

Intelligence partner

FROST 🕉 SULLIVAN









Table of Contents

Pref	ace	2		
Exe	Executive Summary			
1.	Introduction	4		
2.	Bottom-Up Risk Assessment Approach	9		
3.	Defining the Risk Scale	10		
4.	India - Emerging Superpower with Optimized Corporate Risk Handling	12		
5.	India Showcasing an Optimized Risk Handling	14		
6.	Pharmaceutical Sector Insights 2022	16		
7.	Pharmaceutical Sector Risk Index 2022 Vs 2021	18		
8.	Key Highlights	19		
9.	ICICI LOMBARD: Key Solution Offerings	34		
Bibl	ibliography			

Table of Figures

Figure 1: India's Growth of manufacturing exports.	. 12
Figure 2: Corporate India Risk Index 2022	. 14
Figure 3: Corporate India Risk Index 2022 Sector Score	. 15
Figure 4: Detailed Comparative Analysis 2021 Vs. 2022	. 18



Preface

Corporate India Risk Index is primarily an academic exercise to understand the level of risk that companies are facing and also assist in developing a successful risk aversion plan, CIRI is a first-of-its-kind risk measurement tool to gauge the level of a company's risk exposure and preparedness.

This Corporate risk comprises of various aspects of the business–spanning customer, competition, regulatory environment, business operations, technology finances, environmental factors etc. The impact of unprecedented events is significantly higher now.

This Index is a comprehensive framework that draws upon global risk management best practices and comprises of 32 risk elements across 6 broad dimensions. The Risk Index is based on the principles of Lean and Six Sigma that qualify business processes by measuring effectiveness and efficiency.

ICICI Lombard's Corporate India Risk Index provides a crucial tool for assessing and addressing risks, fostering resilience and adaptability in the ever-evolving global landscape. In the current climate of increasing macroeconomic uncertainties, it is essential for corporates to prioritize robust risk management. We believe that a proactive approach to risk management not only fortifies individual businesses but also contributes significantly to India's overall economic growth and stability.



Executive Summary

Risk management is a crucial aspect of the pharmaceutical industry in India. Given the complex regulatory environment, highly competitive market, and other external factors, pharmaceutical companies need to adopt a comprehensive risk management framework to identify, assess, and mitigate potential risks.

One of the primary risks that Indian pharmaceutical companies face is related to regulatory compliance. Companies need to ensure that they comply with various laws and regulations related to drug development, manufacturing, and distribution. Failure to do so can result in penalties, legal liabilities, and damage to the company's reputation.

Another significant risk is related to intellectual property rights. Indian pharmaceutical companies need to be careful not to infringe on the patents and trademarks of other companies, as this can result in costly legal disputes.

Other risks that companies need to manage include supply chain disruptions, quality control issues, and reputational risks. Companies need to ensure that they have adequate risk management policies and procedures in place to minimize the impact of these risks.

In conclusion, Indian pharmaceutical companies need to prioritize risk management and invest in developing comprehensive risk management frameworks to ensure sustainable growth and long-term success in the industry. By identifying and mitigating potential risks, companies can protect their reputation, reduce costs, and increase profitability. The overall risk management scores have gone up with the rising stature of the industry globally, government focus and better risk management frameworks.



Introduction

ICICI Lombard Corporate India Risk Index is a one of its kind, unified, credible, standardized corporate Risk Index that spans over the country level, the industry level, and the company level. The index has a comprehensive sector coverage.

Aerospace and Defense, Agriculture and Food Processing, Automotive and Ancillary, BFSI, Biotech & Life sciences, Chemicals and Petrochemicals, Education Skill



Development, Energy, FMCG, Healthcare Delivery, Infra and Realty, IT/ITES, Manufacturing, Media and Gaming, Metals and Mining, New Age & Startup, Pharmaceuticals, Telecom and Communication Technology, Tourism and Hospitality, Transportation and Logistics.

The impact is identified across key business risk (internal and external) under the following 'Strategic Risk Areas', The ICICI Lombard Corporate India Risk Index Framework comprises of 32 risk elements across 6 broad dimensions.

Market and Economic Risk

Corporate Risks arising due to market and economy related factors, such as internal or external political uncertainty, global slowdown, taxation-regulatory changes etc. Market and economy related risks are also identified as 'Systematic Risks', we have further classified the risks into below mentioned categories.

- Inflation: Inflation is the general increase in prices within the economy. The rising prices for businesses could result in bigger production spending and a fall in profitability. The companies should be attentive, acute, and responsive to changes in inflation to efficiently manage the prices of final products.
- Taxation: In a large democracy like India, complexity of multiple taxes (multiple taxes like GST, custom duties, central excise duty, etc.) is a major concern. The changing legislations, increased scrutiny by tax authorities and increasing public attention are together resulting in tax risks for organizations. There is, thus an increasing urgency for firms to manage their tax affairs efficiently to minimize tax risks.



- Regulatory Risks: Regulatory risk is the risk of changes in regulations and laws that might affect an industry or businesses. The regulatory changes can pertain to tariffs and trade policies, business laws pertaining to employment, minimum wage laws, financial regulation, Foreign Direct Investment etc.
- Foreign Exchange Risk: The exchange rate plays an important role for firms who export goods and import raw materials. The fluctuations in foreign exchange will have great impacts on the prices of traded goods. For example, if the currency depreciates (devaluation), the exporting firms will benefit. However, the firms importing raw materials will face higher costs on imports. The firms need to hedge their exposure to foreign exchange risks to insulate themselves from the impact from forex changes.
- **Geo-political Tension:** Geopolitical risk means the political and economic risks that are a potential threat to the financial and operational stability of companies.
- **Competitive risk:** Competitive risk is the risk associated with the fact that there are multiple companies competing in the market, each seeking to obtain the highest position and consumer ratings, to gain maximum benefits for themselves. The companies devise different strategies to garner a higher market share and acquire customers from competitors. Any failure in managing the competitive stand could lead to losses in business, thereby making marketing and competition a major risk in market.

Technology Risk

Technology risks are also identified as information technology related risks which may arise due to failure of any installed hardware or software system, spam, viruses or any malicious attack. Also delay/over/under adoption of trending disruptive technologies can lead to technology related risks. We have classified the risks in below mentioned categories.

- Innovation Risk / Obsolete Technology: Innovation is the key to success in all the industries. Risk of redundancy and losing out to competition on account of poor R&D is a major concern.
- **Intellectual Property risk:** Dependence on trade secrets and unpatented proprietary know-how.
- **Disruptive Technologies:** These will fundamentally alter the financial prospects of the industry.

Data Compromise: Hardware failure refers to malfunctions within the electronic circuits or electromechanical components (disks, tapes) of a computer system; Software failure refers to an operating system crash. Such failures lead to stoppage of entire computer or operating systems creating substantial losses to business.



Operational and Physical Risk

Risk of losses caused due to faulty or failed processes, systems or human resource related inefficiencies are classified as operational and physical risks. We have classified Operational & Physical risks in below mentioned categories.

