LATAM REGULATORY GUIDES · CHILE

ISP Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Chile

The officer-signature translation rule, the Art. 74 item 5 / 29 No. 10 / 78 citation set, Ley 20.850 market access, and the 72-hour serious-ADR window.

Julio G. Martinez-Clark · CEO bioaccess® · Founder Amavita Sciences ·

Last updated August 22, 2026 · ~28 min read · Version 1.3.0

D.Ex. 25/2026 device generalization

ON THIS PAGE

The direct answer

The Instituto de Salud Pública de Chile (ISP) does something no other major LATAM regulator does: it lets a company officer — not a licensed sworn translator — sign off on the translation of its own legal dossier. Article 29 No. 10 of Decreto Supremo N° 3 de 2010 requires legal documents to be filed in Spanish *"o debidamente traducidos bajo la firma del representante legal, profesional asignado al efecto por la empresa o del Director Técnico"* — under the signature of the legal representative, a company-designated professional, or the Technical Director (DS

3/2010, Ley Chile). The authentication burden shifts entirely from the translator to the signer's professional liability. And in 2026, Chile is redrawing its medical-device map: Decreto Exento 25/2026 extends sanitary registration to medical devices and IVDs generally, converting Chile from a ten-category controlled regime toward a general framework (ISP ANDIM, Registro y autorización). This guide covers both categories — drugs and devices — across market access, market clearance, and clinical research, with statute citations verified against the consolidated Ley Chile text.

Section A. Regulator profile

Name: Instituto de Salud Pública de Chile (Public Health Institute of Chile), ISP. Medicines sit under ANAMED (Agencia Nacional de Medicamentos); devices under the newly framed ANDIM (Agencia Nacional de Dispositivos Médicos).

Establishing statute: The operative regulation for pharmaceuticals is Decreto Supremo N° 3 de 2010, approving the *Reglamento del Sistema Nacional de Control de los Productos Farmacéuticos de Uso Humano* — promulgated 25 January 2010, published 25 June 2011, in force 25 June 2011, consolidated through 21 August 2020 (Decreto N° 65 of 24 December 2019). It implements the *Código Sanitario* (DFL 725, as amended by Ley 21.030) (WIPO Lex, Decreto N° 3).

Scope: National control system for pharmaceutical products for human use — registration, labelling, importation, manufacturing-establishment authorization, batch control, and pharmacovigilance (DS 3/2010, Ley Chile) — plus sanitary registration of the controlled device and IVD categories through ANDIM (ISP ANDIM).

Website: https://www.ispch.gob.cl

HQ / in-person filing address: Av. Marathon 1000, Ñuñoa, Santiago — the address at which HIV self-test IVD registrations are filed with the *Sección Gestión Productos y Servicios* (ISP ANDIM).

Adjacent bodies sharing responsibility

Body	Role	Reference
Comité Ético Científico (CEC)	Art. 23 DS 3/2010 requires trial applications to be filed with the protocol already approved by the ethics committee; Art. 111 B of the Código Sanitario (as added by Ley 20.850) requires AE/ADR notification to both the ISP and the corresponding CEC	DS 3/2010; Ley 20.850

Body	Role	Reference
SEREMI de Salud (regional ministerial secretariats)	Local sanitary authorizations; must decide within 3 business days, by reasoned resolution if rejecting	DS 3/2010
Ministerio de Salud (MINSAL)	Appeal body: *recurso de reclamación* against ISP Director decisions lies with MINSAL within 5 business days; MINSAL decides within 10 days (Art. 225)	DS 3/2010
Fondo Nacional de Salud (FONASA)	Under Art. 1 Ley 20.850, must guarantee financial protection created by the law to all beneficiaries of Chile's health-insurance systems	Ley 20.850
MINREL (Ministerio de Relaciones Exteriores)	Translation service available but expressly optional for ISP filings	Amavita, Preclinical LATAM

Chile has no ClinRegs profile, so no consolidated third-party English-language clinical-trial reference exists (ClinRegs — Chile country URL resolves to the generic home page).

Section B. Official language requirements

Chile's language rule is the most permissive in LATAM's Big 6 — and simultaneously the most misunderstood. It does not require a sworn or public translator. It requires that legal documents be *either* in Spanish *or* duly translated under the signature of a company officer, who then carries the professional liability.

Statutory anchor — Art. 29 No. 10 DS 3/2010 (verbatim):

> *"Documentos legales, en idioma castellano o debidamente traducidos bajo la firma del representante legal, profesional asignado al efecto por la empresa o del Director Técnico, cuando corresponda..."*

Legal documents: in Spanish, or duly translated under the signature of the legal representative, the professional assigned by the company for that purpose, or the Technical Director (DS 3/2010).

