hand, Licensor had provided an exclusive license to Licensee, in other words, did not have a right to use the object of intellectual property rights in a sphere that is restricted by this license and grant other entities with the license

to use the drug in a specified sphere, namely a "TRIFUZOL" trademark.

That is why, in order to introduce and promote the result of their intellectual activity, the authors of the active ingredient with biological properties for treating animals' diseases and stimulating and modulating the immune response had to terminate the license agreement with LLC "Research and Production Enterprise Luhfarma," register a new veterinary drug, and then register a new trademark (a sign for goods and services) according to Law of Ukraine "On protection of rights for trademarks for goods and services" from 15.12.1993 [13]. "TRIFUZOL-NEO" that contains piperidinium [5-(furan-2-yl)-4-phenyl-1,2,4-triazol-3-ylthio]acetate became the new drug. That said, "Trifuzol 1% solution for injection" and "TRIFUZOL-NEO" are absolutely identical in terms of chemical composition and pharmacological properties. However, the developers of the drug have spent much time receiving a patent (a sign for goods and services), waiting for scientific expertise and registration of the medicinal product. According to the registration certificate issued by Derzhspozhyvsluzhba (no. AB-07793-18 from 27.07.2018), the owner of the registration certificate is LLC "Alyians-2017", while the manufacturer is LLC "BROVAPHARMA." We hope that new partners will be doing business in a fair manner. However, a more effective step would be to strengthen the legal position; if the licensee avoids adhering to the terms, licensor shall use their right to terminate the agreement on a unilateral basis and sign a new license agreement regarding the same veterinary medicinal product with another licensee.

CONCLUSIONS

Summarizing all above-mentioned information, the procedure of the introduction of new veterinary medicinal products to the market in Ukraine needs betterment. It is urgently important to apply legal steps to simplify (shorten the terms of) the process of receiving a patent (a sign of goods and services), protect developers' rights, set responsibilities for unfair parties in relations of production and trade of veterinary drugs and other commodities.

Foreign practice may be helpful in enhancement of the domestic system. The experience of other countries shows that patenting and licensing activities within the market is an important aspect of forming technical policies and a key factor of a progress in science and technology [14, p. 183]. Among the specifics of this activity in foreign countries that are worth adopting in Ukraine, the following are of the greatest interest: 1) in the U.S., the patent is issued due to one-step expertise of patentability, during which the entity is assessed for specific criteria of a patentable invention, as well as its novelty and non-obviousness; 2) in Germany, automatic patent application is introduced, which provides temporary and limited protection of the invention before the expertise (third parties are allowed to use the invention and are obliged to pay a moderate reward to the owner); 3) in France, two protective acts for proposals that comply to the criteria of patentability are introduced, namely a patent (valid for up to 20 years since application date) or, on party's choice, a certificate of usability (valid for 6 years since application date). Both documents grant equal monopoly rights for the invention, but their issuing procedures are different. Certificate of usability is issued according to a classic registration system, whereas that for a patent is modified and distinguished by mandatory application of search report for searching relevant information before patent issuance; the report is added to the patent as its integral part and may be bought by third parties in patent office. Search report helps third parties, applicant and, in case of contestation of an issued patent, the court to develop their own opinion on the patent's compliance to patentability criteria (novelty and non-obviousness); 4) in Japan, severe penalties are introduced for infringements in patent and license sphere [15, p. 250–254].

In our opinion, if the infringement of license agreement is evidenced in the court, such unfair licensees deserve strict administrative penalties, whereas unfair entities should be debarred from business activity in the sphere for at least 3 years. In addition, the Registry of Unfair Licensees should be created to be able to quickly search for these and for protection of rights and legal interests of subjects of intellectual property rights.

That said, the main aim of betterment of the process of introduction of veterinary medicinal products to the market in Ukraine must be an enforcement of human rights and freedoms, protection of national interests, and creation of supportive environment for using achievements of science and technology in production, while the main lines of activity should be the development of effective mechanism of the state support for scientific research, advancement of innovative business; simplification (term shortage) of patent issuance (a sign of goods and services), for instance, by means of decentralization of patent and license activity;

creation of consulting service with highly qualified specialists in management, law, and experts in intellectual property (patent attorneys) for correct document completion in drug legalization, explanation of inventors' rights, advisory on the process of drug introduction and so on; setting the responsibility regarding unfair entities in relations of production and trade of veterinary drugs and other commodities.

Experts have suggested a worthy solution on making potential investors and licensees interested in developing innovative inventions, which is achieved by regular arrangement of round tables with participation of inventors and scientists in fields that correspond to business activity of the customers (investors or licensees), a so-called "scientific force" with aim to enable promotion.

For effective implementation of the mentioned suggestions, some legal changes must be done, including Laws of Ukraine "On veterinary medicine" and "On the protection of rights for trademarks for goods and services." In this way, in case of unfair actions of licensee and presence of court sentence with evidence of guilt, legal norms must be introduced regarding the debarment of licensee from using the veterinary drug, which will allow licensor to quickly find a new partner to establish successful business without losing extra time and resources for registration procedures.

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