- Critical Infrastructure Failure / Machine Breakdown: Industries with a heavy dependence on machinery consider any rise in machinery breakdowns a hindrance to their businesses operations. An untimely equipment breakdown can bring businesses to a standstill or be the root cause for fires and explosions. Mostly, human errors and deferred maintenances are the major reasons for such breakdowns. The companies should actively invest in timely maintenance of all machineries.
- Business Continuity / Sustainability: Non adoption of Business Continuity/ Sustainability Plans and Lack of Internal Control tools would result in: Failure of businesses, Brand Equity / Loss of reputation, Financial Loss, Business model Failure, Ineffective engagement/communication with stakeholders, Losses in productivity, Lack of opportunity monitoring.
- Supply chain risk: Raw Material unavailability and Heavy Dependence on Global Supply Chains / Supplier concentration risk. Unavailability of raw materials owing to disruption in the supply chain or heavy dependency on one source (company/country) which is unable to supply owing to some geopolitical tensions, fires, or any other incidents. Transportation is one of the key activities for companies making it an important risk to mitigate. The loss of goods in transit and spillage is one of the major concerns as it accounts for a sizeable loss of revenue to companies.
- **Commodity Price Risk Volatility in prices of raw materials:** The fluctuations in raw material prices creating a margin pressure / top-line pressure in the scenario of rising input costs.
- Portfolio Risk: Loss of key customers, Customer concentration Key customers accounting for a larger share of revenue, Over-dependence on suppliers, Business Model Risk: Transformative changes in business model, Tail Risks: Ability to overcome or manage extreme worst-case scenarios.
- **Environmental Hazard Risk:** Any environmental hazard having the potential to affect the surrounding environment.
- Workplace Accident: Fire and Explosion Hazards, Containment Incidents, Workplace Injuries
- Human Resource: Key person risk: This risk occurs when a business or business unit becomes heavily reliant on a key individual. Talent acquisition and retention The companies require a highly skilled labor force for R&D as well as continuous production. Accessing skilled resources and expertise on an on-going basis is one of the major challenges; moreover, retention of trained staff is imperative. Labor shortages, Union Strikes & Industrial Actions, Employee health, safety, and security (SHE/Sustainability risk).



- Financial Risk: Financial Reporting Risk: Material misstatement of Financial Statements, whether due to fraud or error. Interest rates and equity prices: Interest rate risk arising out of working capital borrowings at variable rates. Equity price fluctuations affect the Company's income or the value of its holdings of financial instruments. Liquidity Risk (Credit Risk / Receivables).
- Breaches of law (local/ international): Voluntary/ involuntary breaches of law can lead to costly lawsuits.

🗊 Crime & Security Risk

Cybersecurity risks relate to the loss of confidentiality, integrity, or availability of information, data, or information (or control) systems and reflect the potential adverse impacts to organizational operations. These attacks can cause major financial losses, reputational harm, and a loss of client trust. Regarding cybersecurity, the BFSI industry in India has several difficulties, including difficult-to-secure legacy systems, a shortage of qualified cybersecurity personnel, and the requirement for ongoing system and network monitoring. There is a significant investment in cybersecurity tools like network monitoring, endpoint security, access control, and threat intelligence. Many organizations are also implementing cutting-edge technology like artificial intelligence and machine learning to strengthen their security posture. Around 7.4% of the attacks in the Asian region were targeted at India in 2022.

We have classified Crime & Security risks in below mentioned categories.

- Cyber Crimes: Data Theft, Spam, scams and phishing, Hacking, Malwares and Viruses, Piracy, Fraud, Corruption, Malicious attacks
- Counterfeiting: Counterfeiting of goods/services leads to loss of revenues, profits and ultimately affects the brand equity
- Threat to Women Security
- Terrorism: Un-lawful use of violence and intimidation, especially against civilians, in the pursuit of political aims.



Natural Hazard Risk

A natural hazard is the threat of an event that will likely have a negative impact. A natural disaster is the negative impact following an actual occurrence of natural hazard if it significantly harms a community. Due to India's geographical structure, it is one of the most disaster-prone countries in the world. Natural hazards like floods, earthquakes, landslides, and cyclones are common risks faced by India. The situation has worsened due to rise in GHG emissions, loss of biodiversity, deforestation, and degradation of environment. From Surat Gas leak to landslides in the north and cyclones in Bay of Bengal, the year 2022 was no exception. Such natural disasters hamper the day-to-day operations of corporates, and it is important for them to understand that such risks cannot go unheeded. Over the years, Indian corporates have learnt to mitigate such risks by diversifying their supply chains, having multiple logistics partners, diversified geographical presence and multiple vendors.

Pandemic and other global epidemic diseases: Risk to business owing to disruptions caused by COVID-19 pandemic and similar another global epidemic.

Strategic risk

- Strategic risk is the risk that failed business decisions may pose to a company. Strategic risk is often a major factor in determining a company's worth, particularly observable if the company experiences a sharp decline in a short period of time. Several factors, such as unethical or unlawful activities, poor customer service, product recalls, data breaches, or unfavorable media coverage, can lead to strategic risk. An organization's reputation can be severely harmed by a single negative incident, such as a high-profile data breach or fraud scandal, resulting in a loss of clients, income, and market share.
- Resource scarcity / Misutilization / Overall Utilization: Difficulties in acquisition of land, water, fuel, or other resources for operations of business.
- **Public Sentiment:** Current events playing out in the public scene can change the public sentiment.
- **Delay in execution of projects:** Delays in execution of projects can surge in the capex.
- Increased number of recalls and quality audits: Impacts both the brand equity and increased operational expenses.
- Failed / Hostile Mergers & Acquisitions: High dependence on inorganic growth.



Bottom-Up Risk Assessment Approach



- Evaluation Parameters*: The index maps the risks faced by any enterprise basis of Awareness, Probability, Criticality and Preparedness against the defined Risk elements. The evaluation Parametersare defined as: Awareness - Level of awareness of potential risk affecting the firm. -Likelihood of riskto affect the business goals of the firm adversely. Criticality - Level of impact of the identified risk on the success of business goals. Preparedness - Risk handling practices/ mechanisms already in place tohandle the risk.
- Determining Risk Importance*: Importance/Impact of individual risk element is established against individual sector based on the published corporate risk reports, in depth sector understanding by F&Steam and SMEs.
- **3. Calculating Maximum Sector Risk Score**: Weighted Sum of all risk elements based on their importanceto the respective sector.
- 4. Company Level*: All the Risk Index scores for companies in a sector are averaged to represent the sector; and sectors average to India. Risk Exposure is defined as the function of corporate's Risk Awareness and Probability of risk occurrence. Risk Management is defined as the function of an enterprise risk preparedness and criticality risk impact assessment.
- 9 | Pharmaceutical Sector Risk Report 2022



Defining the Risk Scale

We have selected 20 sectors to understand the current stand of our country today in terms of risk. Risk for various sectors is measured on the risk exposure scale and risk management scale.

A. ICICI Lombard Corporate Risk Exposure – Scale

Risk Exposure: The impact of any internal, external or strategic occurrence on the financial performance of an organization is defined as the corporate risk exposure. Risk has traditionally been seen as something to be avoided – with the belief that if behavior is risky, it's not something a business should pursue. But the very nature of business is to take risks to attain growth. Risk can be a creator of value and can play a unique role in driving business performance. Let's look at the risk exposure scale.

	Score, if less than 30 means there is very low risk exposure, and the sector has minimal exposure to overall risk.
	Score between 30 to 50 indicates low risk exposure and its risk exposure is within acceptable or tolerable limits.
	Score between 50 to 60 indicates moderate exposure, indicating corporate can balance the impact of overall risks up to a certain extent.
60 - 80	Score between 60 to 80 indicates High risk exposure, and its impact is very high in the industry in which the corporate operates.
	Score greater than 80 indicates very high-risk exposure. The corporate is unable to foresee risk incidents & probability of occurrence of these incidents may be extremely high.

B. ICICI Lombard Corporate Risk Management – Scale

Risk Management: Identification, Evaluation and Prioritization of corporate risks followed by wellcoordinated steps to minimize the occurrence of uncertainties in the foreseeable future is defined as the Corporate Risk Management. The risk management scale works in the opposite to that of the risk exposure scale. Let's look at the risk management scale.