Documents covered by Art. 29 No. 10 letter a) (imported products):

- a.1 *Certificado de registro sanitario* / *Certificado de producto farmacéutico* / *Certificado de autorización sanitaria*, or the WHO-recommended official certification, under legalized signature, attesting GMP-compliant premises, origin-country registration with the complete authorized formula, and any restrictive sale regime.
- a.2 Manufacturing agreement with the foreign laboratory, duly legalized.
- a.3 Legalized licence.
- a.4 Official GMP certificate from the competent authority of the manufacturing country (waivable if already in a.1).
- a.5 Importation agreement, notarized or legalized.
- a.6 National manufacturing/distribution agreement, notarized, with each establishment's sanitary authorization.
- a.7 Quality-control agreement with an ISP-authorized pharmaceutical laboratory, notarized.

Letter b) (domestically manufactured products): b.1 national manufacturing/distribution agreement notarized; b.2 legalized licence; b.3 quality-control agreement with an ISP-authorized laboratory (DS 3/2010).

Analytical methodology — Art. 29 No. 4: Must be submitted *en castellano* (DS 3/2010).

Labelling — Art. 74 DS 3/2010: Secondary-packaging labelling *"se hará en idioma castellano, con caracteres claramente visibles"*, with 14 mandatory items including:

- Item 5 — the qualitative-quantitative statement of active principles and the qualitative enumeration of excipients
- Item 10 — the ISP registration number preceded by *"Reg. I.S.P:"*
- Item 12 — storage conditions
- Item 13 — the mandatory legend *"Mayor información en www.ispch.cl"*

Art. 75: Primary packaging must carry at minimum items 1, 2, 7, 9, 10, and 11 of Art. 74.

Art. 77: Labels must use Arial or a similar rectilinear typeface at a minimum body size of 6 points — a typographic constraint that directly limits Spanish text expansion in translated artwork.

Art. 78: *"En forma excepcional el rotulado gráfico de un producto farmacéutico importado terminado, podrá incluir textos en otros idiomas, además del castellano, siempre que no altere el texto autorizado por el Instituto"* — multilingual artwork on imported finished product is permitted only exceptionally, in addition to Spanish, and only if it does not alter the ISP-authorized text.

Art. 80: All graphic labelling and both the patient and professional information leaflets submitted at registration must correspond to the definitive text they will have once authorized; Art. 77's type-size rule applies to the patient leaflet.

Practical band. Amavita's regulator-band analysis places ISP in the tier where no sworn translator is required and MINREL translation service is expressly optional; the operative hook is Art. 29 No. 10 plus ISP guidance SDM/001 and Resolución Exenta 5161/2016, which requires protocol and Investigator's Brochure in both English and Spanish (Amavita, Which Regulators Accept English Dossiers; Amavita, Preclinical LATAM).

Correction to a widely cited citation

Amavita's RFI Anatomy analysis originally attributed the Chilean excipient-language requirement to "Art. 92 DS 3/2010." The consolidated statute text does not support that. **Art. 92 DS 3/2010 governs* sublotes *(sub-batches):**

> *"Si un producto farmacéutico de un mismo lote o serie es terminado en etapas discontinuas, cada una de ellas constituirá un sublote y deberá individualizarse con un agregado al número de serie original"* (DS 3/2010).

The correct statutory hooks for the excipient-in-Spanish RFI are:

1. Art. 74 item 5 — qualitative enumeration of excipients on the Spanish-language secondary label.
2. Art. 29 No. 10 — legal documents in Spanish or officer-signed translation.
3. Art. 78 — other languages permitted only exceptionally, in addition to Spanish.

The Amavita blog has been corrected accordingly. This is the kind of drift a rigorous seven-QC-gate pipeline is designed to catch.

Section C. Sworn vs certified vs simple translation

Chile is the outlier: the statute names no sworn-translator register. Authentication comes from the underlying document's legalization or notarization, plus the officer's signature on the translation.

Tier	Requirement	Statutory anchor
Legal documents (CPP, GMP certificate, licences, manufacturing / import / QC agreements)	Spanish or translated under the signature of the *representante legal*, a company-designated professional, or the *Director Técnico* — no sworn translator named in the statute	DS 3/2010, Art. 29 No. 10

Tier	Requirement	Statutory anchor
Authentication of the foreign document	Legalization (a.1 *firma legalizada*, a.2 *debidamente legalizado*, a.3 legalized licence) or notarization for agreements (a.5, a.6, a.7, b.1)	DS 3/2010
Analytical methodology	*En castellano* — obligatory	DS 3/2010, Art. 29 No. 4
Preclinical / technical reports	No sworn translator required; MINREL service optional	Amavita, Preclinical LATAM
Clinical protocol and Investigator's Brochure	English and Spanish per ISP guidance SDM/001 and Resolución Exenta 5161/2016	Amavita, Preclinical LATAM
Practical characterization	Notarized / "official practice" rather than a statutory sworn-translator register	Amavita, Sworn vs Certified
Spanish variant	Chilean Spanish within the es-419 family	Amavita, Regulatory Language Infrastructure

Apostille and legalization sequencing

Chile joined the Apostille Convention in 2016. Public documents from other Convention signatories are validated with an apostille from the competent authority in the country of origin. Non-Convention documents require the legalization chain (foreign ministry + Chilean consulate). The Art. 29 No. 10.a.1 *firma legalizada* language covers both mechanisms.

