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HRS RESILIENCE FOUNDATION

SECTOR READINESS ASSESSMENT 08

Pharmaceutical & Medical Supply Chains

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About this series. The Western Hemisphere Readiness Series is HRS Resilience Foundation's ongoing program of independent, sector-level research on critical infrastructure and strategic resilience across the Americas. Each Sector Readiness Assessment applies the HRS Readiness Cycle and the HRS Strategic Dependency Test to a distinct sector. This edition addresses pharmaceutical and medical supply chains.

EXECUTIVE SUMMARY

Pharmaceutical & Medical Supply Chains

Medicines and medical supplies are not only healthcare commodities. They are industrial systems whose continuity depends on manufacturing capacity, active pharmaceutical ingredients (APIs), key starting materials (KSMs), specialized equipment, packaging, quality systems, energy, water, transport, cold chain, data, and skilled labor.

The strategic vulnerability of a pharmaceutical supply chain is not defined simply by whether a country imports medicines. It is defined by whether critical products and their inputs remain available, replaceable, traceable, and recoverable when a supplier, production site, transport corridor, energy system, regulatory pathway, or external market is disrupted.

The United States has treated pharmaceutical supply-chain resilience as a national security and industrial-capacity matter. Recent federal actions have sought to accelerate domestic pharmaceutical manufacturing, replenish strategic ingredient reserves, and address import dependence for critical medicines. At the same time, the Western Hemisphere is developing additional regional capability: regional manufacturers' share of pooled vaccine procurement through PAHO's Regional Revolving Fund grew substantially between 2020 and 2025, and more than thirty manufacturing facilities across seven countries now participate in the regional vaccine value chain. [1-5][12]

HRS does not recommend autarky. This assessment recommends a resilient supply architecture: domestic capacity where critical, regional production where efficient and substitutable, diversified external sourcing where necessary, strategic reserves for selected products and inputs, and infrastructure capable of maintaining continuity during disruption.

CENTRAL FINDING

Pharmaceutical resilience must be measured at the system level. A country can have several suppliers of a medicine and still remain vulnerable if those suppliers depend on the same API, key starting material, packaging component, sterilization technology, manufacturing equipment, energy source, or logistics corridor.

SECTION 01

Strategic Context

The pharmaceutical and medical supply chain has become a strategic industrial system in its own right. The COVID-19 pandemic exposed weaknesses in concentrated manufacturing, transport bottlenecks, shortages of critical inputs, and limited visibility below the level of the final supplier. [16]

Recent U.S. federal policy reflects a shift toward manufacturing depth, supply visibility, and substitution capacity as strategic assets. This includes measures directing domestic manufacturing of critical medicines and components, replenishment of a strategic active pharmaceutical ingredients reserve, and adjustments to pharmaceutical import policy. Regulatory bodies have reported a multi-year decline in new drug shortages alongside a growing number of prevented potential shortages, and have introduced expedited review pathways intended to reduce barriers to new domestic pharmaceutical manufacturing facilities. [1-5]

These developments do not eliminate exposure. They demonstrate a sustained policy direction — consistent across recent administrations in its broad emphasis on supply-chain security, even where specific tools and priorities have varied — toward treating medical-supply resilience as an element of national preparedness rather than a purely commercial matter. HRS approaches this direction descriptively, as a feature of the current U.S. policy environment, without adopting a position on the merits of any specific administration's program.

SECTION 02

The Pharmaceutical and Medical Supply Chain as Critical Infrastructure

A conventional analysis often begins with the finished product. HRS begins earlier. The relevant unit of analysis is the full chain of capabilities required to manufacture, qualify, distribute, and replace a critical medical product.

LAYER	EXAMPLES	READINESS QUESTION
Inputs	KSMs, APIs, excipients, reagents, resins, glass, polymers	Can critical inputs be replaced or sourced from multiple qualified origins?
Manufacturing	Finished dosage forms, sterile injectables, biologics, vaccines, devices	Is there sufficient qualified capacity and surge capability?
Quality / regulation	GMP, testing, certification, registration, traceability	Can products remain legally and technically deployable during disruption?
Packaging / components	Vials, stoppers, syringes, filters, labels, electronics	Can a bottleneck outside the medicine itself stop production?
Logistics	Ports, air cargo, roads, cold chain, warehousing	Can products reach users if a primary route fails?
Data	Inventory, batch, demand, supplier, and shortage information	Can decision-makers see the system early enough to act?

HRS principle: the weakest non-substitutable node determines the resilience of the entire system.

SECTION 03

HRS Analytical Framework

This assessment applies the HRS Readiness Cycle used across the Western Hemisphere Readiness Series — Baseline, Exposure, Dependency, Continuity, Recovery, and Adaptation — together with the HRS Strategic Dependency Test, HRS's own proprietary methodology for evaluating criticality, concentration, substitutability, recovery time, infrastructure dependence, and regulatory friction.