	Score less than 40, means poor risk management The enterprise is unable to understand the concept of Risk management.
40 - 50	Score between 40 and 50 indicates the risk management is below par so there are inefficient risk management practices which is reactive to newer or unknown risks.
 50 70	Score between 50 to 70 indicates acceptable risk management. The corporate is prepared to handle known risk and the criticality of its risks are not severe.
	Score between 70 to 80 indicates superior risk management. Top class risk management practices have been employed to manage dynamic & Unknown risk.
	Scores above 80 indicate Exemplary risk management. The companies are overprepared in risk management practices and are proactive to emerging risks.



C. ICICI Lombard Corporate Risk Index – Scale

Risk Index: Risk Index is a measurement tool to gauge the level of Risk Exposure against Risk Preparedness. The score intends to give companies/Sector/Country access to an extensive and quantifiable metrics of risk management.

Let's look at the risk Index scale.

< 40	Score under 40 is ineffective indicating that the corporate has very high-risk exposure or very poor risk management practices or both.
40 - 55	Score between 40-50 is sub-optimal risk index indicating, not all risks are handled effectively. Risk management practices are likely dated or inefficient.
	Scores between 55-65 is optimal risk index indicating, most current risks are being handled effectively. Emerging risks associated with strategic initiatives need more diligence.
65 - 80	Score between 65-80 is superior risk index indicating, <u>Very</u> effective and efficient risk management practices. Well positioned to handle current and future risks across dimensions.
> 80	Score above 80 is over preparedness indicating, High investment in risk mitigation practices. Likely over-investment in one or more risk dimensions. Difficult to justify ROI.



India - Emerging Superpower with Optimized Corporate Risk Handling

Manufacturing sector contribution to India's GDP in 2022 stands at 17% and is expected to grow to 25% by 2025, the expected growth is attributed to various favorable schemes initiated by Government of India like 'Make in India', 'Digital India', Improved Road Infrastructure, implementation of modern technologies of manufacturing resulting in optimized and effective production, Also the pandemic has made business realize that they cannot just rely on a single manufacturing hub; hence notion of "China+1" is making the world realize the significance of India. China is in a trade war with the USA, which is positively shaping the role India will play in the global arena.



The below chart showcases the gradual increase in India's manufacturing exports.

Figure 1: India's Growth of manufacturing exports. (Source: Redseer)

Indian manufacturing sector is also focusing on electronics manufacturing like mobile phones, industrial electronics consumer electronics, etc. due to government initiatives the production has doubled since 2015.

Aerospace and defense sector in India have evolved significantly, Govt. of India have identified A&D as area of focus due to the belligerent neighborhood, steps like Make in India(Atmanirbhar Bharat) is helping the overall defense sector, however India still remains the largest importer of arms and ammunition, favorable policies and ease in regulations is helping the drone industry in India and many new start-ups and big players are entering in this space.

Urbanization is another phenomenon evolving in India and it is estimated that by 2030 more than 400 million people will be living in cities, due to this megatrend huge push towards realty and infra sector is observed which is also the growth of ancillary industries like metals, cement, water availability, sanitation, mobility etc., the government along with the private sector is working on multiple initiatives to manage the huge inflow.

India has observed a steady adoption towards EVs in recent years, though India adoption still remains very low in comparison to Europe, Canada, China, however all big auto players are coming with new lines of EVs, and significant strategic investment have been made. The adoption is primarily due to lower running

12 | Pharmaceutical Sector Risk Report 2022



costs, lower maintenance, zero tailpipe emissions, tax and financial benefits by the government, convenience of charging.

BFSI sector in India is showcasing a significant robustness in the time of global crisis, there is a growing demand for financial services as there is a gradual rise in income across income brackets, with a rapid increase in mobile penetration and internet availability more than 2100 fintech companies have emerged in India, the traditional banks are also adopting the digital technologies at a required pace, investment on making the systems secured from cyber threats is utmost priority. Policy support by the government in the union budget 2021-22 is taking up shape and is helping the BFSI sector in 2022 and coming years, like government approval of 100% FDI for insurance intermediaries have increased the FDI limit to 74% from 49%.

Healthcare sector is also continuously growing healthcare has become the one of the India's largest employers, employing around 4.7 million people, though in 2021-22 India only spends 2.1% of its GDP in healthcare, in the union budget 2022-23, US\$ 11.28 billion was allocated to the Ministry of Health and Family Welfare (MoHFW). there is still huge room for improvement in the overall healthcare system in India. Efforts towards having well trained medical professionals in India is top priority. There were exemplary development in the vaccine manufacturing by India, Bharat Biotech Covaxin and Oxford AstraZeneca's Covishield manufactured by SII, helped India get a protection shield against Covid. There is a plan by the government of India to infuse US \$ 6 billion to boost the healthcare infrastructure in India.

The IT/ITes sector is a key engine for fueling India's economic growth and contributing to 7.5% of India's GDP in 2021-22, the Big four IT firms in India have recruited over 1 million employees, As the world is moving towards era of digital economy Indian IT-sector will be contributing significantly towards this journey, the rollout of 5G communication technologies and adoption of new age technologies across industries; like AI, Robotics, Internet of Things will further increase the size of Indian IT sector.

Indian enterprises are also concerned about the risks emerging out of the growing economy and the globalization India is heading towards, its observed that Indian enterprises are taking significant steps towards risk management and keeping budget allocated to implement best in class risk mitigation practices.



India Showcasing an Optimized Risk Handling



Figure 2: Corporate India Risk Index 2022

Corporate Risk Index Score of 63 implies that Indian enterprises are handling the risk in an optimal way but still there is scope of improvement to get into superior risk handling territory, Indian enterprises have a well-defined risk management practice in place for inherent risks, however risk management can be improved further as a potential buffer against potential risk events arising from market & economy, operational and technology related Risk events, openness towards adoption of technology and having a well-defined risk management team was observed across enterprises in India.

Sectorial categorization across above stated five categories, it was found that risk management is getting a paramount importance in the growth strategy of every organization and all the organization fell either into 'Superior Risk Management' or 'Optimal Risk Management' category.

From a risk exposure front the intensity of impact due to market and economy related risks increased due to the heightened inflation, global recession, and geopolitical tensions though from a regulation point the sector specific policies by the government helped the industries. Some of the inherent risks exposure due to the operational aspect did not see a significant change as compared to previous year, however companies are adopting diversification, technologically enabling the supply chain, and creating better hedging against financial related risks, whose results will be seen in coming years.





Below is a broader categorization of sectors in terms of risk index:

Figure 3: Corporate India Risk Index 2022 Sector Score

Superior Risk Index

Superior risk handling was found in five industrial sectors: Telecom & Communication, Pharmaceuticals, Automotive & Ancillary, FMCG, Healthcare Delivery.

Optimal Risk Index

Optimal risk handling was found in 15 industrial sectors: Tourism & Hospitality, BFSI, Aerospace & Defence, Biotech & Lifesciences, Education Skill Development, Manufacturing, Media and Gaming, IT & ITES, Transportation & Logistics, Agriculture and Food Processing, New Age & Startup, Energy, Infrastructure & Realty, Chemicals & Petrochemicals, Metals & Mining.



Pharmaceutical Sector Insights 2022

The Indian pharmaceutical industry is an important contributor to the Indian economy and one of the largest pharmaceutical industries in the world. However, this industry faces several risks that can significantly impact its operations, profitability, and growth.