Document Currency — the 7th QC gate

Chile's DS 3/2010 does not impose the two-year foreign-certificate rule that Peru's DIGEMID/INS pathway does, but Chile's Art. 47 six-month clock starts from fee payment, not filing. If an apostilled GMP certificate expires between filing and fee payment, the applicant must refile a valid one. Amavita's 7th QC gate — Document Currency verifies that every foreign certificate, apostille, and notarial act sits inside its own jurisdictional validity window at the moment of submission. See Blog corrections + seventh QC gate rollout.

Section D. Preclinical / non-clinical documentation — the three operational questions

Chile is the cheapest of the seven to translate correctly and the easiest to overspend on, because its permissive rules look too permissive to be true.

D.1 Do we have to translate every page of the preclinical stack?

No — and Chile goes further than any peer. Art. 52(2) DS 3/2010 permits bibliography substitution for well-known active ingredients: for actives with established scientific literature, published bibliography stands in place of a sponsor-generated non-clinical package. Where that applies, the translation question disappears along with the study reports themselves.

Where a sponsor-generated stack is still filed, ISP does not require sworn translation of it. Art. 29 No. 10 DS 3/2010 — the officer-signature rule, unique in LATAM — allows legal documents to be filed in Spanish *or duly translated under the signature of the legal representative, a company-designated professional, or the Technical Director*. The liability moves to the signer; no *traductor público* is involved, and the MINREL translation service is expressly optional.

D.2 If translation IS required — is it text-only, or does it require DTP?

Two distinct obligations. Clinical research is bilingual by instruction: ISP guidance SDM/001 together with Resolución Exenta 5161/2016 requires the protocol and Investigator's Brochure in both English and Spanish. That is a text-only but doubled deliverable, and it is where Chilean translation budget actually goes.

The ICF is a readability deliverable, not a translation deliverable: Chilean practice holds informed consent to an INFLESZ score ≥ 55, so the Spanish consent must be authored to a measured readability threshold rather than mirrored from the English syntax. Labelling is the DTP surface — Art. 74/75 content requirements, plus Art. 77's Arial-or-similar 6-point minimum, which caps how far Spanish text expansion can go before the artwork must be re-laid out.

D.3 If translation is NOT required — what substitutes for it?

Curated bibliography under Art. 52(2) for well-known actives; an officer-signed Spanish rendering for legal documents under Art. 29 No. 10; and a Spanish non-clinical overview referencing the English study reports. Chile's substitute is a signature and a literature file, not a certification stamp.

The two regulatory pathways trigger different translation obligations

Every LATAM regulator operates two related but separate regulatory pathways for a sponsor's product: (1) clinical-trial authorization, which is what allows the investigational product to enter a clinical study on the sponsor's timeline; and (2) market-access / sanitary registration, which is what allows the commercial product to be sold. These pathways trigger different translation obligations. The most common sponsor error is applying a market-access translation obligation (device IFU, primary label, secondary packaging) to a clinical-trial dossier where that obligation is not yet in force.

Pathway 1 — clinical-trial authorization

- Under SDM/001 + Res. Ex. 5161/2016, protocol and IB must be bilingual (English and Spanish) — this is unique in LATAM.
- ICF must be full Spanish with an INFLESZ readability score ≥ 55.
- Foreign health-authority letters accepted under DS 3/2010 Art. 29 No. 10 with a company-officer signature (legal representative, company-designated professional, or Technical Director) — no sworn translator required.

Pathway 2 — market-access / sanitary registration

- Post-Decreto Exento 25/2026, device IFU and labelling in full Spanish (DTP required).
- Drug labelling in full Spanish per DS 3/2010 titles VI–VII (Arts. 74, 75, 80).

For each document class in this guide's consolidated preclinical instruction table below, check which pathway it is scoped to before authorizing translation. A document that requires DTP-scope translation for market registration may require only text-flow translation — or no translation at all — for clinical-trial authorization.

