NOTIFICATION

Addendum

The following communication, received on 10 May 2019, is being circulated at the request of the Delegation of the Republic of Korea.

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| 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" |
| The proposed regulations seek to:* 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).

<https://members.wto.org/crnattachments/2019/SPS/KOR/19_2770_00_x.pdf> <https://members.wto.org/crnattachments/2019/SPS/KOR/19_2770_01_x.pdf> <https://members.wto.org/crnattachments/2019/SPS/KOR/19_2770_02_x.pdf> <https://members.wto.org/crnattachments/2019/SPS/KOR/19_2770_03_x.pdf> |
| **This addendum concerns a:** |
| [ ] Modification of final date for comments |
| [ ] Notification of adoption, publication or entry into force of regulation |
| [ ] Modification of content and/or scope of previously notified draft regulation |
| [ ] Withdrawal of proposed regulation |
| [ ] Change in proposed date of adoption, publication or date of entry into force |
| [**X**] Other: This addendum contains the attachments which should appear in Item 5 of G/SPS/N/KOR/636. |
| **Comment period: *(If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)*** |
| [ ] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: 28 June 2019 |
| **Agency or authority designated to handle comments: [ ]****National Notification Authority, [****X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** |
| Ministry of Agriculture, Food and Rural Affairs /MAFRA 94 Dasom2-ro, Government Complex-Sejong, Sejong-si 339-012, Republic of KoreaTel: +(82 44) 201 2080/2081Fax: +(82 44) 868 0449E-mail: wtoagri@korea.kr  |
| **Text(s) available from: [ ]****National Notification Authority, [****X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** |
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