Guy Savoir â?? CEO, Carnot Laboratories

With an efficient, transparent, well-funded COFEPRIS, the primary market access barriers become solvable.

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Guy Savoir, CEO at Carnot Laboratorios, brings strategic vision to Mexicoâ??s pharmaceutical reindustrialisation. Leading a company that has achieved balanced growth across Mexican and Latin American markets, he articulates an ambitious vision for North American pharmaceutical integration whilst navigating complex regulatory environments. Under his leadership, Carnot has committed 150 million USD to expanding manufacturing capabilities in QuerÃ©taro, positioning Mexico as a strategic partner in regional pharmaceutical supply chain resilience.

As you assess the Latin American pharmaceutical landscape, which structural trends are most decisively reshaping the industry, particularly in Mexico?

The predominant underlying trend is the integration of North America as a unified, robust pharmaceutical supply hub. We are witnessing the US government actively and seriously pursuing supply chain de-risking from China and India, seeking reliable partners capable of fulfilling this supply requirement.

Mexico increasingly emerges as that reliable partner. Authorities on both sides â?? Mexican and American â?? are identifying this strategic opportunity and advancing it aggressively. This partially explains Plan Mexico and the substantial investments we have observed. It also informs the USMCA renegotiation dynamics. This represents the fundamental situation currently unfolding.

Mexico unquestionably occupies a privileged position to support the US in this endeavour. Specifically regarding finished dosage forms, we possess high capacity and sophisticated capabilities â?? approximately 140 facilities already FDA-approved, with perhaps a similar number that could achieve approval in the near future.

Regarding active pharmaceutical ingredients, we naturally discuss considerably lower current capacity on both sides. However, once finished dosage form exports from Mexico to the US increase substantially, API demand will correspondingly expand to support that necessity. Mexico currently maintains approximately a dozen FDA-approved API facilities, with another dozen potentially achievable. Obviously, supplying requisite volumes would necessitate scale-up investments, though the industry demonstrates a willingness to execute such investments.

Finally, genuine de-risking requires addressing key starting materials. Candidly, both the US and Mexico face significant disadvantages relative to Asian suppliers in this domain, necessitating a long-term developmental process. However, once APIs achieve local manufacturing scale, market incentives for KSM local production naturally emerge.

Regarding API production, can competitive positioning truly be achieved against the pricing and volume advantages India and China possess?

We must address pricing considerations separately from volume capacity. Price competitiveness requires market incentives â?? specifically, differentiated tariff structures favouring North American products over Indian and Chinese alternatives. This represents a critical element within the USMCA renegotiation. Without this tariff architecture, subsequent considerations become essentially irrelevant.

Regarding volume, we cannot immediately address high-volume, high-criticality products. We must commence with high-criticality, medium-volume products, subsequently progressing to high-criticality, high-volume products as we execute scale-up investments.

However, pricing is not the sole challenge. We must address multiple interconnected elements systematically. We require intelligent rules of origin that incentivise local manufacturing. We need alignment of government procurement, favouring regionally manufactured products â?? encompassing Mexican public tenders alongside Medicare, Medicaid, and Affordable Care Act programmes.

Additionally, we require harmonised regulatory and intellectual property environments enabling accelerated, efficient product development and registration regionally, whilst simultaneously facilitating harmonised coexistence of generic and innovative products.

From your perspective, what represents the single most critical institutional and political risk requiring mitigation to ensure long-term sustainability?

As mentioned, numerous prerequisites require fulfilment, with harmonisation proving paramount. For us, COFEPRIS represents the most critical institution. It must demonstrate efficiency, transparency, and adequate funding â?? the latter proving particularly important.

With an efficient, transparent, well-funded COFEPRIS, the primary market access barriers â?? affecting both domestic companies and American enterprises seeking Mexican market entry â??

become solvable.

What level of resourcing would, in your view, constitute adequate funding for COFEPRIS?

The solution proves remarkably straightforward. COFEPRIS receives funding through industry-paid fees â?? derechos in Spanish. Currently, these fees flow initially to the Treasury, with only a budgetary portion subsequently allocated back to COFEPRIS.

The industry demonstrates willingness to pay substantially more for enhanced COFEPRIS efficiency. However, we require assurance that incremental payments either remain with or return untouched to COFEPRIS, enabling full budgetary capacity for personnel recruitment, electronic systems development, and internal quality systems establishment. This funding would facilitate the harmonisation we believe essential, delivered within timeframes the market will require, should we proceed with US integration, forming a unified economic region for pharmaceutical supply chains.

As an industry, we wish to contribute more, provided these funds reach their intended destination. I believe the Ministry of Health demonstrates responsibility in not requesting excessive funding. However, regarding this specific aspect, we could pursue more aggressive COFEPRIS funding requests. I firmly believe such investments would generate immediate returns through additional taxes, increased â??derechosâ?•, and accelerated pharmaceutical industrial growth.

Medicine supply shortages frequently dominate Mexican headlines. Beyond sensationalist coverage, what substantive reality can you articulate for international readers?

