



NOTIFICATION

1. Notifying Member: <u>REPUBLIC OF KOREA</u> If applicable, name of local government involved:
2. Agency responsible: Animal and Plant Quarantine Agency (APQA), Ministry of Agriculture, Food and Rural Affairs (MAFRA)
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 pharmaceutical 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: Proposed regulations: "The designation regulation of the clinical trial institution for veterinary pharmaceutical products"; "The designation regulation of non-clinical trial institution for veterinary pharmaceutical products"; "The designation regulation of the clinical trial institution for veterinary medical devices"; "The guidelines of the clinical trial for veterinary medical devices". Language(s): Korean. Number of pages: 32, 68, 34 and 11
6. Description of content: The proposed regulations seek to: <ul style="list-style-type: none">- Ensure the reliability of "Dossier" to be submitted to get an approval for veterinary pharmaceutical products;- Describe the detailed regulations on the designation of the clinical trial institution and the non-clinical trial institution for the veterinary pharmaceutical products;- Describe the detailed regulations to get an approval for the veterinary medical devices (writing and approval of the clinical trial protocol, the qualification of the principal investigator).
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.
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?

<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>	
9.	Other relevant documents and language(s) in which these are available:
10.	<p>Proposed date of adoption (dd/mm/yy): To be determined.</p> <p>Proposed date of publication (dd/mm/yy): To be determined.</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): To be determined.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 28 June 2019</p> <p>Agency or authority designated to handle comments: <input 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 Agriculture, Food and Rural Affairs /MAFRA 94 Dasom2-ro, Government Complex-Sejong, Sejong-si 339-012, Republic of Korea Tel: +(82 44) 201 2080/2081 Fax: +(82 44) 868 0449 E-mail: wtoagri@korea.kr</p>
13.	<p>Text(s) available from: <input 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>Documents are available from the Animal and Plant Quarantine Agency website at http://www.qia.go.kr. Also available from:</p> <p>Ministry of Agriculture, Food and Rural Affairs /MAFRA 94 Dasom2-ro, Government Complex-Sejong, Sejong-si 339-012, Republic of Korea Tel: +(82 44) 201 2080/2081 Fax: +(82 44) 868 0449 E-mail: wtoagri@korea.kr</p>