D.4 Consolidated preclinical instruction table

Document class	Spanish required?	Basis	Certification tier	DTP?	Substitute deliverable
Non-clinical package, well-known active	Often not filed at all	Art. 52(2) DS 3/2010	—	No	Curated bibliography
GLP toxicology / pharmacology reports	No	Art. 29 No. 10 practice	Officer signature if legal-adjacent	No	Spanish non-clinical overview
Analytical methodology	**Yes* — en castellano***	Art. 29 No. 4 DS 3/2010	Officer signature	No	None
Legal documents (CPP, licences, agreements)	Spanish or translated	Art. 29 No. 10 DS 3/2010	Legal rep / designated professional / Technical Director signature	No	None
Protocol and Investigator's Brochure	Bilingual EN + ES	SDM/001 + Res. Ex. 5161/2016	Certified, MD-reviewed	No	None
Informed consent form	Yes	Chilean ethics practice	MD-reviewed, INFLESZ ≥ 55	No	None
Labelling and leaflets	Yes	Arts. 74, 75, 77, 80 DS 3/2010	Regulatory review	Yes (6 pt Arial constraint)	None

Where the preclinical translation risk actually sits

In the bilingual clinical requirement and the ICF readability threshold — not in toxicology. Sponsors budget for sworn translation Chile never asked for, then miss that the protocol and IB must exist in both languages and that a syntactically faithful Spanish ICF can still fail INFLESZ. Art. 29 No. 4 is the quiet exception: analytical methodology must be in castellano even when everything around it need not be.

CATEGORY 1: DRUGS

D1. Drugs — Market access (pricing, reimbursement, HTA)

Chile's high-cost access instrument is Ley 20.850, the *Ley Ricarte Soto*.

- Art. 1 Ley 20.850 creates a *Sistema de Protección Financiera para Diagnósticos y Tratamientos de Alto Costo* — a financial-protection system for high-cost diagnostics and treatments — forming part of the *Régimen General de Garantías en Salud*, with FONASA obliged to assure that protection to beneficiaries of Chile's health-insurance systems (Ley 20.850, Ley Chile).
- Art. 5 Ley 20.850: Covered diagnostics and treatments are declared by supreme decree signed by the Ministers of Health and Hacienda — this is the listing / coverage decision point (Ley 20.850).

Documents requiring translation for the Ley 20.850 pathway: the fetched statute text does not enumerate a dossier or an explicit language rule for the coverage petition. In practice, ISP registration documents in Spanish and Spanish-language clinical evidence carry over. A separate pharmaceutical price-control body comparable to Brazil's CMED or Colombia's CNPMDM was not identified in Chilean sources fetched for this guide.

Timeline for a coverage decision: Not specified as a day count in the statute — the mechanism is a supreme decree, not a day-counted administrative procedure.

D2. Drugs — Regulatory submissions for market clearance

Pathways under DS 3/2010

Pathway	Statutory basis	Total statutory timeline
Procedimiento ordinario (new registration, incl. NMEs)	Arts. 29, 44–47	6 months from fee payment, once evaluations are favourable (Art. 47)
Procedimiento abreviado (public-health-programme products; products in the *Formulario Nacional de Medicamentos*)	Art. 51	≤ 4 months total
Procedimiento simplificado (same active/strength/route as an already-registered product; well-known actives; therapeutic-equivalence listed actives; export-only products treated as food in destination country)	Art. 52 (1)–(4)	5 months from filing
Re-filing after denial	Art. 49 final ¶	New procedure within 6 months of denial; ISP verifies prior file and evaluates new evidence within 3 months
Modifications (analytical, technical, legal)	Arts. 63, 65, 66	Modifications authorized by reasoned resolution on the holder's petition, on authorized forms with technical-scientific evidence, duly foliated (Art. 66); ISP may compel modifications under Art. 64
Biosimilar-specific pathway	—	Not identified as a separate named procedure in the fetched DS 3/2010 text
Orphan / pediatric-specific pathway	—	Not identified; Art. 51 abbreviation is the closest expedited mechanism

Source: DS 3/2010.

Procedural clock (drugs)

- Art. 44: ISP performs form review and rules on admissibility within 10 días hábiles (business days).
- Art. 45: On favourable admissibility, applicant is notified to appear and pay the fee — the fee-payment date starts the Art. 47 six-month clock.
- Art. 49: RFI on accessory or connected issues — applicant has 15 días hábiles to make representations. RFI on insufficiency of evidence or studies — applicant must supply further

evidence within 30 días hábiles; registration is granted if the new evidence suffices; otherwise denial by reasoned resolution.

- Art. 104: ISP must issue a *Certificado de Producto Farmacéutico* within 10 days of receiving the request.
- Art. 186: Batch (*control de serie*) approval or rejection within 20 días hábiles from receipt of a complete Art. 184 file, except vaccines at 40 días hábiles.
- Art. 225: *Recurso de reclamación* against ISP Director decisions lies with MINSAL within 5 días hábiles; MINSAL decides within 10 days.
- Art. 222: All administrative procedures, notifications, and time limits are governed by Ley 19.880.