Mexico has fundamentally reinvented its supply system over the past six years. This instability and inadequate planning have demonstrably produced negative outcomes regarding patient product availability, manifested through elevated drug prices, reduced unit availability, and diminished fill rates.

I believe the government possesses genuine intentions to establish an effective system. However, such systems cannot materialise overnight. Mexico must select a system, maintain commitment to that system, and evolve within that framework, progressively perfecting requisite elements to generate data enabling supply planning and demand forecasting.

Subsequently, we require distribution mechanisms appropriate for an extremely fragmented distribution network encompassing thousands of utilisation points and points of sale. This necessitates selecting the optimal model and maintaining consistency, understanding that several years prove necessary before the system matures and accumulates sufficient information to deliver highly effective supply.

Despite this volatility, the Mexican pharmaceutical industry appears to maintain a growth trajectory. How would you characterise recent performance?

We must differentiate between historical performance, current conditions, and future projections. Historically, the health industry generally and pharmaceuticals specifically demonstrated growth â?? unit growth, value growth. The national industry particularly experienced growth along primary care lines, whilst multinationals achieved growth in speciality care segments.

The extent to which COVID-19 and post-pandemic dynamics influenced this growth remains subject to analysis. However, we currently observe adjustments. This yearâ??s market demonstrates significantly greater stagnation compared to previous years, particularly in Mexico versus other Latin American countries. The private market appears substantially flatter than its regional counterparts.

Should we achieve North American integration, this dynamic would transform overnight â?? growth would prove enormous. However, this remains speculative.

Should North American integration progress, what implementation timeline strikes you as realistic?

This represents a 10-plus-year initiative â?? certainly not an overnight transformation. Pharmaceutical plant construction requires three years. Nothing in this industry occurs rapidly.

However, achieving a robust supply necessitates immediate commencement. I envision this as potentially a 10-to-20-year programme, analogous to the automotive industry transformation we witnessed during the 1990s, where supply chains developed cross-border configurations â?? components supplied by one nation, manufactured by another, assembled by a third, with consumption distributed across all three countries. This represents our aspirational model.

Given Brazilâ??s scale and regulatory complexity, how challenging is it for Mexican companies to gain meaningful market entry?

A Brazilian saying asserts, â??Brazil is not for beginners.â?• I believe Brazilians reciprocate, suggesting Mexico proves equally challenging for newcomers.

Brazil presents considerable complexities: divergent state-level legislation, bureaucratic intricacy, and labour law complications. Operating there proves challenging by any measure. However, the market possesses sufficient scale and potential to justify the requisite efforts and investments.

Beyond additional manufacturing capacity, what broader strategic intent underpins Carnotâ??s 150-million-dollar investment in QuerÃ©taro?

This represents a commitment to continued internationalisation. We are constructing a facility complying with every regulatory requirement, enabling exports â?? initially to our core markets throughout Latin America: Brazil, Colombia, Peru, Argentina.

Secondly, this facility will possess the capability for US and European exports. We envision this plant catalysing our sustained international growth as an organisation.

For Mexico nationally, this signals industry commitment to function as a strategic partner in pharmaceutical supply. Whilst we initially contemplate US supply â?? though this remains uncertain â?? the facility nonetheless positions us for global market access.

What structural foundations are required to establish a sustainable vaccine-manufacturing ecosystem in Mexico?

This represents a significant challenge for organisations pursuing local vaccine manufacturing. Should Mexico genuinely aspire to domestic vaccine manufacturing capability, it must establish positive incentives, reducing manufacturer and developer risk.

To become a vaccine manufacturing nation, we must prioritise locally manufactured vaccines in public procurement. Vaccines predominantly involve public purchase. We cannot rely exclusively on cost-competitive tender-by-tender procurement, as investment risk becomes prohibitively high without procurement visibility.

How does Carnotâ??s vaccine capability interface with regional mRNA initiatives supported by PAHO, and what distinct role could Mexico assume within Latin Americaâ??s evolving vaccine landscape?

We currently maintain a vaccine portfolio under COFEPRIS registration, positioning ourselves as suppliers to improve timeliness, cost-effectiveness, and local vaccine availability.

We must determine our path forward with our COVID-19 vaccine â?? a viral vector platform. We would enthusiastically make requisite investments to advance this project, provided we achieve market visibility regarding government procurement. Unfortunately, we currently experience difficulty precisely because government COVID-19 vaccine procurement clarity remains absent.

We are additionally developing pertussis, pneumococcal, and influenza vaccines, with several others in our pipeline. We believe this portfolio should enable meaningful supply contribution.

With Carnot aiming to double patient reach by 2030, which internal constraints pose the greatest challenge to sustaining momentum?

We have achieved very significant growth, particularly regarding gastroenterology products, with our gastrointestinal antispasmodic and Acid blocker both continuing exceptional expansion. Both now rank amongst the 20 largest-selling products in Mexico â?? a tremendously satisfying achievement requiring continued momentum.