One of the most significant risks that the Indian pharmaceutical industry faces is regulatory risk. India's pharmaceutical industry is subject to several regulations and guidelines imposed by various national and international regulatory bodies. Changes in these regulations can have a significant impact on the industry's ability to manufacture and distribute products. The Indian pharmaceutical industry is also under increasing pressure to comply with international regulations, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), to export drugs from India to other countries. Any non-compliance with these regulations can result in heavy fines and damage to the reputation of the company. Therefore, the Indian pharmaceutical industry must keep up with these regulations to avoid any regulatory risk.

Another significant risk faced by the Indian pharmaceutical industry is intellectual property risk. India is known for producing generic drugs at a low cost, but this has led to several patent disputes with foreign pharmaceutical companies. As a result, the Indian government has been pushing for stricter patent laws to protect the interests of foreign pharmaceutical companies. This has led to increased pressure on Indian pharmaceutical companies to develop new drugs instead of relying on producing generics. Indian pharmaceutical companies also face the risk of patent infringement lawsuits, which can result in substantial penalties and loss of revenue. Therefore, the Indian pharmaceutical industry must navigate the intellectual property landscape carefully to avoid any legal risk.

Competition risk is another major risk faced by the Indian pharmaceutical industry. The Indian pharmaceutical industry is highly competitive, with a large number of domestic and foreign players. The increasing competition has resulted in price pressure, reduced margins, and a need for innovation and differentiation to stay ahead. In addition, many Indian pharmaceutical companies are focused on the domestic market, which is highly price-sensitive, leading to intense competition. To mitigate competition risk, the Indian pharmaceutical industry needs to focus on innovation and differentiation, especially in areas such as biotechnology and research and development, to maintain a competitive edge.

The Indian pharmaceutical industry also faces supply chain risk. The pharmaceutical industry is highly dependent on raw material imports from China and other countries. Disruptions in the supply chain can lead to delays in production and delivery, affecting the industry's ability to meet demand and resulting in financial losses. Moreover, the COVID-19 pandemic has highlighted the vulnerabilities of the pharmaceutical industry's global supply chain, with disruptions in logistics and transportation leading to delays in drug delivery. To mitigate supply chain risk, Indian pharmaceutical companies need to diversify their supplier base, invest in contingency planning, and strengthen local manufacturing capabilities.



Cybersecurity risk is another significant risk faced by the Indian pharmaceutical industry. The pharmaceutical industry collects and stores sensitive patient data, making it a prime target for cyber-attacks. Cyber-attacks can lead to loss of data, damage to reputation, and legal and financial liabilities. As the industry becomes more digitized, the risk of cyber-attacks will increase, making it crucial for Indian pharmaceutical companies to invest in cybersecurity measures to safeguard their data and operations.

Finally, environmental risk is a growing concern for the Indian pharmaceutical industry. The pharmaceutical industry is a significant contributor to environmental pollution due to the release of chemicals and pharmaceutical waste into waterways and the atmosphere. Strict environmental regulations and pressure from stakeholders to adopt sustainable practices are placing greater pressure on the industry to reduce its impact on the environment. To mitigate environmental risk, Indian pharmaceutical companies need to adopt sustainable manufacturing practices, invest in eco-friendly technologies, and comply with environmental regulations.

In summary, the Indian pharmaceutical industry faces several significant risks, including regulatory, intellectual property, competition, supply chain, cybersecurity, and environmental risks. Managing these risks effectively is critical to the industry's long-term success and sustainability. The industry must continue to innovate and differentiate itself while complying with regulations and adopting sustainable practices to reduce its impact on the environment.



Pharmaceutical Sector Risk Index 2022 Vs 2021



Figure 4: Detailed Comparative Analysis 2021 Vs. 2022

Pharmaceutical Sector Risk Index 2022 Vs 2021

India Risk Index (Optimal Risk Handling): The overall Risk Index for pharmaceutical sector negligibly rose from 62 to 63 in 2022, this was driven by significant growth in concerns relating to supply chain, technology, crime and security risk. The most significant increase in risk happened due to the increase in regulatory risk as 2022 saw the cancellation of licenses of multiple Indian FDA approved manufacturing facilities.

There was no significant change in the operational and physical risk and other risks. This was due to the modestly rising inflation primarily led by the increase in fuel prices and the change in regulations due to the launch of the New Draft Policy on Clinical Trials. Operation risk reduced only slightly due to the continued shortage of infrastructure facilities and high risk of worker accidents.

Pharmaceutical sector Risk Management 2022 Vs 2021

There was a significant increase in the India Risk Management, rising to 74 from 65 in 2022. Factors like Inflation, Taxation and Regulatory Risks faced major disruption due to the fuel price hike and post Covid era effects. A huge increase in the risk management is therefore due to greater government support and involvement and macro-economic factors like easing inflation, with greater focus on IP Laws and reduced industrial activities.

Pharmaceutical Sector Risk Exposure 2022 Vs 2021

Pharmaceutical Sector Risk Exposure went up due to heighten geopolitical tensions, global slowdown in GDP growth resulting in reduced industrial activities, all-time low rupee valuation and high raw material dependency. The Risk exposure for pharmaceutical sector went up to 68 vs 62 in 2021. The Market and Economy dimension showed the highest increase in the risk exposure, the major increase is accounted due to the slowed-industrial activities resulting in financial risks and geo-political tensions arising due to the Russia-Ukraine tensions.



Key Highlights

We Risk Dimension Analysis: Market and Economy

Risk Exposure Score: 64

Risk Management Score: 69



Inflation

- Inflation rate in India has hovered around
 6.35% to 6.52% in India since January 2023.
- Operating profit margin has contracted from 23.5% (Q1 FY 2022) to 19.9% (Q1 FY 2023) on the back of rising inflation and pressures in pricing
- Inflation particularly in Europe has impacted the cost of imports of key starting materials (KSMs)/ active pharmaceutical ingredients (APIs), including excipients, especially acute therapies.
- Increasing energy costs because of geopolitical issues, where fuel and power costs have increased five times faster than overall consumer prices in the last 20 months, has affected the margins of companies severely.
- Increased employee costs because of increasing living standards, and lower availability of skilled manpower has also caused the employee welfare expenditure to increase drastically.

Taxation

- Implementation of GST has been a positive move for the industry with the removal of cascading effect of multiple taxes applied on One Product, in the previous VAT structure. (Source: ClearTax).
- Traditional Cost and Distribution Model will get replaced by supply chain efficiencies due to the discontinuance of the Central Sales tax and interstate transactions between two dealers will become tax neutral. (Source: SAG Infotech).



- Reduced corporate tax on companies in India from 34% to 25% has been a favorable move, promoting greater incentive for foreign companies to settle in India.
- Some particularly favorable taxation policies have been- (Source: EY-FICCI report).
- Full deduction in respect of revenue expenditure and capital expenditure on R&D.
- Weighted tax deduction in respect of in-house R&D facility approved by Department of Industrial and Scientific Research. This deduction was earlier allowed at 200% since 2010 and was reduced to 150% from 2017 and further reduced to 100% from 2020.
- Further, amount paid to an approved research association, college or university for scientific research was eligible for deduction @ 150% from 2010 and has been reduced to 100% from 2020
- Amount paid to an approved company for scientific research was eligible for deduction @ 125% from 2009 which has been reduced to 100% from 2018
- Government clarification on the Income tax Act for the freebies and gifts given to doctors, excluding them as deduction while computing business income, is a good move ensuring safety in drugs market.

