

Colombia is open to your medicines. Own your market entry.

A US\$6 billion pharmaceutical market growing close to 8% a year, and a regulator (INVIMA) that lets foreign manufacturers hold their own registrations. With 33 years of filings before INVIMA and the SIC, SPI Américas keeps your molecule, your brand and your registration under your control.

US\$6.0B

PROJECTED COLOMBIAN
PHARMACEUTICAL
SALES, 2026¹

~8%

AVERAGE ANNUAL
MARKET GROWTH SINCE
2014¹

US\$388M

PHARMACEUTICAL
EXPORTS IN 2025, 85%
TO LATIN AMERICA¹

US\$1.77B

MEDICAL DEVICE
MARKET 2025, 77%
IMPORTED²

01 THE OPPORTUNITY · COLOMBIA

A growing pharmaceutical market with a hub position in Latin America.

- 1 Sustained demand.** Pharmaceutical sales have grown close to 8% a year since 2014, driven by wider health coverage and an aging population.¹
- 2 A regional export platform.** Over 85% of Colombia's US\$388M in pharmaceutical exports went to Latin American markets in 2025.¹
- 3 A broad life sciences market.** Beyond medicines, a US\$1.77B medical device market (77% imported) heading to US\$2.22B by 2030, plus cosmetics and food, all under INVIMA.²
- 4 A predictable regulator.** Medicines are registered under Decree 677 of 1995, with 5-year renewable registrations, online filing and pharmacovigilance after launch.

THE DECISIVE ADVANTAGE

In Colombia, a foreign manufacturer can be the owner of its INVIMA registration.

You are not forced to hand your sanitary registration to a local distributor or licensee. Hold the title yourself, keep the freedom to appoint or change distributors, and protect the dossier you invested in.

SPI structures the local representation so the registration stays in your name.

02 YOUR PARTNER · SPI AMÉRICAS

One point of contact, from dossier to resolution.

1993

FOUNDED IN
BOGOTÁ

+15,000

PERMITS,
TRADEMARKS
& PATENTS

+120

COUNTRIES
VIA
PARTNERS

1

POINT OF
CONTACT

01 · DIAGNOSE

Free initial assessment

Product category, applicable filing, timeline and fees for your portfolio, before you commit.

02 · REGISTER

INVIMA health registration

Medicine dossiers under Decree 677, amendments and renewals, labeling review and pharmacovigilance. Also devices, cosmetics and food.

03 · PROTECT

Patents, trademarks & data

Patents (PCT) and trademarks (Madrid Protocol) before the SIC, test-data protection for new molecules, defense against infringement.

04 · OPERATE & GROW

Legal base and partners

Company formation, distribution and licensing contracts, compliance, and distributor search for Colombia and the region.

Built for life sciences companies.

A Regulatory Affairs team filing medicines, devices, cosmetics and food before INVIMA, coordinating filings across Latin America.

Medicines · Devices · Cosmetics · Food

5-year renewable registration

Pharmacovigilance

+120 countries

"Above all, their deep knowledge of INVIMA procedures. Second, their high level of organization and attention to detail."

HEALTH SCIENCES CLIENT · PERU

Considering Colombia or Latin America?

Send us your portfolio, your brand or your plan. We'll tell you which filing applies, how long it takes and what it costs. The first conversation is free.

spiamericas.com/en

Bogotá, Colombia

linkedin.com/company/spiamericas

¹ ProColombia, "Mercado farmacéutico colombiano abre espacio para nueva inversión extranjera" (17 Mar 2026), citing DANE and Fitch Solutions/BMI. ² ProColombia, "Dispositivos médicos: Colombia tiene mercado y espacio para nueva inversión extranjera" (6 Oct 2026), citing sector analysis and DANE. Market values include estimates and forecasts.