



18 March 2019

(19-1674)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:
2. Agency responsible: European Commission, Health and Food Safety Directorate-General
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: 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. Language(s): English, French and Spanish. Number of pages: 125 https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_e.pdf https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_f.pdf https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_s.pdf
6. Description of content: Regulatory framework for authorisation and use of veterinary medicinal products, obligations of applicants, marketing authorisation holders, regulatory authorities. Date of application: 28 January 2022.
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.
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 type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input checked="" type="checkbox"/> None Does this proposed regulation conform to the relevant international standard? <input 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:
10.	Proposed date of adoption (dd/mm/yy): 18 December 2018 Proposed date of publication (dd/mm/yy): 7 January 2019
11.	Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 28 January 2022 The regulation will apply from 28 January 2022. <input type="checkbox"/> Trade facilitating measure
12.	Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable 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: European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu
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: European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu