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Legal Basis Of Trade Of Veterinary Drugs Through The Example Of “Trifuzol” In The Republic Of Belarus: Prospects And Issues.

Anishchenko Mykhaylo Anatoliyovych^{1*}, Parchenko Volodymyr Volodymyrovych¹,
Hamburh Inna Arkadiivna², Hunchak Alla Volodymyrivna³,
Alekseev Oleks and Hermanovych¹, Samura Tetiana Oleksandrivna¹, Makukh Oxana
Volodymyrivna², Gutyj Bogdan Volodymyrovych⁴, Hunchak Vasyl Mikhailovich⁴, Kulish
Sergiy Mykolayovych¹, and Samko Anatoliy Vasiljevich¹

¹Zaporizhzhia State Medical University, Zaporizhzhia

²Classic Private University, Zaporizhzhia

³Institute of Animal Biology of The National Academy of Agrarian Sciences of Ukraine, Lviv

⁴Lviv National University of Veterinary Medicine and Biotechnologies named after S.Z. Gzhytskyi, Lviv

ABSTRACT

This article covers the issues of legal regulation of trade of veterinary medicinal products in the Republic of Belarus based on the actual Belarusian law and international legal acts of the Eurasian Economic Union (EAEU); underlines the importance and development prospects for the market of veterinary drugs on EAEU territory through the example of veterinary medicine “Trifuzol” for owners of property and nonproperty rights for the specified drugs imported from other countries; new suggestions regarding the amendments in laws that control trade of veterinary drugs have been developed.

Keywords: circulation of veterinary pharmacy preparations, legislation of the Republic of Belarus, international legal acts of the Eurasian Economic Union

**Corresponding author*

INTRODUCTION

The most urgent accomplishment that is required for a progressive development of any country is to fulfill economic, social, cultural and other human and society demands. To achieve this goal, the state must support science, a source of economic development and intellectual fulfillment of citizens. Apart from that, the priority must be set at scientific branches that directly affect public health, which is the highest value in democratic, social states.

In this way, experts in chemistry, pharmacology, and pharmacy extensively cooperate aiming to devise new medicines that may be suitable both for humans and animals (veterinary pharmacy). Veterinary medicines affect the safety and quality of products of animal origin (POAO) and, indirectly, may impact human health as the latter is POAO consumer. It creates number of tasks related to the trade of veterinary medicinal products for the state, namely the support (funding, primarily) of scientific research that is targeted at creation and improvement of drugs; the development of optimal (by terms and complexity) procedure of drug legalization and introduction onto consumer market; the creation of efficient mechanism for quality control; the protection of rights of domestic inventors and state's interests in terms of the drug distribution in foreign countries; the application of global scientific achievements; etc. Considering the importance of these tasks, they must have clear legal regulation.

Several regulatory acts regarding the control of the procedure of veterinary drug promotion from its creation to consumption have been introduced in Ukraine, such as Law of Ukraine "On veterinary medicine" from 25.06.1992 [1], 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 [2], Act of Cabinet of Ministers of Ukraine "On the Enactment of the Resolution on the Pharmacological Commission of Veterinary Medicine from 06.06.2007 [3], Act of Cabinet of Ministers of Ukraine "On the Enactment of resolutions on the registration of veterinary drugs, feed additives, premixes and ready feeds" from 21.11.2007 [4], Decree of State Committee of Veterinary Medicine of Ukraine "On the enactment of application forms, list of files in new drug application and the procedure of its forming" from 14.07.2008 with amendments from 20.11.2015 [5], Decree of Ministry of Agrarian Policy and Food of Ukraine "On the enactment of rules of trade for veterinary medicinal products and drugs" from 23.07.2001 [6] and others.

However, according to experts' estimations, the current situation on the market of Ukraine regarding the development of new innovative products is complicated. No new original drugs of domestic manufacturers are being introduced; the production of substances for the manufacturing of veterinary drugs is not launched. The technology level of domestic manufacturers of medicinal and veterinary products is rather low. Competitive ability of domestic production is practically absent, while new drug development demands considerable funding [7, p. 133].

