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Draft EAEU SPS Measure on Veterinary Drugs Notified to WTO

Report Categories:
WTO Notifications
Sanitary/Phytosanitary/Food Safety
FAIRS Subject Report

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Report Highlights:
On September 14, 2015, Russia notified the World Trade Organization (WTO) of draft EAEU [1] rules for circulation of veterinary drugs via G/SPS/N/RUS/106. According to the notification, the document introduces common requirements for safety, registration and labeling procedures, quality assurance system, and inspections of veterinary drugs for the EAEU member-states. The 60-day public comment period for the draft will close on November 13, 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point (us.spsenquirypoint@fas.usda.gov). For potential inclusion in the U.S. official position, please send your comments by November 1, 2015.
[1] Current members are Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia.

General Information:
The Eurasian Economic Commission (EEC), which is the regulatory body of the Armenia-Belarus-Kazakhstan-Kyrgyzstan-Russia Eurasian Economic Union (EAEU), published the following draft document on its website:

- On Approval of the Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union

On September 14, 2015, Russia notified the World Trade Organization (WTO) of this draft document via G/SPS/N/RUS/106. According to the notification, the document introduces common requirements for safety, registration and labeling procedures, quality assurance system, and inspections of veterinary drugs for the EAEU member-states. It also provides measures for mutual harmonization and unification of legislation in the field of veterinary medicines for member-states of the Eurasian Economic Union.

The 60-day public comment period for the draft will close on November 13, 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point (us.spsenquirypoint@fas.usda.gov). For potential inclusion in the U.S. official position, please send your comments by November 1, 2015.

An unofficial English translation of the most relevant parts of the above-referenced draft document as well as a list of all annexes to the document can be found below.

BEGIN UNOFFICIAL TRANSLATION:

EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

_____ 20 **No.**

On the Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union

In accordance with p. 14 of the Protocol on the Application of Sanitary, Veterinary and Sanitary, and Quarantine Phytosanitary Measures (Annex No. 12 to the Treaty on the Eurasian Economic Union of May 29, 2014), the Council of the Eurasian Economic Commission **decided**:

1. To approve the attached Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union.

2. To establish that:

The Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union shall become effective from 1 2016, except provisions of Article 14 of the Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union relating to the expedite procedure of registration of veterinary medicinal products; provisions of Article 14 of the Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union relating to the expedite procedure of registration of veterinary medicinal products shall become effective from January 01, 2020.

3. This Decision shall become effective upon expiry of 6 months from the date of its official publication.

Members of the Council of the Eurasian Economic Commission:

From the Republic of Armenia	**From the Republic of Belarus**	**From the Republic of Kazakhstan**	**From the Kyrgyz Republic**	**From the Russian Federation**
V. Gabrielyan	**V. Matyushevsky**	**B. Sagintaev**	**V. Dil'**	**I. Shuvalov**

ANNEX

to Decision of the Council of the
Eurasian Economic Commission dated _____2015, No.

Rules Regulating Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union

Chapter 1. General Provisions

Article 1. Scope of Application

…

These Rules establish common principles and rules regulating the circulation of veterinary drugs in the Customs Territory of the Union. Regulation of the circulation of veterinary drugs in the Customs Territory of the Union is implemented in accordance with these Rules, other international agreements and acts comprising the law of the Union and the legislation of the Union member states (hereinafter – the "member states"), not contradictory the law of the Eurasian economic Union (hereinafter – the "Union").

…

The requirements of these Rules apply to producers of veterinary drugs, right holders of registration certificates on veterinary medicinal products, their attorneys, authorized bodies of the member states, expert institutions of the member states, organizations involved in marketing and sales of veterinary drugs and other parties engaged in the circulation of veterinary drugs.

...