Regulatory Risks

- 50% of India's Pharma industry is composed of export demand for generics and antiretroviral drugs for Acquired Immune Deficiency Syndrome (AIDS), primarily to US, UK, South Africa, Russia and Brazil, needing companies to meet international quality standards and applying for multiple regulatory approvals.
- 60 Official Action Indicated openings for Indian Pharmaceutical facilities in the past 3 years and 5 OAIs particularly in last year alone with 2 of them being denied import rights, define the difficulty in managing regulatory risks.
- Inspection outcomes of USFDA, forming the globally pioneering regulatory body on pharmaceuticals, affects export demand in multiples unrelated geographies as well.
- Introduction of New Drugs and Clinical trials Rules (2019) has enabled a regulatory framework for drug trials in the country opening opportunities of research and development of novel drugs.
- Pricing control measures implemented through the National Pharmaceutical Pricing Authority in India or other authorities outside India, including the recent downward revision of some of the most purchased formulations of paracetamol and amoxicyillin, negatively impact the profitability of the manufacturers, given the rising prices of APIs.
- These price regulations have caused a 75% decline in new launches post 2011, according to an IMS Health Study.



Foreign Exchange Rates

- Given that more than 50% of Indian Pharma Sector value is derived from exports, revenue is highly susceptible to adverse foreign exchange fluctuations.
- India is heavily dependent on China and European countries for supply of APIs/ KSM, importing 70-80% needs from these countries, making cost of these materials highly subject to risks of foreign exchange fluctuations.
- India's import of medical equipment has grown five-fold over the last six years, which is alarming, and is fueled by the government's move to keep the basic tariff on such imports to be between 0-7.5%.
- This overdependence is highest in the electronics and equipment category which is primarily composed of MRI machines, CT scanners, ultrasound machines, X-ray machines, cancer diagnostics, dental drills and minimally invasive surgical devices.
- Moderately depreciating rupee over the past year against major currencies, has made it favorable to explore foreign markets for generating revenue with China, Japan and Canada emerging as the leading markets to tap.

Competitive Risk

- Price competition in generic formulations is the highest within the country as well as globally.
- Indian pharmaceutical industry environment is globally cost competitive, with the cost of setting up an FDA-inspected plant being 50% less than in a developed country. Operation and production costs run 40 to 70% lower than in developed nations (factors include local equipment sourcing, tax incentives and a focus on process innovation) and labor costs are on average 60 to 70% less than developed countries.
- Globally burgeoning M&A activity for consolidation and synergy exploration, in the pharmaceutical sector, has led to price erosion. The number of deals went over 62,000 in 2021 up 57% from 2020, totaling in value to a whopping \$5.1 trillion.
- The pharma industry faces stiff competition from countries like Vietnam and Malaysia as well, which can only be overcome with special focus on development of innovation facilities at home. There are some 3,000 pharma companies in India with 10,500+ manufacturing facilities, offering 60,000 generic brands, signifying intense competition in the sector.
- Efficiency improvement alongside R&D focus can help overcome the loss out of non-exclusive generics and biosimilars segment in the industry.



Risk Dimension Analysis: Technology

Risk Exposure Score: 67

Risk Management Score: 66



Innovation Risk/ Obsolete Technology

- Indian Pharmaceutical industry has primarily been involved in creating formulations and production of generics rather than innovating new products.
- The primary reason being the cost and the time period involved, makes it really difficult for companies to undertake such process. 90% of molecules that companies start with, do not go anywhere. Even on the generic products side, one in two complex products do not end up succeeding due to complexity.

India has a lot of scope for driving innovative pharmaceuticals in the field of biosimilars and clinical development.

Innovation risk is high for the Indian Pharmaceutical industry, given the stiff competition from the developed countries. The prime reasons for lack of R&D focus in India is two-fold:

Lack of motivation

- 1. Time bound faculty promotions resulting in little incentive for clinicians to conduct research
- 2. Higher regards and monetary benefits for clinical specialists vs. scientists
- 3. Lack of training curriculum in conducting systematic research and documenting observations in medical practice.

Limited Resources

- 1. Paucity of funds for biomedical research & development
- 2. Lack of sophisticated research infrastructure
- 3. Clinicians overburdened with patient care in most large hospitals
- Research and development expenditure as a percentage of revenue for Indian companies is 7.8%, whereas for global pharma companies it is 16.5%
- 22 | Pharmaceutical Sector Risk Report 2022



Data Compromise

- Indian healthcare and life sciences companies are grappling with largest volumes of cybersecurity and data security breaches among all industry sectors. In 2021, specifically, the pharmaceutical sector reported the third-highest average cost of a data breach after healthcare and financial services.
- The emergence of digital technology during the COVID pandemic amplified the risk of cyber-attacks, particularly in the pharmaceutical sector with access to vast volume of sensitive data
- Top 3 data protection issues facing the pharma industry are employee negligence, Internet of Things (IoT) and Third-party vendors.
- Given employees are the primary drivers of data breaches across the globe it is imperative to provide them, educational training and awareness of common attack methods for staying meticulous against hackers.

Risk Dimension Analysis: Operational and Physical

Risk Exposure Score: 63

Risk Management Score: 62



Critical Infrastructure Failure / Machine Breakdown

- Lack of critical infrastructure in the pharma sector leads to overdependence on import of equipment from outside the country and leads to lower research & innovation output.
- This lack of infrastructure also prompts students to pursue their studies from outside India. In 2018, more than 750,000 Indian students were studying abroad and about 28% of these students went to the US. More than 70% of Indian students in the US are in STEM field.
- India presently houses just 8 R&D centers of top global life sciences companies compared to 79 in Europe, 73 companies in US and 21 in China, which could prove to be a big untapped area of revenue for pharma companies, given India's huge population provides a genetically diverse group for drug trials coupled with its low-cost proposition.



- India's worst performance is in the infrastructure sub-component while calculating the score for Global Innovation Index, making it fall behind countries like China, Malaysia, Vietnam and Thailand.
- Non-availability of storage and transportation infrastructure along with requisite high-end, sophisticated machinery at research facilities hinder innovation in India.
- Gol's has introduced a Scheme on Promotion of Bulk Drug Parks for financing Common Infrastructure Facilities in 3 Bulk Drug Parks with financial implication of INR 3,000 crore for 2020-2021. Assistance under the scheme will be admissible for such facilities by State Government in Bulk Drug Parks. Parks will have common facilities such as solvent recovery plant, distillation plant, power and steam units, common effluent treatment plant.
- Pharmaceutical companies use reactors, dryers, and sterilizers in their plants, a breakdown in one of them can stop production. The lack of an effective maintenance system can lead to:
 - 1. Excessive machine breakdowns.
 - 2. Shortened life-span of the facility.
 - 3. Sub-standard products.
 - 4. Delay in delivery dates.
 - 5. Disproportionate investment in spare parts and maintenance materials.

Environmental Risk

- Global pharma's emission intensity was 48.55 metrics tons of carbon dioxide equivalents per million dollars of revenue which was 155% of the automotive industry in 2015.
- Pharma companies' primary sources of energy consumption include HVAC systems and machinery. With the need for maintain uniform temperature and clean environment, companies need reliable sources of energy which need to be clean.
- CO2-neutral energy or installing solar panels and using heat pumps instead of natural gas-fired heating, could be some of the better alternatives for clean energy sources.
- Not just this, use of more efficient motors and optimized air compression systems, which lead to greater manufacturing capacity, by the implied reduction in time for cleaning and disinfection, could be explored.
- Greenhouse gases are heavily emitted in this industry at every stage of the supply chain, right from sourcing or producing APIs to disposal of expired medicines. The biggest greenhouse emitting stages include raw material production, cold chain storage, packaging & transport, and disposal of biowaste.