In such conditions, the problem of popularization of veterinary medicinal products gains its urgency, solution of which requires appropriate drug promotion not only in Ukraine, but also demands entering global markets, paving the way for achievement of a significant socially useful goal and considerable economic performance.

Some Ukrainian and foreign researchers touched the topic of veterinary pharmacy and drug introduction onto global markets, including the following: V. Abramov, G. Abgarian, V. Skrypnyk, V. Dukhnytskyi, I. Bushuieva, V. Dovhan, A. Nemchenko, Yu. Palytsia, O. Havryliuk, O. Bogdan, A. Palamar, O. Horoshko, A. Troshyn, N. Danylevska, C. Kh. Duran, R. Bruskiwitz, V. Yablonski, S. Khomin, et al. However, since legal issues of veterinary pharmacy and drug trade on global markets is yet under-explored and considering that relationships in this sphere develop rapidly, 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 of the Republic of Belarus and customs territory of EAEU, review EAEU international legal acts that regulate trades of veterinary pharmaceutical products, delineate the prospects of trades of veterinary products on EAEU territory, develop recommendations on legal improvement within the specified sphere.

MATERIALS AND METHODS

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

MAIN BODY

In such a complicated situation, only some achievements of Ukrainian science may stand out, one of which is “Trifuzol,” a synthetic immune modulator that is prescribed for combination therapy against suppurative inflammations (wounds, abscess, etc.) in animals, enhancement of reparative processes, recovery of animals, activation of natural mechanisms of organism protection.

After the registration had been completed, in accordance with the legislation, the drug was allowed for practical application, further showing good performance and gaining support from agrarians and physicians [8]. Its active ingredient demonstrated its biological activity in treating animal’s diseases and showed potent immunostimulant and immune modulant effects. That is why other countries, including Belarus, have shown interest in this drug.

It is not surprising that the drug found application way beyond Ukraine, and the territory, on which this product is being used, continues to expand. This is due to the drug having remarkable pharmacological properties and being successfully applied for treatment and prevention of pathologies in cattle, pigs, sheep, dogs, cats, poultry, as well as it is definitely is competitive on the market.

The analysis of dynamics of some biochemical values allows for indication of the following aspects of trifuzol effect on animal organism: intensification of protein and carbohydrate metabolism that enables immune modulant, antioxidant, hepatoprotective, and anti-inflammatory activities. Apart from that, the drug use has positive outcome in the dynamics of hematology values, while it does not affect the parameters of clinical condition. Therefore, veterinary drug “Trifuzol” is a versatile medicine that provides a combined action against the pathogenesis and can be used for disease prevention [9, p. 44-47].

This is the reason why the owners of intellectual and property rights for this drug put much of their efforts in promotion of the product on Ukrainian and foreign markets, aiming to fulfill their own intellectual accomplishments and expand the drug application not only in Ukrainian veterinary practice, but also globally. Registration of “Trifuzol” in the adjacent state Belarus will open the way to the market of the Customs Union, which is a form of interstate trade and economic integration of the countries that are members of EAEU (enacted from January 1, 2015, it is a legal successor of the Customs Union of Belarus, Kazakhstan, and Russia, which had been concluded on January 1, 2010).

In this way, according to statistics for the mid-2017, the following values of animal husbandry development were present in Russian Federation:

- number of cattle was 19.709 million animals;
- number of pigs was 23.760 million animals;
- number of sheep and goats was 27.528 million animals;
- number of poultry was 581.927 million animals [10].

At the same time, the data of National Statistical Committee of the Republic of Belarus shows that by the end of 2017 there were 4.362 million of cattle, 3.156 million pigs, 155 thousand sheep and goats, 49 thousand horses, and 50.7 million of poultry managed on farms in the state [11].

According to the Committee on statistics of The Ministry of national economy of the Republic of Kazakhstan, at the beginning of 2017 farmers managed 6247.2 thousand of cattle, 831.1 thousand pigs, 17947.2 thousand sheep and goats, 2113.2 thousand horses, 172.5 thousand camels, and 37.8 million of poultry of any kind [12].