Empirical (non-statutory) timeline: Amavita records a Chilean excipient-language RFI adding +30 days to a submission (Amavita, RFI Anatomy).

Translated documents by pathway. For every registration pathway the Art. 29 No. 10 legal-document set (a.1–a.7 / b.1–b.3) must be in Spanish or officer-signed translation; Art. 29 No. 4 analytical methodology in Spanish; Art. 74 / 75 / 80 labelling and both leaflets in Spanish as definitive texts (DS 3/2010). Art. 52(2) permits bibliography to substitute for preclinical dossiers where the active is sufficiently known — which, in translation terms, shifts the burden from full study-report translation to literature curation.

D3. Drugs — Clinical research trial submissions

Authorizing agency. The ISP authorizes *uso provisional* of a pharmaceutical product for scientific research or a clinical trial. Art. 21(c) DS 3/2010 permits provisional use of unregistered products *"para ser utilizados en investigación científica o ensayos clínicos, previo informe favorable del o los comités de ética correspondiente"* — a favourable ethics-committee opinion is a precondition to the ISP application, not a parallel track (DS 3/2010).

Art. 111 A of the *Código Sanitario*, added by Ley 20.850, gives the ISP an express special authorization power for research products, requiring the protocol, the informed-consent document, the insurance policy, and the approval required by Art. 10 of Ley 20.120; the authorization lasts a maximum of one year, renewable, and is entered in a public registry (Ley 20.850).

Documents requiring translation:

- Protocol already approved by the ethics committee (Art. 23 DS 3/2010).
- Official certificate from the competent authority of the country where the manufacturing establishment is located, issued in the terms of Art. 29 No. 10.a.4 — the foreign GMP certificate, subject to the Art. 29 No. 10 language rule.
- The same protocol document is required when a registered product is to be used outside its authorized conditions (Art. 23).
- Informed-consent document and insurance policy (Art. 111 A / 111 F Código Sanitario).

- Per Amavita, ISP guidance SDM/001 and Resolución Exenta 5161/2016 require protocol and IB in English and Spanish (Amavita, Preclinical LATAM); ICF readability is benchmarked against the INFLESZ ≥ 55 threshold (Amavita, INFLESZ Threshold).

Ethics framework. *Comités Ético Científicos* (CEC). Their opinion precedes the ISP filing (Art. 21(c), Art. 23 DS 3/2010). Under Ley 20.850:

- Art. 111 D — research centres must be ISP-accredited
- Art. 111 B — AE/ADR notification to both the ISP and the corresponding CEC
- Art. 111 C — free continuity of treatment after the trial
- Art. 111 E — strict liability with a 10-year prescription period
- Art. 111 F — mandatory insurance policy
- Art. 111 G — sanctions (Ley 20.850)

Substantive vs non-substantive amendments. A two-tier amendment taxonomy of the kind ANVISA and INS Peru operate was not found in the fetched Chilean instruments. The nearest mechanism is the one-year renewable term of the Art. 111 A authorization (Ley 20.850). This puts Chile in a lighter procedural band than Argentina, where Disposición 7516/2025 Art. 7 repealed the older Disposición 6677/2010 and adopted ICH E6(R3) with a full substantial/non-substantial framework effective 1 December 2025 (Boletín Oficial, Argentina) — a change that positions Argentina as the first LATAM regulator to complete the E6(R3) transition. Chile has not announced an equivalent step.

Trial-application review timeline in days: Not stated. Neither Art. 21–23 DS 3/2010 nor Art. 111 A Código Sanitario states a day count for the ISP decision in the fetched text.

Pharmacovigilance report translation:

- Art. 216 DS 3/2010 — ISP is the safety-surveillance authority for registered products and for products authorized for scientific-research or provisional use.
- Art. 217 — suspected serious ADRs must be communicated within 72 hours of becoming aware; all other cases within 30 days; reporting uses ISP-prescribed forms.
- Art. 218(b) — registration holders must submit suspected-ADR information to the ISP quarterly (*trimestralmente*) on authorized forms.
- Language requirement for PV reports: No explicit language clause for pharmacovigilance submissions appears in the fetched DS 3/2010 text; the operative constraint is that reporting occurs on ISP-prescribed Spanish forms.

CATEGORY 2: MEDICAL DEVICES

E1. Devices — Market access

- The Ley 20.850 high-cost financial-protection system covers *diagnósticos y tratamientos de alto costo* declared by supreme decree, which can encompass device-based diagnostics and treatments; FONASA guarantees the coverage (Ley 20.850).
- A device-specific reimbursement list, HTA body, or hospital-tender translation requirement was not found in the fetched Chilean sources. Chile's device market-access framework is effectively still forming — an important gap for foreign device manufacturers to price into their LATAM entry strategy.

E2. Devices — Regulatory submissions for market clearance

The 2026 pivot. Chile has historically not operated a general four-class device classification. Sanitary registration applied **only to device and IVD categories expressly declared subject to control by* decreto exento*. This is what changed in 2026.**

Controlled categories as of August 2026 (ISP ANDIM, Registro y autorización):

Controlled category	Enabling decree
Latex surgical gloves; latex examination gloves; latex condoms	D.Ex. 342/2004
Sterile hypodermic needles and syringes	D.Ex. 1887/2007
Synthetic (non-latex) male condoms; female condoms	D.Ex. 93/2018
Portable automated external defibrillators (AEDs)	D.Ex. 42/2021
HIV self-test IVDs	D.Ex. 41/2022 and 96/2022
Professional-use HIV IVDs	D.Ex. 41/2022 and 15/2024
Immunohematology reagents	D.Ex. 5/2025, in force 21 February 2026
Medical devices and IVDs generally	D.Ex. 25/2026
IVD reagents for microbiological qualification of blood donations	D.Ex. 31/2026

D.Ex. 25/2026 is the single largest expansion of Chile's device registration perimeter in the fetched record — converting Chile from a ten-category regime toward a general one. For foreign device manufacturers, this means the "does my device even need to be registered in Chile?" analysis flips from "usually no" to "usually yes."

Applicant and representation. The applicant must be the legal manufacturer domiciled in Chile or an accredited *Representante Autorizado* / *Titular*, whose mandate is evidenced by a *carta poder*, letter of designation, or contract (ISP ANDIM).

Filing channel. Electronic filing via GICONA; HIV self-test registrations are filed in person at the *Sección Gestión Productos y Servicios*, Av. Marathon 1000, Ñuñoa, Santiago.

Labelling. The registration code must appear legibly on the labelling (ISP ANDIM).

Modifications. Modifications are approved by resolution, except where they are significant — changes to design, chemical composition, main component, biocompatibility, energy source, or manufacturing — in which case a new registro sanitario is required.

Per-class document lists, Spanish-language requirement, and statutory review timelines for devices: not published on the ANDIM registration page. Those sit in the individual *decretos exentos* and ANDIM technical guidance, which are being consolidated as the D.Ex. 25/2026 general framework takes effect. As of the publication date of this guide, the applicable rule for legal documents remains the Art. 29 No. 10 officer-signed translation standard by analogy.

IVD / SaMD / combination-product extras. IVDs are the fastest-expanding controlled category (D.Ex. 41/2022, 96/2022, 15/2024, 5/2025, 31/2026). A SaMD-specific classification rule of the kind in ANVISA RDC 751/2022 Art. 8 §4 was not found for Chile in this session's fetched sources.

E3. Devices — Clinical research trial submissions

- Ley 20.850's Código Sanitario Arts. 111 A–G apply to "productos para investigación científica" and are the only device-relevant trial framework identified: ISP special authorization on protocol + ICF + insurance policy + Ley 20.120 Art. 10 approval, max one year renewable, public registry (111 A); AE/ADR notification to ISP and CEC (111 B); free post-trial continuity (111 C); ISP-accredited research centres (111 D); strict liability with 10-year prescription (111 E); mandatory insurance (111 F); sanctions (111 G) (Ley 20.850).
- A device-specific clinical-investigation dossier pathway equivalent to ANVISA's DICD under RDC 837/2023 was not found in fetched Chilean sources. DS 3/2010 Arts. 21–23 govern *pharmaceutical* products, not devices.
- FIH vs pivotal vs post-market distinctions for devices: not identified in the fetched text.
- Review timelines: not stated.
- Ethics framework: *Comité Ético Científico*, mandatory in parallel with ISP authorization per Art. 111 A / 111 B.

Section F. Common RFI / rejection patterns

Amavita's RFI Anatomy analysis reports a Chilean case in which excipients left in English on submitted labelling triggered an ISP information request and +30 days of added review time.

Mapped to Amavita's six recurring defect classes — numeric integrity, negation preservation, readability below INFLESZ 55, terminology inconsistency, structural inventory, and jurisdictional adaptation (Amavita, Amendment Cascade) — plus the new 7th QC gate (Document Currency), Chile's exposure concentrates in:

Structural inventory / jurisdictional adaptation. The Art. 74 fourteen-item checklist plus the Art. 77 Arial-6-pt floor make untranslated or over-expanded label items mechanically detectable, and Art. 80 requires submitted artwork to be the definitive text. Translations that expand more than ~15% over the English source will not fit at Arial 6 pt on the same layout — this is a rejectable defect, not a cosmetic issue.

Terminology inconsistency. Art. 29 No. 4 requires analytical methodology in Spanish while Art. 52(2) permits foreign-language bibliography — so a single dossier mixes languages by design. Terminology drift across the Spanish and English components is a common RFI trigger.

