



17 May 2019

(19-3457)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>REPUBLIC OF MOLDOVA</u> If applicable, name of local government involved:
2. Agency responsible: National Food Safety Agency (ANSA)
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 medicine 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: Parliament Law No. 119 from 5 July 2018 regarding veterinary medicine products. Language(s): Romanian. Number of pages: 26 http://lex.justice.md/md/376819%20/
6. Description of content: This law establishes the conditions and procedure for the registration, manufacture, import, export, storage, distribution and release of veterinary medicinal products for the purpose of their placement on the Republic of Moldova's market.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input 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. Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): - <input checked="" type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): – Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2018 – Section 1.1 o Chapter 1.1.8 – Principles of veterinary vaccine production o Chapter 1.1.9 – Tests for sterility and freedom from contamination of biological material intended for veterinary use – VICH Guidelines <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): - <input type="checkbox"/> None Does this proposed regulation conform to the relevant international standard? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

If no, describe, whenever possible, how and why it deviates from the international standard:	
9. Other relevant documents and language(s) in which these are available:	<p>The regulation was approved in the context of harmonization of the national legislation with EU <i>acquis communautaire</i>:</p> <ul style="list-style-type: none"> – Directive 2001/82 on the Community code relating to veterinary medicinal products; – Directive 2006/130 as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription; – Regulation 540/95 establishing procedures for communicating suspected unexpected adverse reactions that are not serious which appear either in the Community or in a third country to authorized medicinal products for human or veterinary use; – Regulation 1662/95 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorisations for products for human or veterinary use.
10. Proposed date of adoption (dd/mm/yy):	5 July 2018
Proposed date of publication (dd/mm/yy):	17 February 2018
11. Proposed date of entry into force: [X] Six months from date of publication, and/or (dd/mm/yy):	
[X] Trade facilitating measure	
12. Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (dd/mm/yy):	16 July 2019
Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:	
13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:	<p>Mrs Diana Gherman Head of International Relations Department National Food Safety Agency of the Republic of Moldova Tel: +(373 22) 29 47 09 E-mail: diana.gherman@ansa.gov.md</p> <p>Ms Elena Cravet Trade Regimes and bilateral economic cooperation National Notification Authority Ministry of Economy and Infrastructure of the Republic of Moldova Chişinău, Piaţa Marii Adunări Naţionale 1. MD - 2033 Tel: +(373 22) 250 639 E-mail: elena.cravet@mei.gov.md</p> <p>http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=376819</p>