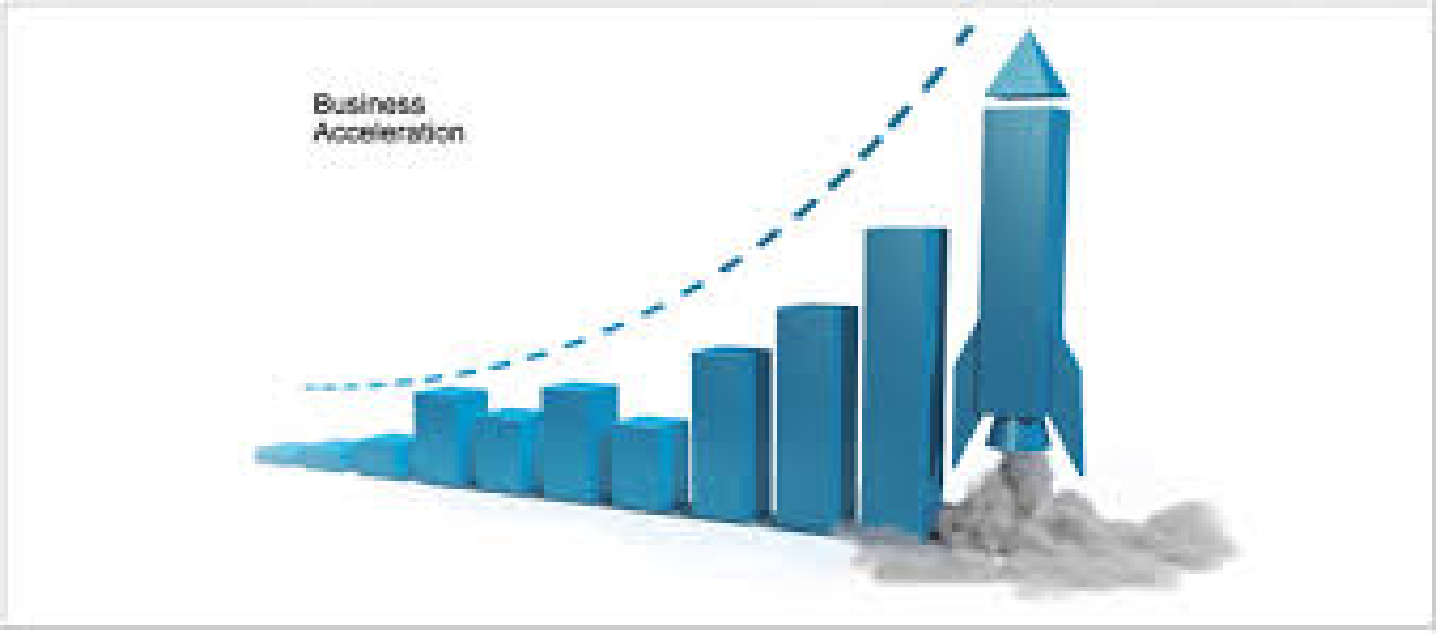
Emerging Pharma Accelerator: The 6-Step GTM Methodology.

A high-stakes framework for SEA & LATAM markets.



