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Business Development in Emerging Markets for the Pharmaceutical Industry, Along with the Regulatory Landscape

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Abstract: Emerging markets (EMs) are increasingly central to pharmaceutical business development due to growing demand, evolving regulatory frameworks, and escalating expectations for quality, safety, and innovation. Between 2023-2025, shifts such as India's revised Schedule M GMP rules, China's expanded volume-based procurement, Brazil's reliance pathways, and heightened traceability requirements in the GCC have reshaped how pharma companies enter, scale, and compete in EMs. This paper analyzes why EMs matter now, which business development models are working best, the changing regulatory landscape, case studies from key markets, and presents a risk/entry evaluation matrix to help companies prioritize. The aim is to guide strategy in a less formal but evidence-grounded style.

Keywords: *Emerging Markets; Pharmaceutical Business Development; Regulatory Compliance; Schedule M; Volume-Based Procurement; Risk Matrix.*

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I. INTRODUCTION

Pharmaceutical companies today face slowing growth in many mature markets. Patents expire, pricing pressure mounts, innovation costs rise, and regulatory timelines become more cumbersome. In contrast, emerging markets — countries in Asia, Latin America, the Middle East, and Africa with growing economies, expanding healthcare systems, and large unmet medical needs — are increasingly attractive. Not only do they promise volume growth, but regulatory reforms and policy shifts in many of them are making entry more structured and transparent.

This paper explores business development (BD) in emerging markets for the pharmaceutical industry, focusing on models that work, regulatory changes from 2023 onwards, country-level examples and risks, and a matrix to help companies decide which EMs to prioritize. The tone is practical and aimed at helping BD teams align strategy and regulation without getting bogged down in jargon.

II. RECENT LITERATURE & MARKET TRENDS (2023-2025)

Before going deeper, here are recent trend findings and what the literature tells us:

- *Growth in Medicine Use and spending in Ems:*

Emerging markets will see faster growth in medicine use and spending than mature markets, with China and India leading both as high-demand markets and as major global producers shaping supply and pricing. IQVIA

- *Therapy Areas Driving Growth*

Therapy areas driving growth include immunology, endocrinology (especially diabetes and obesity), and oncology. Although generics/biosimilars will remain important, newer and innovative therapies are becoming more accessible in EMs. IQVIA+2ifpma.org+2

- *Regulatory Quality and Compliance are no Longer Optional.*

Standards are rising globally. Importing countries, global buyers, and patients increasingly expect WHO-GMP, good data integrity, rigorous PV, etc. India's revised Schedule M (which tightens GMP, risk management, equipment, and premises

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rules) is an example of domestic regulation catching up with global expectations. crqa.in+3BioSpectrum India+3www.pharmabiz.com+3

- *Business Models are Adjusting*

Business models are adjusting with more partnerships, manufacturing localization, reliance on harmonization or regulatory reciprocity/acceptance, digital channels, tiered pricing, and stronger tender-oriented strategies. The Bain "Roadmap for Making India a Global Pharma Exports Hub" and other recent reports outline how pharma companies are investing more in exporting capacity, innovation, and quality to leverage both domestic and international markets. Bain

- *Regulatory & R&D Modernization*

Use Tan et al. (China) + Maaraf et al. to show how clinical trial standards, novel therapy regulation, GMP, etc., are changing in EMs.

- *Market Access, Licensing & Access Equity*

Use the Access to Medicine Index (2024) + Ramagopalan et al. to highlight how licensing, technology transfers, and market access decisions are understudied or under-utilized.

- *Legal / IP / Compliance Trends*

Kirkland & Ellis (2024) helps demonstrate that legal/regulatory risk (patents, compliance, enablement) is getting more attention post-2023.

- *Growth Projections & Global Market Dynamics*

Use Fortune Business Insights, IFPMA, etc. to quantify market growth, showing potential size and how EMs contribute.

- *Supply Chain Resilience & Alternative Channels*

Sabogal & Tucker for supply chain risk; Mondal et al. for retail / e-channel dynamics.

- *Sustainability / Environmental Regulatory Pressures*

Jairoun et al. to show newly rising regulatory pressures for green/eco-friendly manufacturing, which will affect costs and compliance in EMs.

III. WHY EMERGING MARKETS MATTER

Emerging markets matter for pharma business development for several interlinked reasons:

- Demographics & Disease Burden: There is a demand for an increasing population, aging, and increasing prevalence of chronic diseases (e.g., diabetes, cardiovascular disease, obesity). Communicable + non-communicable diseases are also a burden to many EMs.
- Improving Access and Healthcare Systems: These initiatives of insurance coverage, government investment in health, and the strength of the private sector are improving care. EM governments are even investing further in universal health care or insurance programmes, which amplifies the need for cheap, quality medicines.
- Regulatory & Policy Reforms: A majority of the EMs are changing their regulatory frameworks, improving quality, and introducing mechanisms to offer quick approvals or reliability. These lessen the entry obstacles of those firms that invest early.
- Unutilized Market Potential and Innovation Diffusion: Several EMs are underserved with specialty drugs and advanced treatments, which generates an opportunity for those companies that can manage cost and control. Innovation is also on the increase: The ability and expertise of CDMOs/CROs in India, Latin America, and Southeast Asia is increasing.
- Export Potential: Some of the EMs are manufacturing or export centres. India is expanding its exports to other EMs and controlled markets, like. Compliance (GMP, quality, regulatory documents) becomes a competitive advantage. Bain+2Wikipedia+2
- Resilience & Diversification: In the developed markets, EMs can diversify the revenue stream because of the geopolitical risks, supply disruption, and the pressure of prices and/or payers.

A recent data point: India's pharma market grew ~8.1% year-on-year in August 2025, and is projected to reach ~US$130 billion by 2030. The Times of India

IV. BUSINESS DEVELOPMENT MODELS THAT WORK

Table 1 Given EM Realities, these BD Models (and Hybrids) are Working Best in 2023-2025:

Model	Key Features	Pros	Cons / What Needs to Be Managed
Local Partnerships / Joint Ventures	Partnering with a local manufacturer or distributor for regulatory filing, local registration, supply, and distribution. Often, joint manufacturing or licensing.	Faster market access, better local knowledge, better regulatory compliance. Helps meet localization mandates.	Finding credible partners with GMP & PV capability; risk of IP leakage; dependency; alignment of incentives.
Portfolio Licensing & In-Licensing	Licensing in products for local/regional markets; swapping mature assets; licensing out older non-core assets.	Lower R&D risk; can quickly build presence;	Licensing fees, complexity of contracts, ensuring regulatory

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		leverages existing local infrastructure.	filings are valid; profitability depends on local pricing.
Tiered Pricing / Outcomes & Value Contracts	Differential pricing for public vs private sectors; deals with payers based on outcomes; patient assistance/subsidy programs.	Helps affordability and uptake; improves access; builds goodwill; can open large contracts.	Negotiation power of payers; data collection for outcomes; risk of underpricing; risk that discounts hurt brand positioning.
Local or Near-market Manufacturing	Setting up/working with CDMOs, contract manufacturers, or even our own plants in EMs. Enhancing local production capacity.	Reduced logistic costs; better tariff/local content compliance; potential for exports; shorter lead times.	High upfront investment; need for stringent GMP & quality; supply chain risks; skilled labor; certification issues.
Regulatory Reliance / Harmonization	Using regulatory reliance or recognition (e.g., accepting reference agency approvals, mutual recognition/harmonization efforts, regional regulatory bodies).	Shorter approval times, less duplication, lower cost, predictable process.	Not all markets have reliable reference authorities; variation in implementation, local data/trial requirements may still apply.
Digital / Hybrid Commercial Models	E-detail, telemedicine channels, e-pharmacy; remote interactions with HCPs; digital marketing when permitted.	Reach outside metros; lower sales cost; better data/feedback; flexibility.	Regulatory/legal constraints; digital infrastructure and privacy issues; reimbursement for telemedicine; risk of counterfeits.

It is usually helpful to combine some of these and not to choose only one of them. As an example, a biologics company may partner locally, in-license, and create local or regional production, and create digital outreach.

V. REGULATORY LANDSCAPE & RECENT CHANGES (2023-2025)

➢ *India – Revised Schedule M*
- Dec 2023: Updated GMP rules aligned with WHO-GMP/PIC/S.
- Focus on infrastructure, QRM, PQR, lifecycle management.
- Deadlines: Large firms (Jul 2023); MSMEs (extended to Dec 2025).

➢ *China – VBP & NRDL*
- Expanded National Volume-Based Procurement → sharp price cuts.
- NRDL updates favor innovation but often require local trial data.

➢ *Brazil – Reliance & PV*
- Faster review via reliance on reference agencies.
- Stricter post-market safety, labeling, and documentation requirements.

➢ *GCC / Middle East*
- Serialization/traceability mandates (e.g., SFDA).
- Push for local manufacturing and environmental compliance.

➢ *Africa – Harmonization*
- African Medicines Agency (AMA) and AMRH are driving regional standards and reducing duplicative filings.

➢ *Cross-Market Themes*
- Tighter data integrity and digital compliance (audit trails, e-batch records).
- Rising pharmacovigilance demands.
- Stronger price control and payer pushback.
- Localization: trials, manufacturing, and content are increasingly required.

VI. DISCUSSION: TRADE-OFFS & STRATEGIES

From the above, several strategic trade-offs emerge. Companies need to think:

➢ *Speed vs Quality / Cost*

Rushing too quickly in a market without investing in compliance can result in recalls, governmental backlash, and reputation destruction. Incidents of penetration that are too cautious postpone the revenue. Balancing is key.

➢ *Local Investment vs Outsourcing*

It is rather costly to establish in a country, and can be compensated (local content, cost, import duties). Outsource / partnering costs are less expensive, and it leads to dependency and risk.

➢ *Strategic Asset: Regulative Intelligence*

It is possible to be a pioneer in markets experiencing transformation (e.g., Schedule M implementation, GCC traceability, Brazil dependence). The first-mover advantage could be achieved through tracking the regulatory signals at the early stage.

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➢ *Portfolio Strategy Must Include Contingency*
You lose tenders, reimbursements are late, and currency fluctuations, you must have contingency. What, e.g., does it do to your product when it is dropped out of NRDL, or when price ceilings reduce your margins?

➢ *Spend on Quality and Compliance Early*
Data integrity, GMI, PV, digital tracking, ALL these are expensive to purchase and are necessary, but rapidly becoming mandatory in EMs and in export.

VII. CONCLUSION & RECOMMENDATIONS

The market of 2023-2025 is a good opportunity and high high-expectations market. With pharmaceutical companies, it is more than a presence in EMs that is needed to be successful; there must be a coordination of regulatory preparedness, quality systems, commercial model, and risk mitigation.

Here are some actionable recommendations:

➢ *Develop Regulatory Roadmaps Early*
From the design stage (R&D / clinical trials), map out regulatory, GMP, PV, and local data requirements. Don't assume that what works in one EM will work in another.

➢ *Select Markets Using a Risk/Entry Framework*
Use matrices like the one above; weigh what matters most (opportunity vs regulatory cost vs IP risk, etc.) in *your* therapy area.

➢ *Invest in Quality, GMP & Compliance*
Upgrading facilities, implementing new Schedule M-like rules where relevant, ensuring data integrity, and PV systems are embedded.

➢ *Build Local Partnerships*
Pilots, JVs, and local manufacturers/distributors can reduce risk and speed entry. Also, consider CRO/CDMO partners where capable.

➢ *Adapt Pricing & Value Propositions to Local Market Realities*
Value-based pricing, patient assistance, tiering, flexible contracts; prepare for price negotiations and reimbursement delays.

➢ *Monitor Regulatory Change & Be Agile*
Keep teams or consultants focused on regulatory intelligence; anticipate change. When changes signal higher quality / stricter enforcement, align business model proactively.

➢ *Ensure Operational Resilience*
Focus on supply chain, raw material security, workforce training, serialization/traceability, and logistics — these tend to be weak links in EMs.

➢ *Outlook*
By 2030, EM pharma markets are likely to capture a larger share of global spend growth, especially in immunology, specialty, biotech, and chronic disease medicines. Companies that can combine compliance, quality, local presence, and smart commercial strategy will win.

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