



30 March 2026

(26-2505)

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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 Economy, Environment and Agriculture 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 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 Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Regulation on State Registration of Veterinary Medicinal Products and Repealing Certain Resolutions of the Cabinet of Ministers of Ukraine". Language(s): Ukrainian. Number of pages: 179 https://me.gov.ua/Documents/Detail/20efed90-1e32-4c8e-995e-189390213e29?lang=uk-UA&title=ProktPostanoviKabinetuMinistrivUkrainiproZatverdzhenniaPolozhenniaProDerzhavnuRestratsiiuVeterinarnikhLikarskikhZasobivTaViznanniaTakimiSchoVtratiliChinnistDeiakikhPostanovKabinetuMinistrivUkraini https://members.wto.org/crnattachments/2026/SPS/UKR/26_01734_00_x.pdf https://members.wto.org/crnattachments/2026/SPS/UKR/26_01734_01_x.pdf https://members.wto.org/crnattachments/2026/SPS/UKR/26_01734_02_x.pdf https://members.wto.org/crnattachments/2026/SPS/UKR/26_01734_03_x.pdf https://members.wto.org/crnattachments/2026/SPS/UKR/26_01734_04_x.pdf https://members.wto.org/crnattachments/2026/SPS/UKR/26_01734_05_x.pdf
6. Description of content: The draft Resolution is developed to establish requirements for the state registration of veterinary medicinal products manufactured industrially or by a method involving an industrial process and intended to be placed on the market. The draft Resolution provides for: <ul style="list-style-type: none">- procedures for state registration of veterinary medicinal products, including submission of applications and the required documents in electronic form; examination of applications by the State Service of Ukraine on Food Safety and Consumer Protection; timelines for decision-making; grounds for suspending the processing of applications; procedures, timelines and fees for assessment of registration dossier materials by the authorized (designated) authority; grounds for taking a decision on the state registration or refusal of such registration;- specific provisions for the state registration of certain types of veterinary medicinal products, including antimicrobial veterinary medicinal products; veterinary medicinal products containing or consisting of genetically modified organisms; veterinary medicinal products intended exclusively for export; immunological veterinary medicinal products for notifiable or rare (exotic) animal diseases and generic, hybrid, combined and homeopathic veterinary medicinal products;

<ul style="list-style-type: none"> - requirements for applications, registration dossiers and other documents attached to the application; - conditions for the suspension, restoration and termination of the state registration; - time limits for remedying deficiencies specified in the notification of suspension of the application processing. <p>The draft Resolution also proposes to establish transitional periods for certain provisions, taking into account the relevant transitional provisions of the Law of Ukraine "On Veterinary Medicine and Animal Welfare", in particular:</p> <p>non-application of the requirement to submit documents confirming compliance of manufacturing sites with GMP requirements of (until 1 July 2027); possibility to submit applications and other documents in paper form (until 1 March 2030); non-application of requirements for the registration dossier and supporting documents regarding the research, testing, and risk assessment of genetically modified organisms (until 16 September 2026) and non-application of requirements for confirming compliance with relevant good practices in the registration dossier (until 1 July 2032).</p> <p>The draft Resolution aims to align national legislation in the field of animal health and welfare with European Union law.</p> <p>It is also notified under the TBT Agreement.</p>
<p>7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input checked="" type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p>
<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: Laws of Ukraine "On Veterinary Medicine and Animal Welfare", "On Administrative Procedure"; Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.</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 Resolution will enter into force on the date of its publication. <input type="checkbox"/> Trade facilitating measure</p>

12. Final date for comments: Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 29 May 2026

Agency or authority designated to handle comments: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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13. Text(s) available from: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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