Overview of legislation in the field veterinary medicines (veterinary preparations).

1. Regarding licensing of the type of economic activity for the production of veterinary drugs.

To conduct a type of economic activity for the production of veterinary drugs in the customs territory of Ukraine, business entities must obtain a license for the production of veterinary drugs .

Today, the issue of obtaining a license to conduct economic activity for the production of veterinary drugs is regulated by **the Law of Ukraine "On Licensing Types of Economic Activities"** and the Licensing Conditions for Conducting Economic Activity for the Production of Veterinary Medicines, approved by the Resolution of the Cabinet of Ministers of Ukraine dated 03.10.2018 № 808 "On Approval of the Licensing Conditions for Conducting Economic Activity for the Production of Veterinary Drugs" (hereinafter referred to as the Licensing Conditions).

By Resolution of the Cabinet of Ministers of Ukraine dated August 5, 2015 № 609 "On Approval of the List of Licensing Authorities and Declaring Certain Resolutions of the Cabinet of Ministers of Ukraine as Invalid," the State Service of Ukraine for Food Safety and Consumer Protection was designated as the licensing authority for economic activities.

In accordance with the legislation, to obtain a license, the following documents are submitted to the State Service for Food and Consumer Protection:

1. Application for a license to conduct business activities for the production of veterinary drugs in the form in accordance with Appendix 1 to the Licensing Conditions;

2. Supporting documents for each place of business activity for the production of veterinary drugs:

information from the business entity regarding the availability of material and technical resources and the availability of specialists with the educational and qualification level necessary for conducting business activities in the production of veterinary drugs, in the form in accordance with Appendix 2 to the License Terms;

a copy of the dossier of the veterinary drug manufacturer's site approved by the business entity;

3. Individuals - entrepreneurs who, due to their religious beliefs, refuse to accept the registration number of the taxpayer's registration card and have notified the regulatory authority thereof, shall submit a copy of the passport of the manager of the license applicant (his authorized representative) with a note from the relevant regulatory authority stating that they refuse to accept the registration number of the taxpayer's registration card due to their religious beliefs;

4. **Data on the accessibility of places of economic activity for low-mobility population groups** in the form in accordance with Appendix 3 to the License Terms;

5. **Information on confirmation of the absence of control over the**

activities of a business entity within the meaning of Article 1 of the Law of Ukraine "On Protection of Economic Competition" by residents of states carrying out armed aggression against Ukraine within the meaning of Article 1 of the Law of Ukraine "On Defense of Ukraine" in the form in accordance with Appendix 4 to the License Terms;

6. Description of documents submitted for obtaining a license, in duplicate, in the form in accordance with Appendix 8 to the License Terms.

Please note that in the case of conducting business activities at several places (addresses) of conducting business activities, information on the state of the material and technical base, and the availability of personnel is filled in by the business entity for each separate place of conducting business activities, which is located at a different address .

2. Regarding the requirements of good manufacturing practice for veterinary drugs in the production of veterinary drugs.

In accordance with Part Three of Article 66 **of the Law of Ukraine "On Veterinary Medicine",** during the production of veterinary drugs, persons must comply with the requirements of good manufacturing practice and other requirements determined by the central executive body that forms policy in the field of veterinary medicine.

Order of the Ministry of Agrarian Policy "On approval of the Regulations on the basic requirements for the production of veterinary drugs and the Rules of Good Manufacturing Practice for Veterinary Drugs" 10.11.2017 № 606, registered with the Ministry of Justice of Ukraine on 24.01. 2018 by № 106/31558 , defines the requirements for GMP production of veterinary drugs, developed taking into account the requirements of the Law of Ukraine "On Veterinary Medicine" (hereinafter referred to as the Law) and the Commission Directive of 23 July 1991 on the principles and working guidelines of good manufacturing practice for veterinary drugs (91/412/EEC), which establishes the principles and rules of good manufacturing practice (GMP) for medicinal products for veterinary use.

3. Regarding the state registration of veterinary drugs.

State registration of veterinary drugs is carried out in accordance with Article 63 of the Law of Ukraine “On Veterinary Medicine” (hereinafter referred to as the Law), the Regulations on State Registration of Veterinary Drugs, approved by the Resolution of the Cabinet of Ministers of Ukraine dated 21.11.2007 № 1349 “On Approval of the Regulations on State Registration of Veterinary Drugs, Feed Additives, Premixes and Ready-Made Feeds” (hereinafter referred to as the Regulations).