HRS FUNCTION	CORE QUESTION	ILLUSTRATIVE APPLICATION
Baseline	What exists today?	Manufacturing sites, products, suppliers, reserves, logistics, and regulatory capacity
Exposure	What can disrupt it?	Geopolitical disruption, trade restrictions, disasters, energy failure, cyber incidents
Dependency	What cannot easily be replaced?	API/KSM concentration, single-site production, unique packaging or sterilization
Continuity	How does the system keep operating?	Inventory, alternate suppliers, routes, reserve capacity, emergency procurement
Recovery	How quickly can capability return?	Restart, qualification, regulatory clearance, workforce and equipment recovery
Adaptation	How does the system improve?	New technology, regional capacity, supplier diversification, reserve redesign

A nominal second supplier does not, under this framework, count as effective redundancy if both suppliers depend on the same upstream node.

SECTION 04

Global Supply Architecture and Strategic Dependencies

Pharmaceutical production is geographically distributed, but dependency is not uniform. Finished medicines may be manufactured in one country while APIs, KSMs, excipients, packaging components, specialized machinery, or testing inputs originate elsewhere. Public federal reporting has indicated that only a modest share of APIs by volume for U.S. prescription drugs are domestically manufactured, though estimates vary depending on the product population measured; HRS treats country of final manufacture as an insufficient resilience indicator on its own and maps dependency upstream instead. [7]

DEPENDENCY	STRATEGIC ISSUE	RESILIENCE RESPONSE
APIs / KSMs	Upstream concentration can affect multiple finished products	Multiple qualified sources, regional capacity, strategic reserves
Sterile manufacturing	Qualification and quality requirements can slow substitution	Redundant sites and validated surge capacity
Vaccines / biologics	Specialized facilities, cold chain, and technical inputs	Regional nodes, platform technology, reserve capacity
Medical devices	Components, electronics, polymers, and sterilization can bottleneck supply	Component mapping, alternate suppliers, repair capacity
Logistics	Transport disruption can convert production into non-delivery	Alternative corridors and distributed stock points

SECTION 05

The Western Hemisphere Supply Landscape

The Western Hemisphere is a network of national health systems, manufacturing clusters, research institutions, ports, trade corridors, procurement mechanisms, and regulatory regimes with different strengths and vulnerabilities. HRS classifies country roles descriptively, in two tiers, to reflect differences in existing manufacturing depth and market scale rather than to rank national importance. Each country retains full sovereign authority over its own health, regulatory, and procurement policy; HRS's classification is an analytical convenience only.

TIER	COUNTRIES	ANALYTICAL ROLE
Tier 1	United States, Canada, Mexico, Brazil, Argentina	Largest combined manufacturing base, R&D capacity, and market scale in the hemisphere
Tier 2	Chile, Peru, Colombia, Paraguay, Uruguay, Guyana	Specialized manufacturing, growing regional markets, and strategic logistics corridors; country-specific mapping required
Central America / Caribbean	Full sub-region	High exposure to imported supplies in most markets; principal value lies in regional stock points and logistics continuity

Country and regional nodes

NODE	ANALYTICAL ROLE
United States	R&D, regulation, advanced manufacturing, medical countermeasures, devices, and financing capacity
Canada	Research, manufacturing, and North American supply-network integration
Mexico	North American manufacturing integration, devices, pharmaceuticals, and logistics
Brazil	Large health market, pharmaceutical and biotechnology base, public production institutions, and vaccine capability
Argentina	Pharmaceutical manufacturing, biotechnology, and emerging vaccine and mRNA capability
Chile / Peru / Colombia	Regional markets, specialized manufacturing, and strategic logistics corridors
Paraguay / Uruguay / Guyana	Smaller markets with growing logistics, trade-corridor, and emerging-resource relevance to regional supply continuity
Central America / Caribbean	High import exposure; value of regional stock points and logistics continuity

Pooled regional procurement mechanisms — most notably PAHO's Regional Revolving Funds — demonstrate that demand planning and regional manufacturing can strengthen supply security without requiring every country to [9][10]

manufacture every product, and can coexist with each participating country's national procurement and regulatory authority.

