



5 August 2022

(22-5854)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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: 27 https://minagro.gov.ua/npa/pro-zatverdzhennya-polozhennya-pro-derzhavnu-yeestracyu-veterinarnih-likarskih-zasobiv
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. Today, the basis for the circulation of medicines in most countries is state registration, which is a prerequisite for the placement of medicinal product on the market legally. The purpose of such registration is to provide the manufacturer with information allowing to evaluate the benefit/risk balance for each product in order to resolve the issue of its admission into circulation. The draft Resolution provides for the approval of the Regulation on state registration of veterinary medicinal products. The state registration procedure provides for scientific evaluation of a veterinary medicinal product by the National Institute of Veterinary Medicine of Ukraine. Services for the scientific evaluation of a veterinary medicinal product are chargeable. The objective of the draft Resolution is to define the procedure for state registration of veterinary medicinal products and to implement the requirements of EU legislation into Ukrainian legislation.
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: Law of Ukraine "On Veterinary Medicine" (available in Ukrainian)</p>
10.	<p>Proposed date of adoption (dd/mm/yy): To be determined. 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 checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 4 October 2022</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p>
13.	<p>Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p>