NOTIFICATION

Addendum

The following communication, dated 23 February 2022, is being circulated at the request of the delegation of Ecuador.

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**Title**: *RESOLUCIÓN Nro. ARCSA-DE-2022-005-AKRG REFORMA PARCIAL A LA RESOLUCIÓN ARCSA-DE-2021-006-AKRG MEDIANTE LA CUAL SE EXPIDE LA NORMATIVA TÉCNICA SANITARIA PARA LA REGULACIÓN Y CONTROL DE MEDICAMENTOS QUE CONTENGAN SUSTANCIAS CATALOGADAS SUJETAS A FISCALIZACIÓN* (Resolution ARCSA-DE-2022-005-AKRG: Partial Amendment to Resolution ARCSA-DE-2021-006-AKRG issuing the Sanitary Technical Regulation for the regulation and control of medicines containing controlled substances)

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [ ] | Notified measure published - date: |
| [ ] | Notified measure enters into force - date: |
| [ ] | Text of final measure available from[[1]](#footnote-1): |
| [ ] | Notified measure withdrawn or revoked - date:Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from:1 |
| [X] | Other: [www.controlsanitario.gob.ec](http://www.controlsanitario.gob.ec/)<https://members.wto.org/crnattachments/2022/TBT/ECU/22_1757_00_s.pdf> |

**Description**: Resolution ARCSA-DE-2022-005-AKRG

Partial Amendment to Resolution ARCSA-DE-2021-006-AKRG issuing the Sanitary Technical Regulation for the regulation and control of medicines containing controlled substances

By means of this Addendum No. 2, the Republic of Ecuador advises that the Sanitary Technical Regulation for the regulation and control of medicines containing controlled substances has been issued pursuant to Resolution ARCSA-DE-2022-005-AKRG of 10 February 2022, the main purpose of which is to extend the time frames established in the Regulation in order to facilitate trade, by the National Agency for Sanitary Regulation, Control and Surveillance (ARCSA, Doctor Leopoldo Izquieta Pérez). The regulation will enter into force on the date of its signature, without prejudice to its publication in the Official Journal.

Text available from: *Ministerio de Producción, Comercio Exterior, Inversiones y Pesca* (Ministry of Production, Foreign Trade, Investment and Fisheries), *Subsecretaría de Calidad* (Under-Secretariat for Quality), *Organismo Nacional de Notificación* (National Notification Authority)

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1. This information can be provided by including a website address, a PDF attachment, or other information on where the text of the final measure/change to the measure/interpretative guidance can be obtained. [↑](#footnote-ref-1)