- SEBI in India has mandated pharma companies in Top 1000 listed companies to provide details of material environmental, social, governance risks and how to mitigate them along with the financial implications under a new BRSR format form 2023.
- There needs to be reduction in usage of plastic, foil, or cardboard in packaging. Aurobindo Pharma's measures have emerged as novel and a frontrunning initiative, by implementing reduction of bottle sizes, removal of filler (cotton/rayon/polyester coils), downsizing of wall thickness of bottles and forming materials of blisters, thermoform blisters in place of 3/4 layers of cold form blisters which reduces pack size by 60 percent and material consumption by 80 percent. In secondary packaging, the company replaced physical medication guides with electronic copy in agreement with the US Food and Drug Administration (FDA) and pharmacists providing print of electronic copy, as per patient demand.
- Industry partnerships should be initiated to overcome such major challenges like antimicrobial resistance in discharged untreated effluents from manufacturing plants.
- Use of technologies like cloud computing, blockchain, APIs in promoting better information sharing, quality management and employee empowerment needs to be focused on.
- Eliminating single-use plastics, a common feature of the products used in hospitals and other healthcare facilities, should be a key focus for the industry. One non-profit organisation for sustainable healthcare, Practice Greenhealth, reports that 25% of waste generated by a hospital is plastic. While 15% of healthcare waste is classified as hazardous, there is scope to reduce waste in the remaining 85%, in which packaging materials are a significant component.
- Adoption of EV vehicles for transportation and rethinking architectural designs of manufacturing and research facilities could help in reducing the overall carbon footprint of the industry.
- According to a Medical Device Network report on the 26th UN Climate Change Conference of the Parties (COP26), if the health sector were a country, it would be the fifth largest producer of carbon emissions in the world. The same report notes that 71% of healthcare emissions are linked to supply chain issues the production and transportation of disposable drugs, chemical agents and medical devices.
- Continuous manufacturing in place of batch manufacturing, local sourcing and investment in green chemistry to produce less hazardous chemicals for drugs should be explored.
- Water is a in high requirement of the pharma industry with around 2/3rd of it being utilized for cleaning processes, and companies move from traditional approaches like sterilization to more modern ones such as ozone cleaning, water usage in this respect would become nominal to none. Recycling usage of water through rainwater harvesting can also help companies adopt a Zero Liquid Discharge (ZLD) approach that recycles wastewater and reduces contaminants to solid waste.



Commodity Price Risk

- Commodity price risk exists for the pharma industry in their activity of APIs/KSM acquisition as a raw material for production of final formulations, which usually follow a commodity cycle.
- API imports have recently faced a price hike of approximately 12-25%, primarily the ones from China and Australia.
- Globally fuel prices have shot up 40% in the past 2 years, while in India they have reduced 2.12%, signifying no major risk to transportation costs.

Portfolio Risk

- Pharma sector offers opportunities for investors with high-risk appetite, given its underperformance over the past year.
- Nifty Pharma Index has fallen 13% over the past year, with the market leader effecting this fall in the index by a fall in value of 23%. This unequal market capitalization of the pharmaceutical companies, leaves little bets to be made on the sector as a whole, other than tactical allocations to specific companies.
- Indian Pharmaceuticals market is expected to grow at 11-12% leading to a \$130 billion sectoral opportunity, which can help in long-term modest wealth creation for investors as the index has returned 36% in the last 5 years.
- Portfolio management techniques like the Economic Analysis Method, Data Envelopment Analysis (DEA), Real Option Valuation (ROV) Method, and Decision Tree Method could prove helpful for product portfolio management for pharma companies. Research and development portfolio requires evaluation of expenditure, clinical risk-benefit, intellectual property, peak sales, profit, and other factors to move ahead.

Workplace Accident

- In GlobalData's poll of industry professionals, health and safety was identified as the most pressing social issue facing pharma by close to half of 133 respondents (49%), followed by human rights (26%).
- The workplace risks in a pharmaceutical unit can be classified under 3 major headers, biological hazard (infection from pathogens through contamination), Chemical hazard (flammable items, hazardous waste) and Physical hazard (hypothermia, hyperthermia.
- Indian Manufacturing is riddled with workplace accidents, with an average of seven accidents reported per month, killing 162 workers. Reactor fire, gas leakage and improper & unsafe disposal of waste are the most common causes.



- Frequent mishaps in cluster pharma units, including the most recent one at JN Pharma City due to leakage of toluene, leading to death of 4 people and one severely injured employee, raise concerns about safety of workplace in world class production units in India. More than 10 such accidents had been reported in the year, in this unit.
- Lack of proper regulatory mechanism has caused pharma units to discharge effluents in nearby water bodies leading to marine pollution and depletion fish.
- Emergency response system absence and non-establishment of protocols regarding safety checks including regular site inspection, let these facilities go unprepared for any exigency.

Human Resource

- Use of digital systems with consolidated data access for employees helps improve operational efficiency and productivity.
- Sun Pharma's experience with adoption of HR process automation and greater transparency for employees has helped them reduce their transaction time for HR and IT by 66%, across geographies and work divisions.
- Attrition rate in the industry has increased from 10% in 2020 to 20% in 2021.
- Even though India has a 900-million working age population strength, its labour force participation rate is still just 41.3%, compared to 63% in China.
- Demand for talent in pharma is increasing at all levels, but there is significant skill shortage in the workforce, given the disconnect between industry and academia alongside the focus on rote-learning techniques.
- Absence of an academic institution for first line jobs in Pharmaceutical manufacturing makes it extremely difficult for any addition to talent pool, leading to just salary hikes and more attractive packages for a negligibly expanding pool.
- India needs atleast 2.5 million skilled people by 2022 to maintain high growth rate of the industry.
- Upskilling facilities and constant L&D expenditure by companies can ensure better workflow and career progression for employees.
- As of 2018-19, only 35% of Indian higher education institutions offered postgraduate programs and just 2.5% offered PhD programs. India is also behind other countries in terms of total number of researchers according to recent Brookings India report, India has only 216.2 researchers per 1 million population compared to 1,200 in China, 4,300 in the US and 7,100 in South Korea.
- National Employability Enhancement Mission of the Government of India focuses on resolving the skill gap in the industry.
- 27 | Pharmaceutical Sector Risk Report 2022



Financial Risk

- Financing constraints for research & development of new drugs has been a big hurdle in India moving up the pharmaceutical value chain.
- Indian Government's investment on research & development has stayed constant for the past two decades at 0.7% of the GDP, which is way lower when compared to the global average of 2.3%
- According to a study at LSE, the cost of development of a new drug costs around \$1.5-2 billion and would take up a time period of 10-15 years, before it is fit for commercial usage, which is too difficult to be undertaken by any private company, highlighting even more the need for public spending on such research and development.
- Out of \$192 billion VC/PE capital investment in India, just 3% has been directed towards pharmaceutical sector, 50% of which was in the previous year alone.

Breaches of International Law

- Cough Syrups made by Maiden India have been accused of causing death of 69 children in Gambia and WHO has issued medical product order asking regulators to remove the company's goods from the market. Laboratory analysis of four Maiden products Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup showed "unacceptable" amounts of diethylene glycol and ethylene glycol, which can be toxic and lead to acute kidney injury.
- FDA has flagged a laundry list of production problems at Intas' plant in Gujarat, India, despite certain employees' alleged efforts to obscure the truth.
- Patent-law related cases have been the major breach of law for pharma companies.



Risk Dimension Analysis: Crime and Security

Risk Exposure Score: 64

Risk Management Score: 68



Cyber-crimes

- Pharma sector has witnessed 9 cyberattacks since 2021, out of which two were publicy listed company attacks, within a month.
- Lupin, Serum Institute, Bharat Biotech, Dr Reddy's Labs, Abbot India, Patanjali and All India Medical Sciences were some of the major organizations targeted by cyberattacks during that phase reportedly from adversaries in Russia, China and North Korea.
- Absence of a regulatory framework addressing data security like what RBI prescribes for BFSI, is one of the major failures.