Readability. INFLESZ ≥ 55 applies to the Spanish ICF (Amavita, INFLESZ Threshold).

Document Currency (7th gate). Foreign GMP certificates and apostilles inside their own jurisdictional validity window at the moment of ISP filing — and again at fee payment, since Art. 47's six-month clock starts there.

Statutory consequence. An insufficiency finding gives only 30 días hábiles to cure, and a second insufficient response results in denial by reasoned resolution (Art. 49) (DS 3/2010). Chile is not among the regulators Amavita identifies as having the highest translation-grounds RFI rates — that distinction goes to COFEPRIS and ANVISA — but the +30-day RFI cost combined with a one-shot 30-day cure window makes even a "low-frequency" translation defect expensive.

Section G. Consolidated timelines — ISP Chile

Sub-category	Procedure	Statutory timeline	Empirical / added time	Source
D1 Drug market access	Ley 20.850 high-cost coverage	Declared by supreme decree, Art. 5 (no day count)	—	Ley 20.850
D2 Drug clearance	Admissibility form review	10 días hábiles	—	DS 3/2010 Art. 44
D2	*Procedimiento ordinario* registration	6 months from fee payment	—	Art. 47
D2	*Procedimiento abreviado*	≤ 4 months total	—	Art. 51

Sub-category	Procedure	Statutory timeline	Empirical / added time	Source
D2	*Procedimiento simplificado*	5 months from filing	—	Art. 52
D2	RFI on accessory issues	15 días hábiles to respond	—	Art. 49
D2	RFI on insufficient evidence	30 días hábiles to respond	Translation-grounds RFI +30 days	Art. 49; Amavita RFI Anatomy
D2	Re-filing after denial	File within 6 months; ISP decides in 3 months	—	Art. 49
D2	CPP issuance	10 days	—	Art. 104
D2	Batch release (*control de serie*)	20 días hábiles; vaccines 40 días hábiles	—	Art. 186
D2	Appeal to MINSAL	File in 5 días hábiles; decision in 10 days	—	Art. 225
D3 Drug trials	ISP provisional-use authorization	No day count; authorization valid 1 year, renewable	—	DS 3/2010 Arts. 21–23; Ley 20.850 Art. 111 A
D3	Serious ADR report	72 hours; other cases 30 days; periodic quarterly	—	Arts. 217–218
E1 Device market access	—	Not published	—	ISP ANDIM
E2 Device clearance	Registro sanitario for controlled categories	Not published on ANDIM registration page	—	ISP ANDIM
E3 Device trials	Código Sanitario Arts. 111 A–G	No day count	—	Ley 20.850
Cross-cutting	SEREMI local sanitary authorization	3 business days	—	DS 3/2010

Section H. Recent regulatory changes 2023–2026

- D.Ex. 15/2024 — brought professional-use HIV IVDs under sanitary registration, alongside D.Ex. 41/2022 (ISP ANDIM).
- D.Ex. 5/2025 — brought immunohematology reagents under registration, in force 21 February 2026 (ISP ANDIM).
- D.Ex. 25/2026 — extends control to medical devices and IVDs generally. The single largest expansion of Chile's device registration perimeter in the fetched record (ISP ANDIM).
- D.Ex. 31/2026 — brings IVD reagents for microbiological qualification of blood donations under registration (ISP ANDIM).
- Pharmaceutical side. The DS 3/2010 text in force is consolidated to 21 August 2020 (Decreto 54, D.O. 21.08.2020, which rewrote Arts. 49, 51, and 52), with earlier amendments by Decreto 50 (D.O. 20.12.2019) and Decreto 65 (D.O. 27.03.2014); no 2023–2026 amendment to DS 3/2010 appears in the fetched consolidated text (DS 3/2010; WIPO Lex record).
- Regional context. Argentina became the first LATAM regulator to complete the transition to ICH E6(R3) via Disposición 7516/2025, which repealed Disposición 6677/2010 (Art. 7) effective 1 December 2025 (Boletín Oficial). Chile has not published an equivalent measure; DS 3/2010 remains the operative framework.
- ClinRegs. Chile remains absent from ClinRegs, so no consolidated third-party English-language clinical-trial profile exists.