SECTION 06

Regional Manufacturing and Capability Nodes

The relevant strategic question is not whether Latin America and the Caribbean can reproduce the full pharmaceutical industry. It is where additional regional capacity can most effectively reduce critical dependencies and improve substitution options. Regional reporting indicates continued movement toward greater vaccine manufacturing capability, including new mRNA infrastructure and increasing participation of regional producers in pooled procurement, with Brazil identified as a significant platform for regional supply development. ^[12]

PRIORITY CAPABILITY	STRATEGIC VALUE
Essential medicines / generics	Reduce exposure to concentrated finished-product supply
API and KSM production	Address upstream dependencies affecting multiple products
Vaccines / platform technologies	Create surge capacity and regional options
Sterile injectables	Strengthen a complex category with limited rapid substitution
Diagnostics	Reduce dependence on single external production chains
Medical devices	Develop component, assembly, maintenance, and refurbishment resilience
Cold chain / quality testing	Protect product integrity and make regional manufacturing usable

SECTION 07

Critical Enablers: Energy, Water, Logistics, Data and Workforce

Pharmaceutical plants, hospitals, warehouses, and laboratories depend on reliable electricity, water, transport, telecommunications, cybersecurity, and skilled technical labor to function. A plant with strong production equipment but fragile power, water, or logistics remains strategically exposed regardless of its manufacturing sophistication. This is a direct cross-sector linkage to the HRS assessments on energy, ports and logistics, and food systems (see Section 12).

ENABLER	FAILURE MODE	READINESS MEASURE
Energy	Production, refrigeration, or data systems fail	Backup duration and recovery time
Water	Required-quality water unavailable	Source diversity and treatment redundancy
Logistics	Ports, airports, roads, or customs delay supply	Alternative routes and stock-point coverage
Cold chain	Temperature excursion damages products	Validated control, backup power, and response
Data / cyber	Inventory or supplier visibility is lost	Integrity, portability, and cyber recovery
Workforce	Specialists unavailable	Cross-training and replacement time

SECTION 08

Resilience Architecture for the Western Hemisphere

HRS proposes a Western Hemisphere Medical Supply Resilience Architecture built around six capabilities. The architecture is modular: countries can strengthen selected layers without creating a centralized system or surrendering national procurement, regulatory, or health-policy authority. No single institutional model is prescribed for all countries; national circumstances differ too widely for a uniform template.

CAPABILITY	PURPOSE
Critical Product Map	Identify essential products and upstream dependencies
Manufacturing Depth	Increase qualified production pathways
Strategic Reserves	Bridge temporary disruption
Logistics Redundancy	Maintain movement when primary corridors fail
Regulatory / Quality Readiness	Ensure substitutes can actually be deployed
Supply Intelligence	Detect and act on emerging shortages early

SECTION 09

Sector Readiness Assessment Matrix

The HRS matrix compares product availability, API/KSM depth, manufacturing capacity, strategic reserves, logistics, regulatory readiness, and data visibility. For each critical product, HRS recommends assessing criticality, concentration, substitutability, recovery time, infrastructure dependence, and regulatory friction. The purpose is to identify where an apparently diversified supply chain still contains a common upstream failure point.

DIMENSION	HIGH	MODERATE	LOW
Product availability	Multiple qualified pathways	Some concentration	High concentration
API / KSM depth	Domestic / diversified	External with alternatives	Concentrated external dependency
Manufacturing	Surge-capable / diversified	Limited redundancy	Single-site exposure
Reserves	Defined, rotated, replenished	Partial coverage	Minimal / poorly maintained
Logistics	Multiple validated corridors	Primary plus partial alternatives	Single corridor
Regulatory readiness	Rapid qualification	Moderate	Substitution delayed
Data visibility	Timely signals	Partial	Fragmented / delayed

SECTION 10

Strategic Outlook: 50-Year and 100-Year Horizons

Consistent with the Foundation's institutional design horizon, this assessment frames its outlook across a 50-year period (2026–2076) and a 100-year period (2026–2126), with 2030, 2050, and 2075 used as intermediate reference points.

REFERENCE	STRATEGIC QUESTION	HRS EMPHASIS
2030	Can immediate bottlenecks be reduced?	Dependency mapping, reserves, manufacturing investment, cold chain, and data
2050 (mid, 50-year horizon)	Has durable manufacturing depth been built?	Regional nodes, advanced manufacturing, resilient energy, and workforce
2075–2126 (100-year horizon)	Can systems adapt to unknown technologies and threats?	Distributed production, adaptable reserves, advanced diagnostics, institutional learning

Advanced manufacturing, continuous processing, digital quality systems, distributed production, and new vaccine platforms may reduce some geographic dependencies while creating new dependencies in software, equipment, data, and technical expertise. The 100-year objective is not to predict which medicines will dominate; it is to build systems capable of changing production faster than strategic vulnerabilities accumulate.