Forms of documents and information submitted for scientific evaluation and examination for the purpose of state registration , re-registration, and amendments to veterinary drugs are determined by the order of the Ministry of Agrarian Policy “On approval of application forms, text information on packaging (labeling), list of materials

of the registration dossier and the procedure for its formation" dated 14.07.2008 № 133, Registered with the Ministry of Justice of Ukraine on 07.08 . 2008 under № 727/15418
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According to part four of Article 63 of the Law:

The Agency for Veterinary Drugs and Feed Additives and/or the Agency for Veterinary Immunobiological Drugs (hereinafter referred to as the Agency) shall assess (examine) the submitted documents, organize the necessary research, take other measures to verify the information and data specified in the documents, and prepare expert opinions for consideration by the State Pharmacological Commission of Veterinary Medicine within a period not exceeding 210 days from the date of receipt of the application, a complete set of documents and the relevant payment.

According to paragraphs 9-11 of the Regulation:

The Agency checks the completeness and exhaustiveness of the submitted materials and makes a decision on accepting the registration dossier for examination or returning it to the applicant for revision.

The Agency conducts an examination on a contractual basis within a period not exceeding 210 days from the date of receipt of the application, a complete set of documents and the corresponding payment.

The Agency determines the need and scope of registration trials and the need for verification under the conditions of drug production, organizes the necessary studies, takes other measures to verify the information and data specified in the documents, and also prepares expert opinions.

In order to obtain additional data on the efficacy, safety and quality of the drug, the agency may request additional documents and materials from the applicant during the examination. The time required for their preparation shall not be counted towards the time allotted for the examination.

The State Pharmacological Commission of Veterinary Medicine considers expert opinions and provides recommendations to the management of the State Service for the Supervision of Food and Consumer Protection of Ukraine regarding state registration, re-registration, and amendments to the relevant veterinary drugs.

The State Food and Consumer Protection Service, based on the application submitted by the applicant, the decision (protocol) of the State Pharmacological Commission of Veterinary Medicine and the assessment (expertise) of the Agency for Veterinary Drugs and Feed Additives and/or the Agency for Veterinary Immunobiological Drugs, makes a decision on state registration of a veterinary drug or on refusal to register.

The applicant is notified of the decision on the state registration of a veterinary drug together with the provision of a registration certificate. The term for issuing a registration certificate by the Department shall not exceed 30 days. The registration certificate shall indicate the name of the veterinary drug, information about the manufacturer and the person who has the right to own the drug, the registration number, and the validity period of the registration. A brief description of the drug, a leaflet (instructions for use) and labeling in Ukrainian must be attached to the registration certificate.

After the decision on state registration is made, the veterinary drug for its circulation and use in Ukraine is entered into the register of veterinary drugs, which is maintained by the Department. The entry in the register contains the name of the veterinary drug, information about the manufacturer and the person who has the right to own the drug, the registration number, the validity period of the registration certificate and other information required by law.

When registering a domestic veterinary immunobiological product, the applicant must deposit strains (cultures) of microorganisms used in the production and control of such immunobiological product in the National Center for Microorganism Strains. The National Center for Microorganism Strains, the regulations on which are approved by the Cabinet of Ministers of Ukraine, is responsible for the storage and maintenance of deposited strains of microorganisms.

The person who has been issued a registration certificate for a veterinary medicinal product shall be obliged to ensure the collection and processing of information on all cases of adverse reactions to this veterinary medicinal product. Such information shall be submitted to the Department or to the institutions designated by it in the form and manner established by the Department.

A package of registration documents is submitted for repeated state registration three months before the expiration of the registration certificate.

4. Of circulation of veterinary drugs.

Requirements for movement (transportation) or storage and any other actions related to a change in ownership or possession, including trade, exchange or donation of veterinary drugs, are determined by the Law of Ukraine "On Veterinary Medicine" and the Resolution of the Cabinet of Ministers of Ukraine dated 07.05.2022 № 537 "Some issues of conducting state control measures over compliance with legislation on food products, feed, by-products of animal origin, animal health and welfare, state veterinary and sanitary control and import of goods into the customs territory of Ukraine during martial law", by the Order of the Ministry of Agrarian Policy of the State Department of Veterinary Medicine dated 13.08.2002 № 44 " On approval of the Rules for transportation and storage of veterinary drugs, substances, ready-made feeds, feed additives and veterinary medicine in veterinary pharmacies, their structural units, at bases, warehouses, etc.", registered with the Ministry of Justice of Ukraine 08/30/2002 under №719/7007, Rules for the sale of veterinary medicines and preparations, approved by order of the Ministry of Agrarian Policy of Ukraine dated 07/23/2001 № 37, registered with the Ministry of Justice of Ukraine on 09/05/2001 under № 786/5977.