To sustain growth, we must continue introducing products that deliver substantial benefits to patients and physicians. This necessitates significant research, development, and clinical trial investment to bring these innovations to market.

What clinical development activities is Carnot currently pursuing, and how do these position the company within the regionâ??s evolving R&D landscape?

We conduct clinical trial development spanning Phase I, Phase II, Phase III, and selected Phase IV studies. Currently, we emphasise Phase IV trials, strengthening the regulatory robustness of our gastrointestinal antispasmodic and Acid blocker dossiers, enabling expanded indications and market access.

We perform Phase IV trials for our innovative central nervous system products. We conduct Phase II and Phase III trials for our novel cardiovascular line, anticipating the launch of an innovative product with an exceptionally positive market profile. We expect our next growth wave to emerge from the cardiovascular therapeutic class, supported by an innovative peptide under development.

Industry leaders increasingly emphasise ecosystem collaboration. How would you describe the current state of collaboration among Mexican pharmaceutical stakeholders?

Currently, we observe something unprecedented in recent Mexican pharmaceutical history â?? certainly unprecedented during my 20-year industry tenure: exceptionally unified industry alignment.

We collectively identify identical opportunities and unmet needs, believing collaborative effort generates substantially more robust industry outcomes. Industry chambers â?? AMIF, ANAFAM, CANIFARMA â?? collaborate in establishing prerequisites for internal structural changes enabling Mexico to respond effectively to market demands.

This unquestionably represents the moment for collaboration between the national and multinational industries. Simultaneously, we observe significant contributions from National Health Institutes, academia, and universities. We are definitely constructing an essential ecosystem.

Some executives argue that the Ministry of Finance should play a more direct role in pharmaceutical access discussions. How do you view this proposal?

This relates to funding system considerations we discussed earlier. Mexican public health funding represents 2.7% of GDP, whilst the WHO recommends 6%. This gap requires closure.

We recognise that immediately allocating an additional 3.3% of GDP to health proves unrealistic. However, we require a programme establishing systematic funding growth over time. Including the Finance Ministry â?? Treasury or revenue authority â?? would prove beneficial in this context.

For organisations entering Latin America and confronting the operational complexities of Mexico or Brazil, what guidance would you offer?

Mexico and Brazil both offer excellent partnerships, with the broader region maintaining strong collaborative partners. Companies such as Carnot, possessing regional reach, can serve as ideal partners for organisations seeking Latin American market access without enduring the difficult learning curve or making substantial local presence investments.

This represents a highly efficient market entry strategy. You can partner with established major players, achieve immediate market access, and, by selecting appropriate partners, secure market leadership positioning for your products within relatively compressed timeframes.

You previously noted a roughly even split between Mexican and Latin American volumes. Does this distribution remain consistent today?

Yes, both markets continue growing at approximately equivalent rates. We consistently desire slightly accelerated international growth, as we aspire toward market-representative positioning everywhere we operate.

However, Mexico has fortunately achieved substantial growth as well. This represents a fortunate challenge â?? both international and Mexican markets are demonstrating significant expansion for

Carnot.

Which strategic levers will be most important for maintaining â?? and accelerating â?? Carnotâ??s growth trajectory?

Returning to earlier discussion: innovation proves paramount. Introducing new products addressing unmet patient and physician needs drives growth. These products will generate future expansion.

International market consolidation provides additional growth, specifically consolidation in Brazil, Colombia, and Peru, representing our largest international priorities. Finally, we pursue new markets outside Latin America, which should initially contribute modest but important seed growth for future development.

Biosimilars face well-known barriers to entry. How is Carnot positioning itself to overcome these challenges?

Biosimilars, unfortunately, continue confronting significant entry barriers. Let me describe our approach.

We launched a new company called CSC â?? Carnot Stein Cares â?? a joint venture between Carnot and Stein. This new enterprise focuses on bringing access to high-complexity and high-speciality products, including biosimilar and bioinnovatives, to the Mexican market.

We currently maintain an exceptionally strong portfolio of innovative and biosimilar products under Mexican registration. Within the next four years, we will launch between nine and 14 products â?? an evidently ambitious goal representing a substantial product volume.

The challenges naturally involve COFEPRIS efficiency and IMPI effectiveness in enabling timely product introduction locally.

As we conclude, what final messages would you emphasise for our readership?

I would emphasise two critical messages. For US readers: we possess a tremendously significant regional opportunity to become a pharmaceutical and health supply powerhouse. However, this will not materialise without regional coordination. We must collaborate, leverage respective strengths, and determine optimal arrangements â?? for instance, how Mexico can optimally supply the US with generics and APIs, how the US can optimally supply Mexico with patented and innovative products, and how COFEPRIS and the FDA can collaborate effectively.

The opportunity exists for our region to become the global centre for health manufacturing. This message requires collective advancement from both sides.

For a broader readership: The Latin American market proves exceptionally interesting and dynamic. I invite organisations with products seeking market entry to engage with us. Should they desire a partner with a distinguished track record and demonstrated reliability, we stand prepared to collaborate.

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