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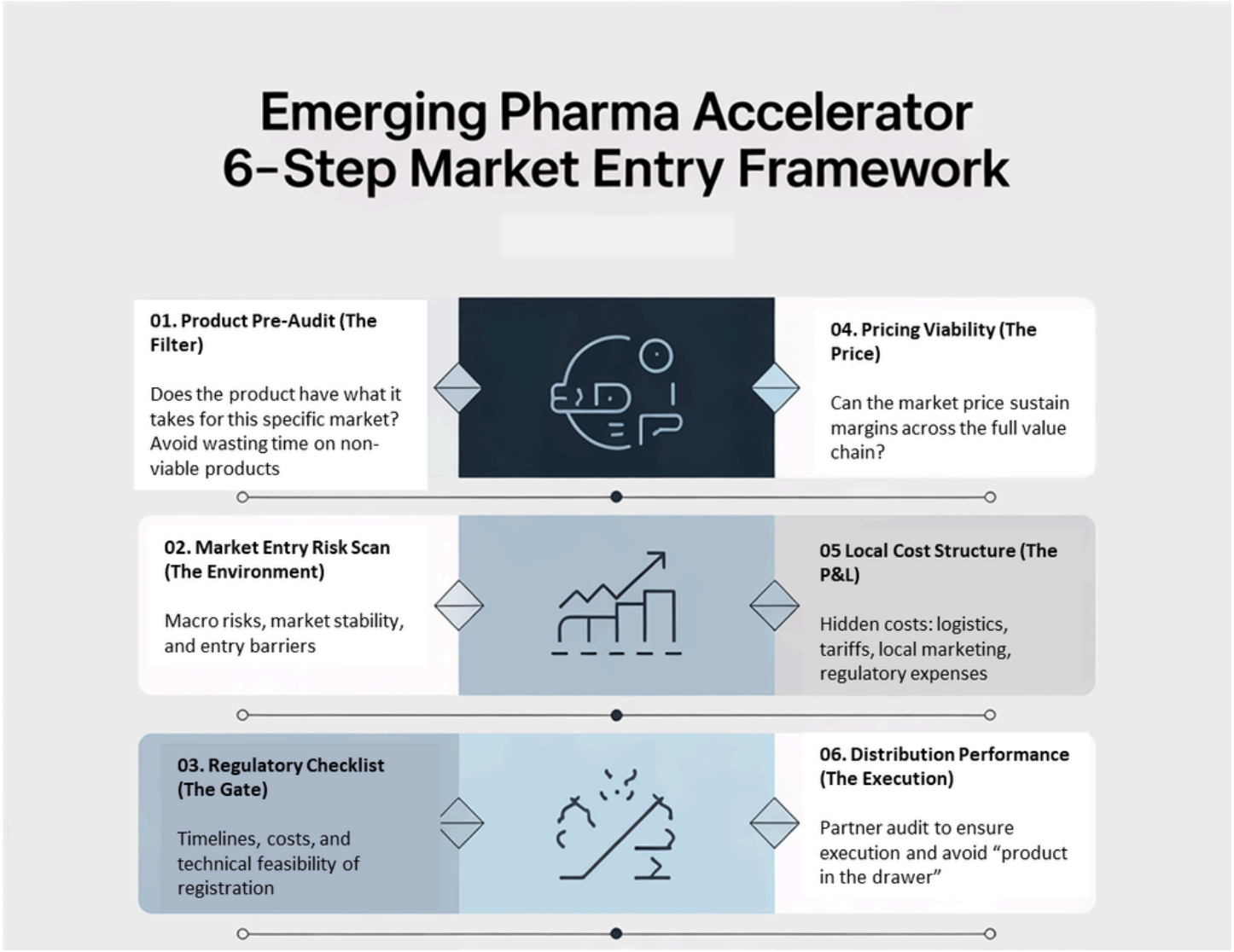
Emergpharma

Methodology



About the author

Twenty years of mistakes and successes

ose Ignacio Diaz is a pharmaceutical business development professional with more than 20 years of hands-on experience working across emerging markets — learning through a combination of hard-earned successes and costly mistakes.

His career has been built in the field, not in theory: launching products that worked, backing projects that didn't, selecting the right partners — and sometimes the wrong ones. These experiences, accumulated over time and under pressure, led him to develop a structured and highly practical approach to market entry and execution, focused on avoiding the most common and expensive pitfalls.

Rather than relying on conventional frameworks, his approach is grounded in real decisions: what to prioritize, what to reject early, and how to maintain control once a product is in the market.

He is the founder of Emergpharma, a platform dedicated to supporting pharmaceutical and nutraceutical companies in navigating complex markets through partner selection, local execution, and strategic coordination. Through this work, he has helped bridge the gap between global ambition and local reality.

His work reflects a simple principle: in emerging markets, success is rarely about the opportunity itself — but about how well execution is managed from day one.

Consultant Note

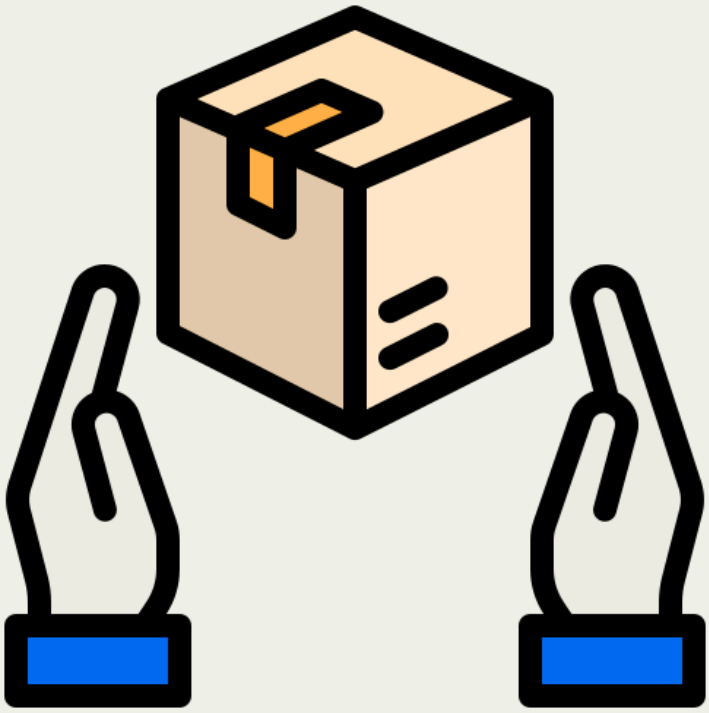
This 6-step GTM methodology is not intended to add complexity, but to eliminate unnecessary risk. Each step reflects a recurring failure point observed across multiple market entries — often underestimated at the decision stage and difficult to correct once execution begins.

Applied rigorously, it allows teams to challenge assumptions early, prioritize effectively, and maintain control throughout the process. Skipping steps does not accelerate execution — it simply shifts risk downstream, where the cost of correction is significantly higher.

The objective is not perfection, but clarity: knowing when to move forward, when to adapt, and when to stop.

Product Pre-Audit Checklist

18 Questions That Prevent Most Failed Product Launches in Emerging Markets



A practical screening tool for

BD, Licensing & Export Teams

How to Use This Checklist

Before searching for distributors, evaluate whether your **product is realistically exportable**.

Each question should be answered with **real data**, not assumptions.

Score each question:

2 = Clear evidence
1 = Partial answer
0 = Unknown / high uncertainty

Maximum score: **36**

1. Regulatory Reality

Can the product **actually be registered** in the target market?

Checklist:

□ Are all **ingredients recognised** in the local pharmacopeia or regulatory lists?

□ Are vitamin / mineral levels / aminoacid **within local maximum limits** (if applicable)?

□ Is there any of the formula's compound included in a banned list?

□ Are **stability studies compatible with the climatic zone**?

□ In case of generics, has the original product been registered in the market?

□ Will authorities accept **existing clinical / bioequivalence data**?

□ Are the **claims and indications acceptable** under local regulations?

□ Does the product require **local studies or additional dossiers**?

If more than two answers are uncertain → **regulatory risk is high**

2. Market Opportunity

Even if registration is possible, **is the market big enough?**

Checklist:

□ Is the **target therapeutic segment** large enough?

□ Is the category **growing or stagnating**?

□ Does the product offer **clear differentiation** vs existing brands?

□ Can the expected demand **absorb at least one MoQ**?