Article 3. Terms and Definitions

…

3) **veterinary medicinal products** – veterinary drugs (including those derived from plants) produced or manufactured from one or more types of pharmaceutical raw materials (including those derived from plants) in a way of finished dosage forms and presented for sales after filling in consumer package;

4) **veterinary drugs** – substances or their combinations coming in contact with the animal body, that are used for the prevention, establishing a diagnosis (except substances or their combinations not contacting with the animal body) of animal diseases, treatment of animals, as well as rehabilitation, maintenance, prevention/interruption of gestation or for the purposes of restoration, correction/modification of physiological functions of the animal body, and euthanasia; and, derived from blood, blood plasma, human or animal internal organs and tissues, plants, minerals by synthesis methods or using biotechnological processes (veterinary drugs include pharmaceutical substances and medicinal products).

…

11) **Unified Registry of Registered Veterinary Drugs of the Eurasian Economic Union** (hereinafter – the Registry of Veterinary Drugs of the Union) – register containing information on all veterinary medicinal products registered in the territory of the Union member states;

…

31) **circulation of veterinary drugs** – activity including the processes of development, pre-clinical trials, clinical trials (tests), expert assessment, registration, standardizations and control of

quality, production, manufacture, storage, transport, import/export in/from the customs territory of the Union, movements from the territory of one member state to the territories of other member states, promotion, dispensing, sales, transfer, use and destruction of veterinary drugs;

…

48) **parties to the circulation of veterinary drugs** – legal entities and physical persons, individual entrepreneurs involved in the circulation of veterinary drugs;

…

53) **Authority in the sphere of circulation of veterinary drugs of member state of the Union** (hereinafter – the Authorized Body of member state) – authorized body of member state with the scope of competence including functions on making decision in the process of registration of veterinary medicinal products in the territory of the Union or an individual member state, expert assessments of veterinary drug in case where appropriate data on veterinary medicinal products are entered in the Unified Registry of Registered Veterinary Medicinal Products of the Eurasian Economic Union, as well as functions on control and/or surveillance of the circulation of veterinary drugs;

Chapter 2. Pharmacopeia

…

Chapter 3. Production of veterinary drugs and pharmacy manufacture of veterinary medicinal products

…

Chapter 4. Circulation of veterinary drugs in the territory of the Eurasian Economic Union

Article 7. Circulation of veterinary medicinal products registered in compliance with these Rules, in the customs territory of the Eurasian Economic Union

1. Veterinary medicinal products are allowed for the circulation in the customs territory of the Union subject to their registration in compliance with these Rules, under the conditions of such registration and entry of data pertaining to them into the Registry of Registered Veterinary Medicinal Products of the Union.

…

5. Registration of veterinary medicinal products, containing drugs specified in Annex No. 2 to these Rules, is not allowed for using in productive animals in the customs territory of the Union.

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…

Chapter 5. Rules for implementing the procedure of registration of veterinary medicinal products and other registration-related procedures

…

Chapter 6. State control and surveillance in the sphere of circulation of veterinary drugs

…

Chapter 7. The Unified Registry of Registered Veterinary Medicinal Products of the Eurasian Economic Union and the Information System of the Eurasian Economic Union in the sphere of circulation of veterinary medicinal products

…

Chapter 8. Requirements for importing/exporting veterinary drugs in/from the territory of the Union

Article 33. General provisions

1. Veterinary medicinal products are imported in the territory of the Union, except cases specified in p. 3, subject to:

- presence of imported veterinary medicinal products in the Registry of Registered Veterinary Medicinal Products of the Union (which includes the period of confirmation of the registration of veterinary medicinal products);
- availability of import permit issued by the authorized body of member state according to the procedure established by the regulatory legal acts comprising the law of the member state;
- availability of document confirming the completion of review (verification) of conformity of the veterinary medicinal products, issued according to the procedure established by the legislation of member state of the Union (prior to entry into force of the GMP Rules in the Union).