Hence, animal husbandry in EAEU countries holds key positions in agriculture, has high values of development, which is why modern veterinary medicinal products have vast prospects for a wide practical application on EAEU territories.

Assuming the above insights, veterinary drug “Trifuzol,” which had already been registered and successfully used in Ukrainian veterinary practice since 2014, was registered in Belarus in December 2017 and offered in two dosage forms: 1% trifuzol solution for oral use (veterinary drug registration certificate no. 5998-10-17 ЗПХ-Ф) and 1% trifuzol solution for injection (Department of Veterinary and Food Control of the Ministry of Agriculture and Food of the Republic of Belarus letter no. 03/3743 from 27.12.2017).

The interest of Ukraine and Belarus in strengthening bilateral trade of agricultural products and foods, as well as deepening of cooperation in such fields as veterinary and food control, livestock breeding, state grade testing and right protection for plant breeding, agricultural engineering, scientific research and practical applications of those, has recently been confirmed by the Meeting of Ukrainian-Belarusian working party regarding the increase of mutual trade of foods, agricultural and other products produced in both countries on Belarusian and Ukrainian markets; the Meeting took place in Gomel, Belarus on 29.10.2018. Veterinary services of Ukraine and Belarus will continue working on the introduction of Ukrainian manufacturers to the registry of companies that are eligible to export products to the countries of Eurasian Economic Union, and the Republic of Belarus in particular [13].

In Belarus, trades of veterinary medicinal products are regulated by veterinary legislation, which is based on the Constitution and comprised of the Law of the Republic of Belarus “On veterinary practice” from 24.10.2016, acts of the President of the Republic of Belarus, and other regulations in veterinary field (e. g., the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus no. 16 from 17.03.2011 that establishes Sanitary veterinary rules of use, trade, and storage of veterinary products in the Republic of Belarus), including international agreements of Belarus. Veterinary legislation is issued in the form of compilations (volumes) that represent the summary of legal acts and include the Law of the Republic of Belarus “On veterinary practice,” Presidential Decrees of the Republic of Belarus, Resolutions of the Council of Ministers of Belarus and other governmental acts (including Veterinary Statue of the Republic of Belarus), and also incorporates acts established by veterinary service administrations. Three volumes have been issued by 2011; the forth volume of veterinary legislation of the Republic of Belarus is being prepared for release [14].

According to the art. 25 of the Law of the Republic of Belarus “On veterinary practice,” importation of veterinary drugs into the Republic of Belarus, their relocation, storage, use, and trade may be only initiated if the conditions provide storage safety and quality that must comply with the requirements of sanitary veterinary rules, mandatory technical legal acts in the field of technical rate setting and standardization, as well as temporary veterinary requirements if initiated.

Importation of veterinary drugs into the Republic of Belarus, their relocation, storage, use, and trade is authorized upon the registration in one of the member states of EAEU, if otherwise defined by legislation, international legal acts, or rules of EAEU [15].

In the EAUE itself, several attempts of the enactment of Regulations for trades of veterinary medicinal products have been made since as early as 2015, which would be applied on customs territory of EAEU. The Regulations have been developed by the Sanitary, Phytosanitary, and Veterinary Measures Department and are yet to be enacted. The conclusion of the working party regarding the legal impact of the draft resolution of United Nations Economic Commission for Europe “On Rules of trade of veterinary medicinal products on customs territory of Eurasian Economic Union” no. 206 from 27.04.2018 provides the following insights.

According to the information provided by the developer department, veterinary medicinal products are authorized for trade on the territory of the Union upon their registration in one of the member states and in case of compliance with national rules and requirements. However, through the years several inconsistencies in the system have been revealed; particularly, some of the member states do not require pre-clinical investigations of veterinary drugs upon the registration. Moreover, there were cases when an authorized body of one member state registered a substance that had been prohibited in another EAEU state. The absence of a consistent registration procedure has led to the creation of the list of hazardous veterinary drugs on the market of EAEU. Mutual complaints of the states’ authorities have caused the introduction of

limitations on importation and relocation of some specific veterinary medicinal products that previously were registered by authorities of different states. It creates the barrier to trade of veterinary drugs within the territory of EAEU.