Counterfeiting

- According to WHO 2017 report, about 10.5% of medicines sold in low and middle-income countries, including India, are substandard and falsified. With Globalization and the increase in healthcare costs, the probability of counterfeiting increases manifold.
- Proliferation of such online marketplaces has brought greater customer ease, but it also enables a higher volume of counterfeit or sub-standard products to go undetected. According to research published by the non-profit Authentication Solutions Providers' Association (ASPA), which promotes anti-counterfeit awareness, instances of substandard and falsified (SF) medical items increased by about 47% between 2020 and 2021.
- In addition to increased morbidity and mortality, counterfeit products might also worsen drug resistance and lead to treatment failure. Fake medications place the user's health at grave risk; but they also adversely hit the entire pharma industry's reputation, operations, and finances.
- The World Health Organisation (WHO) also estimates that there are over one million deaths per annum from counterfeit and substandard drugs, causing \$21 Billion of global financial impact.



- ASPA has recommended using a multi-technology approach, including layers of overt, covert, digital, and analytical technologies to address counterfeiting, tampering, and diversion through a strategy of interdiction, authentication, and digital verification.
- The use of technology such as track and trace systems, barcoding, and blockchain can also help to prevent counterfeiting and ensure product authenticity.

Threat to Women's Security:

- In dollars, only one percent of the approximated US\$200 billion spent on healthcare research and development focuses on women's health. As a result, half the population is left behind the health innovation curve.
- Women in India often face harassment and violence in public spaces, including public transport, which can limit their ability to participate in public life and access economic opportunities.
- A survey conducted by the Thomson Reuters Foundation in 2018 ranked India as the most dangerous country in the world for women, with incidents of sexual violence, harassment, and trafficking being major concerns.
- In public transport, women face various forms of harassment and violence, including groping, stalking, verbal abuse, and assault. According to a survey by Safetipin, a mobile app that crowdsources data on safety, 85% of women in Delhi have experienced harassment on public transport.
- To address these issues, the article suggests various strategies, including improving lighting, increasing police patrols, and providing training for transport staff on gender sensitivity and responding to harassment.
- Other recommendations include the use of technology such as panic buttons, CCTV cameras, and GPS tracking to improve safety, and the provision of women-only spaces in transport and public spaces.
- In a 49.5 million strong pharma workforce, just 11% is female. R&D has 17 per cent female representation, manufacturing has 12 per cent, sales & marketing has a mere 5 per cent while corporate functions stand at 21 per cent.
- DBT or the Department of Biotechnology has started new efforts to encourage young women's participation in Science and Technology. BioCARE is a scheme that allows women researchers, both unemployed and employed to take up research. They also have special awards to recognise the excellence in research & innovation by women scientists also known as Janaki Ammal-National Women Bioscientist Award.
- A report by McKinsey Global Institute states that India could add up to \$700 billion to its GDP by 2025, by paying more attention to the skewed gender equality ratios.



Terrorism

- Narco-terrorism is a rising threat in regions like Jammu and Kashmir, where insurgent groups may use drugs to fund their activities. This can lead to an increased risk of violence and unrest, which can impact the safety and security of transportation and logistics operations in the area.
- Cases of terrorist groups resorting to ransom attacks and selling counterfeit drugs for funding illicit activities has been on the rise.
- According to the latest research by New Delhi-based think tank CyberPeace Foundation, nearly 80 lakh attacks were recorded between October 1 and November 25 on the healthcare sector-based 'Threat Intelligence Sensors' network specifically simulated in India.

Risk Dimension Analysis: Natural Hazard and Event

Risk Exposure Score: 60

Risk Management Score: 63



Natural Hazards:

- India is one of the ten most disaster-prone countries of the world.
- The natural geological setting of the country is the primary basic reason for its increased vulnerability. The geo-tectonic features of the Himalayan region and adjacent alluvial plains make the region susceptible to earthquakes, landslides, water erosion, etc.
- Natural disasters and reduced energy consumption are crucial in regions of severe and recurring natural disasters. Several characteristics, such as higher population density, vulnerable land, and the total population affected by a disaster, are likely to influence an area's energy demand.
- It can be challenging to recognise fire hazards in chemical processes including active pharmaceutical ingredients (APIs), which are present in pipelines and process vessels. Without adequate analysis, the interaction of reactive chemicals under usual or unusual circumstances can also become a problem.



Explosion is a significant concern in the pharmaceutical sector following a fire. While handling, storing, and processing pharmaceutical raw materials and finished items, there is a risk of explosion. Powders can produce lingering dust clouds that serve as fuel for main explosions that might be started by a little spark. A secondary explosion results from the quick burning of ignited suspended particles. The increase in explosive pressure that follows when such an explosion takes place in a sealed area, such a fluidized bed dryer, mixing vessel, or storage vessel, might result in severe damages.

Pandemic and other global epidemic diseases

- During the COVID-19 peak, incidents of counterfeit medical products were observed in 23 out of 29 States and 7 Union Territories of India.
- India's import of Bulk Drugs declined by 24% due to the pandemic and its reliance on China

Risk Dimension Analysis: Strategic Risk

Risk Exposure Score: 56 Risk Management Score: 58



Resource Scarcity

- Scarcity of talented workforce in the sector, creates higher opportunities of salary hikes from attrition.
- Scarcity of learning facilities and laboratories for students pursing higher studies in biosciences, perpetuates this scarcity.
- Lower availability of APIs/KSM within the country creates issues of import sourcing which leads to the implications of geopolitical scenario on the industry
- Lack of connect between industry and academia, creates gap in research opportunities and innovation potential of the country.

Public Sentiment

Indian Pharmaceutical industry is treated with great respect not just in the country but globally by developed nations, because of its mass-production capabilities.



- Given the importance of the industry, the government has devoted huge resources in providing developmental impetus to the industry.
- This positive image is also marred sometimes by the incidents of defective medicine production, mistreatment of workers in production facilities and non-compliance with regulatory standards.

Failed/ Hostile M&A

- Pharma industry witnessed 16 deals during 2022, totaling to a value of around \$1 billion, the highest in a decade. Private equity has been the major financiers for such acquisitions.
- Deals were mostly local manufactures buying out brands in India to diversify away from the beaten up US generics market
- The YTD (year-to-date) 2022 deal volumes are on par with YTD 2021. On the other hand values saw a 47% increase.





ICICI LOMBARD: Key Solution Offerings

Property

a. Businesses are always prone to risks and fire eruption and fire insurance provides a comprehensive protection against damages caused due to fire explosion and other risks. Besides fire related perils, it also protect damages caused due to any natural calamity, bursting of water tanks, theft etc. The built in covers include alterations or extensions, stocks on floater basis, temporary removal of stock, cover for specific contents, start-up expenses, professional fees, costs for removal of debris etc

b. Solutions

- i. **Property Loss Prevention exercise** We have developed the methodology of Property Value Added Services for corporate customers which focuses on technical engagement with detail risk visit, followed by benchmarking of the risk (Industry Risk Profiling).
- **ii. Fire Hydrant IoT** Fire hydrant online monitoring devices use IoT to monitor fire hydrants and assure their availability in emergencies. We've helped multiple corporate customers maintain and monitor this important fire safety component in real time.



