



5 September 2023

(23-5933)

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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): Active substances of veterinary medicinal products
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 Order of the Ministry of Agrarian Policy and Food of Ukraine "On Approval of the Requirements of Good Practice for Distribution of Active Substances used in Veterinary Medicinal Products". Language(s): Ukrainian. Number of pages: 15 https://minagro.gov.ua/npa/pro-zatverdzhennya-vimog-nalezhnoyi-praktiki-realizaciyi-diyuchih-rechovin-veterinarnih-preparativ https://members.wto.org/crnattachments/2023/SPS/UKR/23_12181_00_x.pdf https://members.wto.org/crnattachments/2023/SPS/UKR/23_12181_01_x.pdf
6. Description of content: The draft Order provides for the approval of the requirements of good practice for distribution of active substances used in veterinary medicinal products. These requirements will apply to importers and market operators, as well as to manufacturers who distribute the active substances they have manufactured with the aim of using them as starting material in veterinary medicinal products. The adoption of the Order will ensure compliance with the basic principles and rules, which guarantee that the distributed active substances are registered in accordance with the established law; their storage conditions are constantly observed, including during transportation; contamination of one with another is excluded; and delivery of goods is ensured within the specified time limits. The draft Order is aimed at improving the production of veterinary medicinal products and implementing into Ukrainian legislation the provisions of Commission Implementing Regulation (EU) 2021/1280 of 2 August 2021 as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council.
7. Objective and rationale: <input 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.

<p>8. 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>
<p>9. Other relevant documents and language(s) in which these are available: Law of Ukraine of 4 February 2021 No. 1206-IX "On Veterinary Medicine" (will be enacted one year after the termination or cancellation of the martial law) (available in Ukrainian)</p>
<p>10. Proposed date of adoption (dd/mm/yy): To be determined. Proposed date of publication (dd/mm/yy): To be determined.</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): The Order will enter into force one year from the date of enactment of the Law of Ukraine of 4 February 2021 No. 1206-IX "On Veterinary Medicine" (will be enacted one year after the termination or cancellation of the martial law) and one year from the date of the approval of these requirements.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 4 November 2023</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> <p>Ministry of Economy of Ukraine Department for Trade Agreements and Export Development 12/2 Hrushevskoho Str. Tel: +(38 044) 596 6839 Fax: +(38 044) 596 6839 Email: ep@me.gov.ua Website: https://www.me.gov.ua</p>
<p>13. 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> <p>Ministry of Economy of Ukraine Department for Trade Agreements and Export Development 12/2 Hrushevskoho Str. Tel: +(38 044) 596 6839 Fax: +(38 044) 596 6839 Email: ep@me.gov.ua Website: https://www.me.gov.ua</p>