The aims of the draft resolution of the developer department are to establish unified rules of trade of veterinary medicinal products; unified quality, safety, and efficiency assessment procedures for veterinary drugs; unified veterinary drug registration process; unified principles of organization and pharmacovigilance; unified forms of registration files; unified registry list of the registered veterinary drugs that comply unified rules of the Union. Along with that, the alignment of requirements and procedures by adopting the draft resolution to establish regulation cannot be the goal in itself, but must lead to positive outcomes in forming common commodity markets within the Union. As such, it is suggested for the developer department to set the removal of barriers to free trade of veterinary drugs between all member states as the aim of the regulation. It is worth noting that subsection 3.13 of the Unified procedure of veterinary control (vigilance) at the customs border of Eurasian Economic Union and customs territory of Eurasian Economic Union, which was enacted by the Resolution of Customs Union Commission no 317 from July 18, 2010, in current state of affairs, says that importation, relocation, and use of veterinary medicinal products are permitted upon the registration by the authorized bodies of the Union member states; member states accept the results of registration of veterinary drugs in a mutual manner; importation and relocation of veterinary drugs is not prohibited without veterinary certificate in the record, which approves quality and safety of the product and is issued by the manufacturer [16].

The art. 28 of the Treaty on the Eurasian Economic Union provides the following measures regarding the formation of common market:

- the Union makes arrangements for the functioning of common market, according to the Treaty terms
- common market covers economic territory, in which, according to the Treaty terms, free movement of goods, persons, services, and capital is provided;
- in terms of the functioning of common market, member states do not apply import and export duties (or other duties and charges that have equal effect), non-tariff regulation measures, special protection, anti-dumping, and compensation within mutual trade of goods, except as provided in the Treaty [17].

The main issue is that Belarusian legislation permits importation of goods, including veterinary drugs that are registered in the Republic, not only for the declarant, but also for any market participant. The priority for the declarant is that the one obtains the original set of registration documents for a particular drug and may furnish this set to other business entities for further trade. Usually it is done in case when the declarant company sells the drug to other entities with, understandably, charging extra cost. However, it does not prohibit these entities from importing the drug directly from Ukraine, having the required set of documents, and selling the drug without participation of the declarant.

CONCLUSIONS

According to values of animal husbandry development, the market of veterinary medicinal products on the territory of Eurasian Union is quite large and promising. "Trifuzol" as a drug with a broad spectrum of pharmacological activities has an open window of opportunity to be widely applied in veterinary medicine of the above-mentioned states.

Registration procedure for veterinary drugs on the EAEU territory is rather simplified and free from extra bureaucratic hurdles. Registering veterinary drug in one of the member states, for example in the Republic of Belarus, is sufficient for the drug to be freely traded within the EAEU territory.

As it appears from the above information, regulation of trade of veterinary drugs in Belarus infringes declarant's (developer's/owner's) rights, bars them from receiving a just reward for the results of their scientific/intellectual activity, which is a main motivation for further scientific developments. Thus, it is important to make amends in Belarusian legislation and/or include terms in bilateral agreement on trade of veterinary medicinal products that will ensure that business entities may obtain property rights from the owner only through signing a special agreement and/or by obtaining a special permission (license) to use intellectual property assets.

Rules of trade of veterinary medicinal products actual on EAEU customs territory should largely simplify the trade, as well as promote qualitative achievements of global science in the sphere of veterinary pharmacy and agriculture of EAEU member states. To accomplish that, mutual recognition of the registered veterinary drugs in EAEU countries must be retained, a unified veterinary drug listing must be initiated in EAEU, interstate program of support of high quality and the most demanded drugs must be launched, and, along with all that, property and personal non property rights of scientists, developers of drugs, must be protected.

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