



29 September 2022

(22-7304)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Revision

1.	Notifying Member: <u>UKRAINE</u> If applicable, name of local government involved:
2.	Agency responsible: Ministry of Agrarian Policy and Food of Ukraine
3.	Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Veterinary medicines
4.	Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	Title of the notified document: Draft Resolution of the Cabinet of Ministers of Ukraine "On approval of the Regulation on state registration of veterinary medicinal products". Language(s): Ukrainian. Number of pages: 32 https://minagro.gov.ua/npa/pro-zatverdzhennya-polozhennya-pro-derzhavnu-reyestracyu-veterinarnih-likarskih-zasobiv-doopracovaniy https://members.wto.org/crnattachments/2022/SPS/UKR/22_6539_00_x.pdf https://members.wto.org/crnattachments/2022/SPS/UKR/22_6539_01_x.pdf https://members.wto.org/crnattachments/2022/SPS/UKR/22_6539_02_x.pdf https://members.wto.org/crnattachments/2022/SPS/UKR/22_6539_03_x.pdf https://members.wto.org/crnattachments/2022/SPS/UKR/22_6539_04_x.pdf https://members.wto.org/crnattachments/2022/SPS/UKR/22_6539_05_x.pdf
6.	Description of content: The draft Resolution is developed in accordance with part four and part ten of Article 54 of the Law of Ukraine of 4 February 2021 No. 1206 "On Veterinary Medicine" that establishes new requirements for state registration of veterinary medicinal products. The draft Resolution provides for approval of the Regulation on state registration of veterinary medicinal products that defines, in particular: <ul style="list-style-type: none">• procedure for state registration of veterinary medicinal products;• requirements for the application for state registration, registration dossier and other documents submitted for state registration of veterinary medicinal products;• requirements for tests necessary for state registration of veterinary medicinal products;• specifics of state registration of certain types of veterinary medicinal products;• the procedure for granting permission for the production, import and use of unregistered veterinary medicinal products for scientific research (testing);• the procedure for payment for post-registration monitoring. The draft Resolution aims to bring Ukrainian legislation in terms of registration of veterinary medicinal products in line with EU requirements.

7.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8.	<p>Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
9.	<p>Other relevant documents and language(s) in which these are available:</p> <p>Law of Ukraine "On Veterinary Medicine" (available in Ukrainian)</p>
10.	<p>Proposed date of adoption (dd/mm/yy): To be determined.</p> <p>Proposed date of publication (dd/mm/yy): To be determined.</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): The Resolution shall enter into force from the day of its publication and shall be enacted simultaneously with the Law of Ukraine of 4 February 2021 No. 1206-IX "On Veterinary Medicine" (to be enacted one year after the termination or cancellation of the martial law).</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Thirty days from the date of circulation of the notification.</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p>
13.	Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: