

Prescriptions for Success: Pharma Joint Ventures in India

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Introduction

India's pharmaceutical sector, which is experiencing considerable growth due to a strong domestic market and initiatives such as the "Ayushman Bharat Yojana,"[1] faces a substantial challenge in the form of dependence on China for essential drug ingredients. Although Production-Linked Incentive (PLI) schemes aim to mitigate this, industry leaders focus their attention on high-value Active Pharmaceutical Ingredients (API) and Research & Development (R&D).

As a result of this paradigm change, joint ventures have emerged as transformative forces. Global titans such as Pfizer[2], Bayer[3], and Merck[4] have formed strategic alliances with their Indian counterparts, drawn to the country's immense market potential and regulatory advantage. These Joint Ventures (JVs) represent a convergence of interests. By acquiring critical foreign expertise, India expedites the development of API independence, while these foreign partners gain access to a cost-effective production centre and a gateway to a thriving market.

At this critical juncture, India has the opportunity to leverage this momentum by encouraging private-foreign collaborations to unleash the true potential of the pharmaceutical industry. The objective is to establish a pharmaceutical industry that is globally competitive, promotes innovation and qualified employment, and safeguards India's position as a pharmaceutical superpower. This article aims to provide an overview of joint ventures in the pharmaceutical industry in India in the following manner:

- Benefits and Drivers of JVs in Pharma
- Legal and Regulatory Framework for Pharma JVs in India
- Challenges and Opportunities for Pharma JVs in India

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 - Benefits and Drivers of JVs in Pharma
- *Immediate Access to Local Know-How:*
 - *Local Expertise:* JVs facilitate instant access to local know-how and resources, which is crucial for navigating complex markets. This is particularly beneficial in pharmaceuticals since understanding country-specific circumstances and regulations is crucial.
 - *Accelerated Product Launch:* Engaging a local partner expedites the time to market a product. Local partners bring insights into developing pharmaceutical products, including biological products, tailored to specific market needs.
- *Efficient Distribution Channels:* JVs provide immediate access to established local distribution channels. Establishing such channels independently can be time-consuming and may involve a trial-and-error approach. JVs, on the other hand, offer a shortcut to efficient and effective distribution networks.
- *Risk Mitigation:*
 - *Diminished Entrepreneurial Risk:* Investors often cite reduced entrepreneurial risk as a significant advantage of setting up joint ventures. The shared responsibility with a local partner leads to smaller capital involvement, thus minimizing financial exposure.
 - *Legal Entity Responsibility:* With the involvement of a second legal entity, legal responsibilities are shared, providing an additional layer of protection for the investing companies.
- *Strategic Investment Planning:*
 - *Strategic Equity Acquisition:* JVs are employed as a strategic approach for potential acquisitions. Investors may initially acquire a specific equity percentage of the target company. This phased approach allows for continuity in management and provides the acquiring company with an opportunity to thoroughly understand the target company's operations before a full acquisition.
 - *Evaluation Opportunities:* During the JV cooperation, potential deal breakers and unforeseen issues within the target company, such as "creative" accounting practices, can be identified. This discovery phase allows for a comprehensive evaluation before committing to a full acquisition.
- *Utilizing India's Manufacturing Strength:* India boasts more than 100 FDA-approved manufacturing sites, providing a substantial manufacturing base for foreign companies entering into JVs.[5] This access allows for efficient and cost-effective production, leveraging India's skilled labour and low

production costs.

Legal and Regulatory Framework for Pharma JVs in India

Company Law Provisions

- *Formation*: JVs are usually established under the Companies Act, 2013[6] or as Limited Liability Partnerships under the Limited Liability Partnership Act, 2008.[7]
- *Registration Documents*: Memorandum of Association (MoA), Articles of Association (AoA), and verification of the registered office address are, *inter alia*, the primary registration documents.
- *Directors and Shareholders*: Information on directors and shareholders, including PAN, DIN, and evidence of identification and domicile is required.
- *MCA Registration*: JVs can be registered through the website of the Ministry of Corporate Affairs.

Foreign Exchange Management Act (FEMA) Provisions

- *Regulation of Foreign Investments*: FEMA regulates foreign investments. The Reserve Bank of India (RBI) and the Securities and Exchange Board of India (SEBI), along with the Department for Promotion of Industry and Internal Trade (DPIIT) oversee foreign investment in India.
- *FDI Policy*: The Foreign Direct Investment (FDI) Policy under FEMA outlines the criteria for JVs involving foreign investment.[8]

Intellectual Property Laws

- *Protection under*: Laws like the Patents Act, 1970, the Trade Marks Act, 1999, the Copyright Act, 1957, etc.
- *Registration and Agreements*: JV agreements should include licensing, know-how, technical services, royalty payment, and franchise agreements.
- *Compulsory Licensing*: India's intellectual property laws allow for compulsory licensing in specific circumstances.

Regulatory Framework

- *FDI Policy for Pharma*: Greenfield pharmaceutical projects in India allow 100% FDI via the automatic route, while brownfield investments permit 100% FDI, with 74% through the automatic route and the remaining requiring government approval.[9]
- *Non-compete Clause*: Both greenfield and brownfield investments typically require a non-compete clause.
- *Conditions for Brownfield Investments*: Conditions include maintaining production levels of essential medicines and R&D spending for the next five years.
- *100% FDI for Medical Devices*: Full foreign direct investment is allowed for medical device manufacturing under the automatic route.

Tax Considerations

- *Tax Implications*: Foreign investors must assess tax implications, considering capital gains tax and interest payments.
- *Double Taxation Treaties*: Many countries have double taxation treaties (DTAAs) with India, offering provisions for capital gains tax and interest withholding tax.

Technology Transfer and Licensing Regulations

- *Applicable Laws*: Regulations for technology transfer and licensing include the Patents Act, 1970, Copyright Act, 1957, Designs Act, 2000[10], etc.
- *International Conventions*: India's participation in international intellectual property conventions enhances protection for foreign contributors.

- *Legal Responsibilities:* Parties must adhere to legal responsibilities when transferring or licensing intellectual property rights, preventing confusion or deception.

Challenges, Opportunities and Examples of Pharma JVs in India

Challenges

Joint ventures in the Indian Pharma Sector face challenges, including cultural and language differences, hindering effective communication. The complex regulatory landscape and diverse business practices may impede strategy alignment. Instability in India's political and economic conditions poses a risk, while the pharmaceutical industry grapples with a shortage of skilled workers.

Opportunities

India, the world's third-largest manufacturer of API with an 8% market share, provides an ideal environment for strategic JVs. Key industry companies like Solara, Aurobindo Pharma, and Dr. Reddy's Laboratories provide opportunities for collaborative expertise sharing.^[11]

The Indian biosimilars industry is expected to expand at a Compound Annual Growth Rate (CAGR) of 22% until 2025, indicating great growth potential and making it a profitable arena for JVs to gain market share. JVs can take advantage of India's position as the leading exporter of formulations, leveraging a predicted double-digit growth rate to strengthen production capacities and extend market reach.^[12]

The pharmaceutical packaging business is expected to increase to \$3.25 billion by 2030, creating opportunities for joint ventures to innovate. Furthermore, the INR 448.19 billion OTC medicines industry and the developing Contract Research and Manufacturing Services (CRAMS) sector offer opportunities for strategic partnership.

JVs can actively contribute to India's pharmaceutical independence while receiving financial benefits by aligning with government efforts like the PLI Schemes, which align with the country's objective for pharmaceutical self-reliance.

Some Prominent Examples

- Panacea Biotech collaborates with Chiron for joint venture focusing on vaccine development and marketing.^[13]
- Novavax and Cadila Pharmaceuticals form a joint venture, CPL Biologicals, for the development and manufacture of vaccines, biological therapeutics, and diagnostics in India.^[14]
- Novotech, an Australia-based clinical research company, partners with ETI Klinikal for a strategic venture catering to the growing demand for clinical research and data management services in India.^[15]

Conclusion

The pharmaceutical industry in India provides a dynamic environment for joint ventures, offering prospects in various sectors. By capitalising on India's advancements in API production, the expanding biosimilar market, and favourable government initiatives, joint ventures have the potential to stimulate innovation and advance the nation towards pharmaceutical self-sufficiency. These enterprises, which overcome challenges via strategic collaborations, are positioned to influence the future of the industry and make significant contributions to advancements in global healthcare.

[1] <https://nha.gov.in/PM-JAY>.

[2] <https://www.pfizer.co.in/about-us/our-manufacturing/india-manufacturing#:~>

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[3] <https://www.bayerzyduspharma.com/en/about-us#:~:text=Bayer%20Zydus%20Pharma%20is%20a,of%20oncology%2C%20hematology%20and%20ophthalmology.>

[4] [https://www.merck.com/news/merck-co-inc-and-sun-pharma-establish-joint-venture-to-develop-and-commercialize-novel-formulations-and-combinations-of-medicines-in-emerging-markets/.](https://www.merck.com/news/merck-co-inc-and-sun-pharma-establish-joint-venture-to-develop-and-commercialize-novel-formulations-and-combinations-of-medicines-in-emerging-markets/)

[5] <https://pib.gov.in/PressReleaseDetailm.aspx?PRID=1585342.>

[6] <https://www.mca.gov.in/Ministry/pdf/CompaniesAct2013.pdf.>

[7] https://www.mca.gov.in/Ministry/actsbills/pdf/LLP_27oct2008.pdf.

[8]

https://dpiit.gov.in/sites/default/files/FDI-PolicyCircular-2020-29October2020_0.pdf.

[9]

<https://dpiit.gov.in/sites/default/files/FDI-PolicyCircular-2020-29October2020.pdf.>

[10] <https://www.indiacode.nic.in/bitstream/123456789/1917/1/200016.pdf.>

[11] [https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-](https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-industry-29938.html/#:~:text=Greenfield%20pharmaceutical%20undertakings%20in%20India,approval%20from%20the%20Indian%20government.)

[industry-29938.html/#:~:text=Greenfield%20pharmaceutical%20undertakings%20in%20India,approval%20from%20the%20Indian%20government.](https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-industry-29938.html/#:~:text=Greenfield%20pharmaceutical%20undertakings%20in%20India,approval%20from%20the%20Indian%20government.)

[12] [https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-](https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-industry-29938.html/#:~:text=Greenfield%20pharmaceutical%20undertakings%20in%20India,approval%20from%20the%20Indian%20government.)

[industry-29938.html/#:~:text=Greenfield%20pharmaceutical%20undertakings%20in%20India,approval%20from%20the%20Indian%20government.](https://www.india-briefing.com/news/foreign-investment-prospects-in-indias-pharmaceutical-industry-29938.html/#:~:text=Greenfield%20pharmaceutical%20undertakings%20in%20India,approval%20from%20the%20Indian%20government.)

[13] <https://www.panaceabiotec.com/en/content/success-story.>

[14]

https://www.sec.gov/Archives/edgar/data/1000694/000114420418057994/tv505573_ex10-1.htm.

[15]

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