



**BUSTAMANTE  
FABARA**

**LEGAL BULLETIN**

## **ARCSA Statement on COMEX Resolution No. 017-2025**



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On January 30, 2026, the National Agency for Regulation, Control and Sanitary Surveillance – ARCSA (“**ARCSA**”) issued a statement related to COMEX Resolution No. 017-2025 (the “**Resolution**”). In this statement, ARCSA informs holders of products subject to sanitary control about the entry into force of the Resolution, which will take effect as of April 9, 2026, and which amends Article 4 regarding the authorization for the use of Sanitary Registrations and Sanitary Notifications by third parties for the importation, distribution, and commercialization of products under sanitary surveillance.

The most relevant points are summarized below:

- 1. Endorsement (“endoso”) and holder’s responsibilities:** ARCSA indicates that it does not contemplate the transfer of responsibilities to third parties through the endorsement mechanism. Consequently, the responsibility arising from the Sanitary Registration or Sanitary Notification remains with the holder and/or applicant and is non-transferable.
- 2. Notification to ARCSA and procedure through the VUE:** For the authorization to use Sanitary Registrations and Sanitary Notifications by third parties (for importation, distribution, and commercialization), ARCSA provides that the process must be managed exclusively through the Ecuadorian Single Window (Ventanilla Única Ecuatoriana – **VUE**).

Within the VUE, the user must process the authorization through a modification procedure of the sanitary registration or notification, using the applicable “Reference Code” according to the type of product. ARCSA has defined the following codes:

- **MDM01:** Medical Devices
- **MAE001:** Food
- **AUT:** General Medicines, Biological Products, Natural Products, Homeopathic Products, Pesticides for domestic, public health, and industrial use, and Hygienic Products for industrial use

These codes will be used solely for authorizing the use of Sanitary Registrations and Sanitary Notifications, in order to incorporate third parties as importers and/or distributors of the product, through the corresponding procedure in the VUE. To complete the process, the online modification form must be completed and the documents required by ARCSA must be attached:

- I. Authorization Letter for Importers and/or Distributors of Products for Human Use and Consumption; and
- II. Importer–Distributor Template, in accordance with the official formats established by ARCSA.

**Recommendation:** Considering that the Resolution will enter into force on April 9, 2026—on which date endorsements granted previously will cease to be valid—we recommend that holders operating with third parties (importers/distributors) anticipate the preparation of the documentation and the management of the procedure through the VUE, bearing in mind that the holder and/or applicant retains the sanitary responsibility associated with the registration or notification.

If you would like us to expand on the scope and implications for your operation (e.g., contractual adjustments, risk management, and compliance timeline), we will be glad to assist you. For more information, please contact us:

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