

ISP REQUIRES MARKETING AUTHORIZATION HOLDERS DIGITIZED SUBMISSION OF PROFESSIONAL INFORMATION LEAFLETS AND ORDERS THEIR PUBLICATION ON ITS WEBSITE

On August 6, 2026, the Chilean Public Health Institute ("ISP") published Exempt Resolution No. 3955/26 (the "Resolution"), requiring holders of marketing authorizations ("MAHs") for pharmaceutical products in "Active" or "Voluntary Distribution Suspension" status to submit a digitized version of the Professional Information Leaflet / Summary of Product Characteristics ("SPC") for subsequent publication on the ISP's website.

Main aspects:

- Marketing authorizations subject to the requirement:** The requirement applies to MAHs for pharmaceutical products granted in Chile that are in "Active" or "Voluntary Distribution Suspension" status. Marketing authorizations in "Expired" status are expressly excluded.
- Document format:** For each marketing authorization, the authorized Professional Information Leaflet must be submitted in two formats: Word and PDF. Both must be clean and complete versions, without patches or strikethroughs.
- Submission procedure:** Documents must be sent via email to folletoprofesional@ispch.cl, through a separate submission for each marketing authorization. The subject line must follow this format: "Envío Folleto-RCP - Registro Sanitario [Indicate MA No.] [Product Name]".
- Subsequent updates:** If the submitted documents require subsequent updates, the new versions must be submitted following the same procedure.

Compliance deadline and sanctions:

The maximum and non-extendable deadline for submitting all required documentation is **December 31, 2026**.

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Failure to comply with the requirements within the specified deadline and in the required form, as well as the submission of texts that do not match the authorized versions, will be subject to ISP enforcement and may result in administrative proceedings, fines or applicable sanitary measures.

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