2. Pharmaceutical raw materials are imported in the customs territory of the Union for the industrial production of veterinary medicinal products registered according to the procedure established in the Union and for the pharmacy manufacture of veterinary medicinal products subject to:

- availability of import permit issued by the authorized body of member state according to the procedure established by the regulatory legal acts comprising the law of the member state.

3. Import of veterinary medicinal products not registered according to the procedure established in the Union is allowed subject to availability of an import permit issued by the authorized body of member state according to the procedure established by the regulatory legal acts comprising the law of the member state, for the following objectives:

- to conduct clinical trials of specimens of veterinary drugs and reference specimens of active substances intended for the expert assessment of the veterinary medicinal products within the scope of registration procedure (provided that non-used specimens or residues of the veterinary drugs will be destroyed in the territory of the member state at the expense of their owner after the completion of studies/tests);
- to use as exposition samples (subject to their further destruction in the territory of the member state at the expense of owner of these samples or their return);
- to provide treatment to animals or to eliminate consequences of the emergency situations associated with animal diseases (subject to confirmation of their registration in the producer country (availability of registration certificate on the veterinary medicinal products issued by the competent authority of the producer country or extract from the relevant register provided by the competent authority of the producer country of registration));
- to use for the treatment of animals (subject to confirmation of administration of the imported veterinary medicinal products to a particular animal (a commitment letter/request for import permit from the veterinary organization/prescription from the veterinarian); for the treatment of zoo animals, including exotic species (a commitment letter/request for import permit from the veterinary organization/prescription from the veterinarian); for the treatment of animals imported in the Union territory for the participation in sporting and entertainment events (a commitment letter/request for import permit from the event organizer/prescription from the veterinarian); for the treatment of animals owned by the staff of the diplomatic corps or representatives of international organizations accredited

in the Union territory (a commitment letter/request for import permit from the diplomatic corps / international organization / prescription from the veterinarian)).

4. Import or circulation of falsified, poor-quality or counterfeited veterinary drugs is prohibited in the customs territory of the Union.

Counterfeited, falsified, and poor-quality veterinary drugs are subject to withdrawal and further destruction or return from the customs territory of the Union (if found at the point of crossing the border of the Union).

Veterinary drugs shall be destroyed at the expense of their owner according to the procedure established by the legislation of member states.

Persons who import or had imported falsified and/or poor-quality, and/or counterfeited veterinary drugs in the customs territory of the Union will bear responsibility in accordance with the legislation of the member state in the territory of which the fact of violation is identified.

5. Veterinary drugs are exported from the customs territory of the Union according to the procedure established in the legislation of the member state from the territory of which their export is carried out.

…

Chapter 9. Final and transitional provisions

…

Annex No. 2 to
the Rules Regulating Circulation of
Veterinary Drugs in the Customs
Territory of the Eurasian Economic Union

List of veterinary drugs prohibited for the use in productive animals in the Customs Territory of the Eurasian Economic Union[1]

Registration of veterinary medicinal products containing the following drugs for the use in productive animals is not allowed in the customs territory of the Union:

1. Chloramphenicol (laevomycetin);
2. Nitrofurans (including furazolidone);
3. Nitroimidazoles;
4. Components of the Dutchman's-pipe plant and its pharmaceutical derivatives;
5. Chloroform;
6. Chlorpromazine;
7. Colchicine;
8. Dapsone;
9. Carbadox;
10. Olaquindox;
11. Stilbens, stilben derivatives, stilben salts and their esters;
12. Thyrostatic drugs;
13. Anabolic steroids;
14. Beta-adrenostimulators (beta-agonists);
15. Lactones of resorcylic acid and their derivatives;
16. Azagly-nafarelin (for salmon species the roe of which is intended for human consumption)
17. Malachite green (for commercial fish);
18. Crystal violet (gentian violet) (for commercial fish);
19. Brilliant green (for commercial fish).

[1] The list of veterinary drugs prohibited for use in productive animals may be revised if their scientific justification is available

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END UNOFFICIAL TRANSLATION.