□ Does the expected price fit the **local price corridor**?

□ Is the accessible market size **worth the regulatory effort**?

Many products get registered but **never reach meaningful sales**.

3. Distributor Attractiveness

Will strong distributors **actually want this product?**

Checklist:

□ Can distributors achieve **acceptable margins**?

□ Does the product fit within their **current portfolio strategy**?

□ Is the **promotional effort realistic**?

□ How long until the distributor can **generate revenue**?

□ Is the product **easy to explain and sell** to physicians or pharmacists?

□ Would the product be among their **top 5 priorities**?

If the opportunity is weak, **top distributors simply walk away.**

Quick Scoring Guide

Section	*Max Score*
Regulatory Reality	***12***
Market Opportunity	***12***
Distributor Attractiveness	***12***

Total: 36

Interpretation:

30–36 → Strong candidate for international expansion

22–29 → Adaptation recommended before market entry

<22 → High risk of failed launch

Consultant Note

Most failed product launches in emerging markets do not fail in the market — they fail before entering it. The root cause is rarely the product itself, but the lack of a structured initial filter.

This Product Pre-Audit Checklist is designed to challenge assumptions early, before time and resources are committed. The 18 questions focus on the critical factors that are often overlooked or taken for granted: real differentiation, regulatory fit, pricing logic, and execution feasibility.

In practice, teams tend to push products forward based on global success or internal pressure, rather than local viability. This checklist forces a different discipline: to stop, validate, and, when necessary, reject.

A “no-go” at this stage is not a failure — it is a cost avoided.

MARKET ENTRY RISK SCAN

20 Questions That Prevent

80% of Failed Market Entries

A practical screening tool for

BD, Licensing & Export Teams

HOW TO USE

Evaluate whether a **market entry is realistically viable** before committing resources.

Each question must be answered with **real data, not assumptions**.

Scoring:

- 2 = Clear evidence
- 1 = Partial answer
- 0 = Unknown / high uncertainty

Maximum score: 40

1. REGULATORY & ACCESS REALITY

Can the product realistically enter and remain in the market?

Checklist:

□ Product classification clearly defined (FS / OTC / RX)

□ Registration pathway and timelines confirmed

□ No unexpected local requirements (studies, samples, testing)

□ Claims realistically usable under local regulations

2. PRICING & COMMERCIAL VIABILITY

Is the product financially viable in the market?

Checklist:

□ Price corridor validated vs competitors

□ Distributor margins compatible with market standards

□ No structural pricing barriers (reference pricing, caps)

□ Profitability maintained after all local costs

3. COMPETITIVE LANDSCAPE

Is there real space for the product?

Checklist:

□ Strong local competitors identified and mapped

□ Clear differentiation vs existing products

□ No dominant low-cost generics blocking entry

□ Market not saturated in the target segment

4. PARTNER ACCESS & QUALITY

Can you realistically secure the right partner?

Checklist:

□ Access to relevant distributors confirmed

□ Shortlist includes qualified and proven partners

□ No major portfolio conflicts identified

□ Decision-makers accessible (not blocked by filters)

5. CASH FLOW & EXECUTION RISK

Can the business sustain execution realities?

Checklist:

□ Payment terms aligned with financial capacity

□ Inventory cycles and MoQ manageable

□ Risk of delayed collections understood

□ Time to first revenue acceptable

SCORING TABLE

Section	Max Score
Regulatory & Access	8
Pricing & Viability	8
Competition	8
Partner Access	8
Cash Flow	8

Total: 40

INTERPRETATION BOX

35–40 → Low Risk
Clear pathway, execution feasible

25–34 → Manageable Risk
Proceed with mitigation strategy

<25 → High Risk
Reassess market entry

STRATEGIC RED FLAGS

High Regulatory + High Cash Flow Risk
→ Requires strong financial capacity and long-term commitment

High Partner Risk
→ Execution risk is higher than market risk

High Pricing + High Competition
→ Only viable with strong differentiation or niche strategy

Consultant Note

Market entry failures are rarely the result of a single wrong decision. More often, they stem from a poor understanding of the environment in which the product is expected to operate.

