



18 March 2019

(19-1674)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>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):</b> Veterinary medicinal products
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title of the notified document:</b> 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. <b>Language(s):</b> English, French and Spanish. <b>Number of pages:</b> 125 <a href="https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_e.pdf">https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_f.pdf">https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_f.pdf</a> <a href="https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_s.pdf">https://members.wto.org/crnattachments/2019/SPS/EEC/19_1546_00_s.pdf</a>
<b>6. Description of content:</b> Regulatory framework for authorisation and use of veterinary medicinal products, obligations of applicants, marketing authorisation holders, regulatory authorities. Date of application: 28 January 2022.
<b>7. Objective and rationale:</b> <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.
<b>8. Is there a relevant international standard? If so, identify the standard:</b> <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 <b>Does this proposed regulation conform to the relevant international standard?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, describe, whenever possible, how and why it deviates from the international standard:</b>

<b>9.</b>	<b>Other relevant documents and language(s) in which these are available:</b>
<b>10.</b>	<b>Proposed date of adoption (dd/mm/yy):</b> 18 December 2018 <b>Proposed date of publication (dd/mm/yy):</b> 7 January 2019
<b>11.</b>	<b>Proposed date of entry into force:</b> <input type="checkbox"/> <b>Six months from date of publication, and/or (dd/mm/yy):</b> 28 January 2022 The regulation will apply from 28 January 2022. <input type="checkbox"/> <b>Trade facilitating measure</b>
<b>12.</b>	<b>Final date for comments:</b> <input type="checkbox"/> <b>Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> Not applicable <b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> <b>National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b>  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
<b>13.</b>	<b>Text(s) available from:</b> <input checked="" type="checkbox"/> <b>National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b>  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