/Carey

August 2026

ISP LAUNCHES PUBLIC CONSULTATION ON THE NATIONAL TECHNOVIGILANCE SYSTEM GUIDANCE

On August 27, 2026, the Chilean Public Health Institute ("ISP") launched a public consultation on the document entitled "Guidance on the National Technovigilance System" (the "Guidance").

The Guidance is intended to replace previous editions and updates the operational post-market surveillance framework applicable to all medical devices ("MDs") and in vitro diagnostic medical devices ("IVDMDs") manufactured, imported, or distributed in Chile. Its purpose is to strengthen the prevention, detection, investigation, and reporting of adverse events and incidents, as well as the management of Field Safety Corrective Actions ("FSCAs") and recalls.

Scope

The Guidance is addressed to individual and institutional healthcare providers in both the public and private sectors, institutions of the Armed Forces and Public Order and Security Forces, MD manufacturers, importers, and distributors, as well as the general public using such products. The Guidance also reiterates that the Technovigilance System applies to all MDs and IVDMDs available on the domestic market, whether manufactured, imported, or distributed in Chile.

Key Obligations for Manufacturers, Importers, and Distributors:

• **Technovigilance Officer:** Formally appoint a Technovigilance Officer and an alternate, both having a contractual relationship and performing their duties in Chile and notify the ISP of their appointment and any subsequent changes.
• **Local System and Traceability:** Implement procedures to collect, retain, and analyze complaints, events, incidents, FSCAs, and technical information throughout the product lifecycle; maintain records identifying the product, batch or serial number, manufacturer, and customer or acquiring healthcare provider.
• **Reporting:** Submit reports through the Integrated Surveillance System. Sentinel events must be reported immediately and no later

This news alert is provided by Carey y Cía. Ltda. for educational and informational purposes only and is not intended and should not be construed as legal advice.

Carey y Cía. Ltda.
Isidora Goyenechea 2800, 43rd Floor.
Las Condes, Santiago, Chile.
www.carey.cl

than within two business days; adverse events within ten business days; and adverse incidents showing an increase in occurrence within twenty business days after the trend has been validated.

• **Investigation:** Initiate an assessment upon becoming aware of a sentinel event, coordinate with customers and the manufacturer, and respond to the ISP. The Guidance recommends submitting initial, interim, and final responses within 20, 40, and 60 business days, respectively.

• **FSCAs and Market Recalls:** Notify the ISP using form ANDIM/012 and, simultaneously, notify customers through a Field Safety Notice in Spanish. The general reporting deadline is ten business days; however, recalls and certain actions associated with death or permanent impairment and a high probability of occurrence must be reported within three business days.

• **Documentation:** Retain acknowledgements of receipt, investigation records, risk assessments, distribution records, and reconciliation records for recalled units. The ISP may require annual reports for specific MDs and/or IVDMDs.

The Guidance further states in its preamble that it constitutes an administrative document without the force of law. Accordingly, the ISP reserves the authority to request additional information and to establish requirements not expressly described in the Guidance.

The public consultation will remain open for comments through the designated submission form **until September 27, 2026.**

Authors: Ignacio Gillmore; Alejandra Del Rio; Javiera Péndola; Cristóbal Zamora