This Market Entry Risk Scan is designed to surface the structural risks that are typically underestimated at the outset: regulatory ambiguity, pricing pressure, partner dependency, and cash flow constraints. The 20 questions focus on identifying these factors early, when they can still be managed — not after commitments have been made.

In many cases, companies move forward based on opportunity size, while ignoring execution complexity. This creates a mismatch between expectations and reality, which ultimately impacts timelines, costs, and outcomes.

The objective of this scan is not to eliminate risk, but to make it visible, quantifiable, and actionable.

REGULATORY & ACCESS FAST-TRACK CHECKLIST

15 Questions to Estimate Real Registration Time & Cost

A practical screening tool for

BD, Regulatory & Export Teams

HOW TO USE

Evaluate the **real regulatory burden** before committing to a market.

Each question must be answered with **validated local data, not assumptions**.

Scoring:

- **2 = Clear evidence**
- **1 = Partial answer**
- **0 = Unknown / high uncertainty**

Maximum score: 30

1. REGULATORY PATHWAY CLARITY

Is the registration route clearly defined?

Checklist:

□ Product classification confirmed (FS / OTC / RX)

□ Registration pathway clearly mapped

□ No ambiguity between categories (e.g. FS vs drug)

□ Precedents exist for similar products

2. TIMELINE REALITY

Are timelines realistic and predictable?

Checklist:

□ Official timelines validated vs real market experience

□ Time to approval (best vs realistic scenario) defined

□ Risk of delays identified (queries, backlog, re-submission)

□ Fast-track or priority pathways available (if applicable)

3. COST STRUCTURE

Is the real cost of registration understood?

Checklist:

□ Official fees confirmed

□ Hidden costs identified (consultants, local agents, translations)

□ Testing / analysis costs included

□ Total cost per dossier realistically estimated

4. LOCAL REQUIREMENTS

Are additional local requirements manageable?

Checklist:

□ Need for local studies (BE, clinical, stability) confirmed

□ Sample requirements and timelines defined

□ GMP / CPP / legalization requirements clear

□ Dossier format and documentation complexity understood

5. ACCESS & POST-REGISTRATION REALITY

Does approval translate into market access?

Checklist:

□ No additional approvals required post-registration

□ Pricing / reimbursement process understood (if applicable)

□ Ability to commercialize immediately after approval

□ No hidden barriers delaying launch (tenders, listings, etc.)

SCORING TABLE

Section	Max Score
Pathway Clarity	8
Timeline Reality	8
Cost Structure	8
Local Requirements	8
Market Access	8

Total: 40

INTERPRETATION BOX

35–40 → Clear & Predictable
Registration is straightforward and manageable

25–34 → Moderate Complexity
Proceed with planning and buffer

<25 → High Regulatory Risk
Time and cost likely underestimated

STRATEGIC RED FLAGS

Unclear Classification
→ High risk of delays or rejection

Local Studies Required (BE / Clinical)
→ Major impact on cost and timelines

Mismatch Between Official and Real Timelines
→ Planning risk and delayed ROI

Approval ≠ Market Access
→ Registration does not guarantee commercialization

Consultant Note

Regulatory approval is often treated as a timeline — when in reality, it is a source of uncertainty, cost escalation, and execution risk. In emerging markets, official requirements rarely reflect the full picture. Hidden steps, informal expectations, and shifting interpretations can significantly extend both timelines and budgets.

This Regulatory & Access Fast-Track Checklist is designed to move beyond theoretical pathways and estimate the real effort required to bring a product to market. The 15 questions focus on practical variables that impact feasibility: local testing requirements, dossier gaps, approval dependencies, and true regulatory costs — not just official fees.

