WORLD TRADE ORGANIZATION

G/SPS/N/BRA/2205

23 August 2023

(23-5663)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved:**
2.	**Agency responsible:** The Brazilian Health Regulatory Agency (ANVISA)
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):** Pharmaceutical products (HS code(s): 30)
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** **[X] All trading partners** **[ ] Specific regions or countries:**
5.	**Title of the notified document:** Normative Instruction 241, 3 August 2023. **Language(s):** Portuguese. **Number of pages:** 14 http://antigo.anvisa.gov.br/documents/10181/6637201/IN_241_2023_.pdf/dd2c2335-48ad-4bfb-b807-cb69ea5b9e94 https://members.wto.org/crnattachments/2023/SPS/BRA/23_11934_00_x.pdf
6.	**Description of content:** This normative instruction establishes daily intakeacceptable (ADI), the acute reference dose (ADR) and the maximum residue limits (MRL) foractive pharmaceutical ingredients (API) of veterinary drugs in food of animal origin.
7.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests.**
8.	**Is there a relevant international standard? If so, identify the standard:** **[X] Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:** CXM 2, Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) **[ ] World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:** **[ ] International Plant Protection Convention *(e.g. ISPM number)*:** **[ ] None** **Does this proposed regulation conform to the relevant international standard?** **[X] Yes [ ] 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)*:** 1 September 2023 **Proposed date of publication *(dd/mm/yy)*:** 1 September 2023
11.	**Proposed date of entry into force: [ ] Six months from date of publication, and/or *(dd/mm/yy)*:** 1 September 2023 **[ ] Trade facilitating measure**
12.	**Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** Not applicable **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:** Assessoria de Assuntos Internacionais – AINTE International Affairs Office Agência Nacional de Vigilância Sanitária – Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br
13.	**Text(s) available from: [ ] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** Assessoria de Assuntos Internacionais – AINTE International Affairs Office Agência Nacional de Vigilância Sanitária – Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br