SECTION 11

Implications for the United States

Western Hemisphere medical-supply resilience can support U.S. national health security, industrial capacity, supply-chain security, exporter opportunities, crisis response, strategic access, technology leadership, and private investment. This assessment is descriptively relevant to the current U.S. supply-chain security policy environment, which has identified concentration, sole-source exposure, and over-reliance on a single external source as supply-chain risks; HRS applies the same analytical logic to medical inputs while keeping each country's sovereign procurement and regulatory authority intact. [4][8]

DEPARTMENT / AGENCY	POTENTIAL INTEREST
Department of State	Regional health-security diplomacy and coordination with partner governments
Department of Defense	Medical logistics resilience and continuity relevant to force health protection and regional partner capacity
Department of Health and Human Services (ASPR, FDA)	Domestic and allied manufacturing capacity, strategic reserves, drug-shortage prevention, and regulatory pathway efficiency
Centers for Disease Control and Prevention	Outbreak preparedness, diagnostics capacity, and regional public-health surveillance relevant to medical-supply continuity
Other federal functions	Trade, export-control, and development-finance functions relevant to regional manufacturing investment

SECTION 12

Cross-Series Linkage

This assessment connects directly to prior Sector Readiness Assessments in the series. Energy security (Sector Readiness Assessment 05) underlies the power reliability required for pharmaceutical manufacturing and cold chain. Ports, logistics, and maritime infrastructure (Sector Readiness Assessment 06) determine whether medical products and their inputs can physically reach manufacturing sites and end users. Food security and agricultural resilience (Sector Readiness Assessment 07) shares many of the same regional logistics corridors, cold-chain infrastructure, and dependency-mapping methodology applied here. Readers assessing hemispheric resilience comprehensively are encouraged to consider these assessments together.

SECTION 13

HRS Research Priorities and Decision Framework

Next-stage HRS research should move from sector-wide architecture to country- and product-level evidence. Interventions should advance only when criticality, measurable dependency, credible resilience benefit, legal and regulatory feasibility, and financial and operational sustainability are demonstrated.

PRIORITY	QUESTION
Critical-product mapping	Which medicines, devices, vaccines, and diagnostics are essential?
Upstream dependency mapping	Which APIs, KSMs, components, and equipment are common bottlenecks?
Manufacturing node analysis	Where does qualified capacity exist, and where are the gaps?
Reserve optimization	Which products or APIs justify reserves?
Regional production	Which capabilities can be developed economically in the hemisphere?
Regulatory substitution	How quickly can an alternative be qualified?
Investment feasibility	Which interventions can achieve durable operations?

SECTION 14

Methodology, Research Integrity and Limitations

This publication applies the HRS Readiness Cycle and the HRS Strategic Dependency Test, both proprietary HRS Resilience Foundation methodologies developed across the Western Hemisphere Readiness Series. It is a sector-level assessment and does not substitute for national pharmaceutical, medical-device, regulatory, engineering, financial, or security due diligence.

Priority is given to official U.S. Government sources, PAHO/WHO technical sources, national government sources, and established technical institutions and research organizations. Country-level manufacturing capacity, API origin, inventory levels, commercial contracts, and supplier ownership can change rapidly; this document therefore does not assign definitive country readiness scores and does not make procurement or investment recommendations for specific companies.

Originality statement. This assessment reflects original analysis and synthesis by HRS Resilience Foundation; source material has been paraphrased and integrated into the HRS framework rather than reproduced.

SECTION 15

Conclusion

Pharmaceutical and medical supply chains are strategic systems. Their resilience depends on whether the underlying industrial and infrastructure network can continue to manufacture, qualify, move, monitor, and replace critical products under stress.

The Western Hemisphere has major advantages: a large combined market, advanced research institutions, established pharmaceutical and medical-device industries, extensive logistics networks, and emerging regional vaccine and biotechnology capabilities. It also has uneven manufacturing depth and upstream dependencies.

HRS PROPOSITION

Strategic optionality — more than one viable pathway for critical products and inputs, with reserves and infrastructure capable of bridging disruptions while production recovers. Medical security is strongest when critical health capabilities are distributed across a resilient system rather than concentrated in a fragile chain.

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Independent research for institutional readiness, continuity, and 50-year resilience planning across the Western Hemisphere. The Western Hemisphere Readiness Series applies the HRS Readiness Cycle to critical sectors, translating public-source evidence into practical frameworks built to remain valid for governments, infrastructure operators, investors, and institutional decision-makers across changes in technology, suppliers, and political leadership.

SERIES TO DATE

SRA 01 — Telecommunications & Digital Infrastructure

SRA 02 — Data Centers, Cloud & AI Infrastructure

SRA 03 — Critical Minerals & Strategic Materials

SRA 04 — Rare Earths & Western Hemisphere Mineral Security

SRA 05 — Energy Security & Strategic Power Infrastructure

SRA 06 — Ports, Logistics & Maritime Infrastructure

SRA 07 — Food Security & Strategic Agricultural Resilience

SRA 08 — Pharmaceutical & Medical Supply Chains

SRA 09 — Advanced Manufacturing & Industrial Capacity

SRA 10 — Western Hemisphere Strategic Infrastructure & Resilience

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