In practice, many projects are approved internally based on optimistic assumptions around timing and complexity. Once the process starts, delays and additional requirements become difficult to manage and even harder to reverse.

The objective is to replace assumptions with evidence, allowing teams to anticipate bottlenecks, allocate resources properly, and decide early whether the market is worth the regulatory investment.

PRICING VIABILITY & CHANNEL STRUCTURE CHECKLIST

25 Questions to Validate If Your Product Can Compete—and Make Money

A practical screening tool for

BD, Pricing & Market Access Teams

HOW TO USE

Evaluate whether your **pricing strategy is viable across channels and cost structure** before entering the market.

Each question must be answered with **real market data —not assumptions**.

Scoring:

- **2 = Clear evidence**
- **1 = Partial answer**
- **0 = Unknown / high uncertainty**

Maximum score: 50

1. CHANNEL STRATEGY & FIT

Where is the product actually going to be sold—and does pricing fit?

Checklist:

□ Target channels clearly defined (private, hospital, retail, e-commerce)

□ Product-channel fit validated (not all products fit all channels)

□ Entry barriers per channel understood (listing, access, relationships)

□ Channel mix aligned with pricing strategy

2. COMPETITIVE PRICE LANDSCAPE

Where does your product sit vs real competitors?

Checklist:

□ Benchmark vs low-cost players (India / China / local generics)

□ Benchmark vs premium / branded competitors

□ Clear positioning defined (low-cost / mid / premium)

□ Price elasticity and sensitivity understood

3. PRICE BY CHANNEL

Is your pricing viable across different market segments?

Checklist:

□ Private market price validated

□ Public / reimbursement price constraints understood

□ Tender pricing dynamics analyzed

□ No destructive price gaps between channels

4. MARGIN STRUCTURE (FULL VALUE CHAIN)

Does everyone in the chain make enough money?

Checklist:

□ Importer margin aligned with expectations

□ MA Holder / local partner margin defined

□ Distributor margin realistic for the market

□ Retail / hospital / pharmacy margin validated

5. EX-WORKS & COST BACK-CALCULATION

Does your starting price allow the business to exist?

Checklist:

□ Maximum viable EXW price calculated

□ Landed cost vs final price fully modeled

□ Reverse P&L built from retail price backwards

□ No margin compression across the chain

6. PROFITABILITY THRESHOLD (GO / NO-GO)

Does the business make money—or just revenue?

Checklist:

□ Minimum acceptable margin defined (company level)

□ Scenario analysis (best / base / worst case) completed

□ Break-even volume realistic

□ Clear GO / NO-GO decision threshold defined

SCORING TABLE

Section	Max Score
Channel Strategy	8
Competitive Landscape	8
Price by Channel	8
Margin Structure	8
EXW Viability	8
Profitability Threshold	10

Total: 50

INTERPRETATION BOX

42–50 → Strong Pricing Viability
Competitive and profitable across channels

30–41 → Conditional Viability
Requires adjustments (price, margins, or channel focus)

<30 → Non-Viable
High risk of failure or margin destruction

STRATEGIC RED FLAGS

Premium Price in a Commodity Market
→ No traction without strong differentiation

Channel Mismatch
→ Product priced for private market but forced into tenders

Margin Imbalance
→ Distributor or retailer not incentivized

EXW Too High
→ Business breaks before reaching the shelf

Tender-Driven Price Collapse
→ Erodes entire pricing structure

Consultant Note

Pricing failures in emerging markets are typically structural—not demand-driven. This checklist validates whether your product can compete and remain profitable across the value chain.

Four core risks to pressure-test:

- Price-to-Value Misfit: Pricing based on internal logic rather than local benchmarks or perceived value leads to weak uptake.
- Margin Compression: After distributors, retailers, and incentives, insufficient margins result in low push or delisting.
- Channel Mismatch: Price points often don't fit the realities of target channels, causing erosion or lack of support.
- Hidden Costs: Duties, logistics, fees, and low initial volumes frequently undermine assumed profitability.