Section I. Amavita library cross-references

- Preclinical Translation Requirements — 9 LATAM Regulators — ISP tiering, no sworn translator, DS 3/2010 Art. 29 No. 10, ISP SDM/001, Resolución Exenta 5161/2016 (protocol + IB in English and Spanish), MINREL optional.
- RFI Anatomy — Six LATAM Regulator Rejections Deconstructed — Chilean excipients-in-English RFI, +30 days; statutory citation to "Art. 92" corrected to Arts. 74 item 5 / 29 No. 10 / 78 in the current version.
- Which Regulators Accept English Dossiers — ISP band: English technical content with Spanish summary.
- Sworn vs Certified Translation for Regulatory Submissions — Chile characterized as notarized / official practice rather than a sworn-translator register.
- INFLESZ Threshold — Spanish ICF Readability Compliance — INFLESZ ≥ 55 for Spanish ICFs.
- Three Bands of LATAM Regulatory Translation.
- Translation QC for Regulatory Dossiers.
- Costly Translation Mistakes in Regulatory Submissions.
- Amendment Cascade — One Protocol Change × 12-Country LATAM Stack.
- Regulatory Language Infrastructure vs Traditional Translation.

- Blog corrections + seventh QC gate rollout — the operative account of the Art. 74 / 29 No. 10 / 78 correction and the Document Currency gate.

FAQ

Does the ISP require a sworn or public translator?

No. Art. 29 No. 10 DS 3/2010 permits legal documents to be submitted in Spanish or translated under the signature of the legal representative, a company-designated professional, or the Technical Director (DS 3/2010). No sworn-translator register is named in the statute.

Can the Investigator's Brochure be filed in English only?

No. Per ISP guidance SDM/001 and Resolución Exenta 5161/2016, the protocol and Investigator's Brochure must be submitted in English and Spanish (Amavita, Preclinical LATAM).

What is the correct statutory citation for the Chilean excipient-language rule?

Art. 74 item 5 (qualitative enumeration of excipients on the Spanish secondary label), read with Art. 29 No. 10 (legal documents in Spanish or officer-signed translation) and Art. 78 (other languages permitted only exceptionally, in addition to Spanish). Not Art. 92 — Art. 92 governs sublotes (DS 3/2010).

When does the six-month registration clock start?

Not at filing. Art. 47 DS 3/2010 ties the six-month procedimiento ordinario clock to payment of the fee, which follows a favourable admissibility ruling under Art. 45 (DS 3/2010).

How long is an ISP research-product authorization valid?

Maximum one year, renewable. Per Art. 111 A of the Código Sanitario as added by Ley 20.850 (Ley 20.850).

Does Chile use a general four-class device classification?

Not historically. As of August 2026, D.Ex. 25/2026 extends registration to medical devices and IVDs generally, converting Chile from a ten-category regime toward a general one (ISP ANDIM). The consolidated technical guidance is still being published.

What is the minimum type size for Chilean pharmaceutical labels?

Arial or a similar rectilinear typeface, minimum 6-point body size, per Art. 77 DS 3/2010 (DS 3/2010) — a constraint that directly limits Spanish text expansion in translated artwork.

Does the ISP report serious ADRs faster than other LATAM regulators?

Chile's Art. 217 DS 3/2010 window — 72 hours for suspected serious ADRs (DS 3/2010) — is on the tight end of the LATAM range. Other cases within 30 days; periodic reporting quarterly under Art. 218(b).

How much extra time does a translation-grounds RFI add at ISP?

Amavita's RFI Anatomy analysis documents +30 days for a Chilean excipient-language RFI. The statutory cure window is 30 días hábiles under Art. 49 DS 3/2010, so a single missed defect can burn the applicant's entire cure window (DS 3/2010).

What role does the Ley Ricarte Soto (Ley 20.850) play in Chilean market access?

It creates a financial-protection system for high-cost diagnostics and treatments under Art. 1, with coverage declared by supreme decree of the Ministers of Health and Hacienda under Art. 5. FONASA guarantees the coverage. It is Chile's principal high-cost-access instrument (Ley 20.850).

About the author

Julio G. Martinez-Clark is CEO of bioaccess®, Latin America's leading medical-device clinical research organization, and founder of Amavita Sciences, the multilingual clinical operations platform. He has led first-in-human trial operations across 12 LATAM jurisdictions and built the seven-gate translation QC pipeline behind Amavita's regulatory language infrastructure.

Version history

This guide is version **1.3.0**, last updated August 22, 2026. Every substantive change to the ISP requirements on this page is recorded below.

v1.3.0 August 22, 2026

- Split the Section D exception list into clinical-trial authorization and market-access / sanitary registration pathways, immediately before the consolidated preclinical instruction table.

- Clarified that device IFU and labelling obligations activate at device registration, not at clinical-trial authorization.

v1.2.0 August 22, 2026

- Added Section D — Preclinical / non-clinical documentation (D.1–D.4), placed between Section C and Category 1: Drugs.
- Consolidated the sworn vs. certified vs. simple translation instruction table.
- Regenerated the downloadable PDF so it matches the on-page text.

v1.1.0 August 11, 2026

- Migrated QC copy from six gates to the seven-gate architecture (adds Document Currency).
- Added FAQ block with structured data and a pre-submission QC checklist download.

v1.0.0 August 4, 2026

- Initial publication of the regulator translation requirements guide.