Apply this as a bottom-up price waterfall (ex-factory → retail), stress-testing margins at each layer and validating assumptions with local input.

Bottom line:
The key question is not "Will it sell?" but "Will every player in the chain make money selling it?"

DISTRIBUTOR PERFORMANCE & KPI CHECKLIST (POST-LAUNCH)

20 Questions to Verify If Your Distributor Is Actively Driving the Business

A practical monitoring tool for

BD, Commercial & Export Teams

HOW TO USE

Evaluate whether your distributor is executing—or just holding the product.

Each question must be answered with objective data and measurable KPIs.

Scoring:

- **2 = Clear evidence**
- **1 = Partial answer**
- **0 = No visibility / no activity**

Maximum score: 40

1. SALES PERFORMANCE & TRACTION

Is the product actually moving in the market?

Checklist:

□ Monthly sales vs forecast tracked and reviewed

□ Secondary sales (sell-out) data available

□ Growth trend consistent (not one-off orders)

□ Stock rotation aligned with expected velocity

2. MARKET COVERAGE & EXECUTION

Is the distributor actively pushing the product?

Checklist:

□ Number of active accounts / points of sale increasing

□ Geographic coverage expanding as planned

□ Product listed in key target channels (pharmacy, modern trade, etc.)

□ Field force actively detailing / promoting the product

3. MARKETING & ACTIVATION

Is there real commercial support behind the product?

Checklist:

□ Agreed marketing plan executed (not just defined)

□ Promotional activities implemented on time

□ Visibility in-store / online confirmed

□ Budget utilization aligned with commitments

4. COMMUNICATION & REPORTING DISCIPLINE

Is the distributor transparent and structured?

Checklist:

□ Regular reporting provided (monthly / quarterly)

□ Data quality reliable (no inconsistencies)

□ KPIs shared proactively (not only on request)

□ Issues and risks communicated early

5. INVENTORY & ORDER BEHAVIOR

Is stock managed professionally—or sitting idle?

Checklist:

□ Inventory levels aligned with sales (no overstock / dead stock)

□ Reorders follow a logical consumption pattern

□ No long gaps between orders without justification

□ Expiry risk under control

SCORING TABLE

Section	Max Score
Sales Performance	8
Market Execution	8
Marketing Activity	8
Reporting Discipline	8
Inventory Management	8

Total: 40

INTERPRETATION BOX

35–40 → Active & Engaged Distributor
Driving the business with consistency

25–34 → Partial Execution
Requires close follow-up and alignment

<25 → Passive Distributor
High risk: product likely sitting “in the drawer”

STRATEGIC RED FLAGS

No Secondary Sales Data
→ No visibility on real market performance

Flat Sales After Initial Order
→ Stock-in without sell-out

No Market Expansion
→ Distributor not prioritizing the product

Irregular or Poor Reporting
→ Lack of control and accountability

FINAL NOTE

A distributor not actively managed will:

- Prioritize other products
- Delay execution
- Lock your product without growth

Key question

“Is the distributor building the business—or just holding inventory?”

Consultant Note

This checklist validates whether your distributor is not just present—but actively driving sell-out, coverage, and growth. Four core risks to pressure-test:

- Passive Distribution: Product is listed but not pushed—low field activity, weak sell-out focus.
- KPI Misalignment: Distributor incentives tied to sell-in, not sell-out, leading to inflated pipeline but poor market traction.
- Execution Gaps: Limited coverage, poor in-store visibility, and inconsistent stock availability.
- Capability Constraints: Insufficient salesforce quality, weak data tracking, or lack of category focus.

Apply this through field validation and KPI tracking:

- Sell-in vs. sell-out ratios
- Outlet coverage and frequency
- Stock levels and rotation
- Salesforce activity and incentives

Validate using market visits, distributor data, and retailer feedback—not just reported numbers.