Marine

- a. We offer specially curated plans for covering the risk of theft, malicious damage, shortage, and non-delivery of goods, damages during loading and unloading, and mishandling of goods/cargo
- **b.** Marine Cargo insurance primarily covers loss during transit caused due to fire, explosion, hijacks, accidents, collisions, and overturning
- c. Solutions
 - i. **GPS Device Tracking**: With the help of our advance GPS devices we can have bird eye view on the consignment and vehicle from anywhere in the world. OurSAAS allows us to track and get the visibility of the vehicle on the basis of our requirements which is fully customizable







a. Comprehensive general liability:

- i. This policy is important for every small and medium sized businesses to protect the insured entity against claims arising out of legal liability where they are heldresponsible for third party bodily injury or property damage due to insured's business, premises or products. It should be taken by every new business as it covers all risk a business may face.
- b. Cyber With cyber risk steadily increasing, security/ data breaches affect millions of records a year. Cyber Risk insurance coverage is designed to help an organization mitigate its risk exposure by offsetting costs involved with recovery after a cyber-related security breach or similar event.

c. Solutions

- i. Simulated phishing tests Simulated real looking phishing tests and record employee behavior to phishing attacks along with training collateral in form of co-brandable posters, infographics and videos
- **ii. Cyber maturity assessments** Assess the security posture of your organization and identify the potential risks with our assessment based on ISO 27001 Control measures for Information security
- iii. D&O The need of Directors & Officers Insurance is more than ever before. Any breachor non-performance in the duties can result in claims against directors, officers and employees by reason of wrongful act and need to incur various expenses like defense costs, damages or compensation and other incidental costs. This can affect company's growth and performance.







Group Health

a. Employees are the backbone of an organization and the most valued asset. OurGroup health insurance product is designed to offer health coverage to suit employees of all business types ranging from small & medium enterprises to large organizations.

b. Solutions:

- i. IL Take Care AI enabled mobile app for employees
- **ii. Health assistance services** Health Assistance is a dedicated medical care service that assists you in all your health related queries for identifying specialist/hospital/fixing an appointment with doctors/nutritionist /facilitating2nd opinion
- iii. Tele Consultation Hello Doctor
- **iv.** The insured is eligible to avail unlimited General Physician consultations for routine health issues over the phone by aqualified doctor
- v. Diagnostics & pharmacy services Book a lab test or home delivery of medicines





Bibliography

https://health.economictimes.indiatimes.com/news/pharma/persisting-cost-inflation-and-pricing-pressures-impact-pharma-industry-icra/95256062 https://www.downtoearth.org.in/news/energy/fuel-power-costs-in-india-rose-five-times-faster-than-overall-consumer-prices-from-january-2021-august-2022-rbi-87784 https://cleartax.in/s/impact-of-gst-rate-on-pharmaceutical-industry https://www.thehindubusinessline.com/news/government-tightens-noose-around-pharma-companies/article64968421.ece https://www.businesstoday.in/industry/pharma/story/failure-to-meet-usfda-compliance-can-endanger-indian-pharma-companies-us-generics-business-new-report-warns-3565/4-2022-12-15 https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/costs-of-127-medicines-set-to-go-down-post-nppas-5th-price-cap/articleshow/96416516.cms http://pharmabiz.com/NewsDetails.aspx?aid=89417&sid=2 https://www.cnbc.com/2022/05/27/india-needs-to-fill-china-gaps-to-become-the-pharmacy-of-the-world.html https://www.washingtonpost.com/sf/brand-connect/makeinindia/indias-low-pharma-costs-are-good-for-drug-companies-good-for-consumers/ https://www.aurobindo.com/api/uploads/annualreports/Aurobindo-Pharma-AR-2021-22-4.pdf https://www.forbes.com/sites/forbesbooksauthors/2021/12/03/how-green-is-big-pharma/?sh=6ae7742c3207 https://health.economictimes.indiatimes.com/news/pharma/navigating-indias-green-manufacturing-odyssey/96384329 https://datwyler.com/files/pages/data/downloads/esg-report-2022-esg-in-pharma/b366277519-1670401476/datwyler.com_esg-report_2022_esg-in-pharma.en.pdf https://www.businesstoday.in/opinion/columns/story/how-pharma-companies-are-practicing-authentic-esg-towards-meeting-their-sustainable-goals-355040-2022http://www.pharmabiz.com/NewsDetails.aspx?aid=155481&sid=1 https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-companies-are-paying-up-to-25-more-for-china-apis/articleshow/96384401.cms https://www.livemint.com/news/india/india-contained-fuel-price-rise-developed-nations-saw-a-jump-govt-11662774275189.html https://www.moneycontrol.com/indian-indices/nifty-pharma-41.html https://pharmaoffer.com/blog/3-risks-of-working-in-pharmaceutical-manufacturing/ https://www.industriall-union.org/serious-concerns-remain-about-health-and-safety-in-india https://timesofindia.indiatimes.com/city/visakhapatnam/jn-pharma-city-units-sit-on-tinderbox-as-accidents-rise/articleshow/96558115.cmshttps://www.forbes.com/sites/sap/2022/10/12/sun-pharma-rises-above-global-competition-with-a-transformed-hr-experience/?sh=707cb1ba5cba https://hr.economictimes.indiatimes.com/news/workplace-4-0/talent-management/how-pharmaceutical-industry-is-dealing-with-talent-crisis/88909378 https://www.lexology.com/library/detail.aspx?g=51950483-f37d-44fa-ab1f-f009c359f12c https://www.reuters.com/world/africa/us-cdc-concludes-cough-syrups-likely-blame-childrens-deaths-gambia-report-2023-03-02/#:":text=LONDON%2C%20March%202%20(Reuters),and%20Prevention%20and%20Gambian%20scientists. https://www.fiercepharma.com/manufacturing/burn-after-reading-fda-blasts-intas-cascade-failures-after-investigators-find-heaps https://www.mckinsey.com/featured-insights/future-of-asia/india-as-a-pharma-innovation-hub-an-interview-with-dr-reddys-g-v-prasad http://www.pharmabiz.com/NewsDetails.aspx?aid=149682&sid=1 https://ciso.economictimes.indiatimes.com/news/after-ipca-laboratories-pharma-major-aarti-drugs-hit-by-ransomware-attack-data-leaked-on-dark-web/94913796 https://timesofindia.indiatimes.com/blogs/voices/fighting-the-issue-of-counterfeiting-in-indias-pharmaceutical-industry/ https://timesofindia.indiatimes.com/blogs/voices/counterfeit-drugs-a-major-public-health-threat/ https://www.financialexpress.com/healthcare/pharma-healthcare/what-is-indian-pharma-doing-to-counter-the-rising-menace-of-counterfeit-drugs/2492138/ https://themedicinemaker.com/business-regulation/a-history-of-missed-opportunity https://timesofindia.indiatimes.com/blogs/voices/how-women-are-bridging-the-gap-in-the-pharmaceutical-industry/ https://www.business-standard.com/article/current-affairs/indian-pharma-firms-at-high-ransomware-attack-risk-in-2021-report-120122300776_1.html https://www.marsh.com/content/dam/marsh/Documents/PDF/asia/en_asia/Risk_Consulting_for_Pharmaceutical_Industry.pdf https://www.legal500.com/developments/thought-leadership/impact-of-covid-19-on-the-pharmaceutical-industry-in-india-2/ https://www.cgdev.org/sites/default/files/essential-medicines-supply-chains-press-scan-India-manufacturing.pdf http://www.pharmabiz.com/ArticleDetails.aspx?aid=135427&sid=9 https://www.businesstoday.in/magazine/30th-anniversary-special/story/how-covid-19-has-opened-up-new-opportunities-for-pharma-firms-321693-2022-02-15

Disclaimer:

ICICI trade logo displayed above belongs to ICICI Bank and is used by ICICI Lombard GIC Ltd. under license and Lombard logo belongs to ICICI Lombard GIC Ltd. ICICI Lombard General Insurance Company Limited, ICICI Lombard House, 414, P. Balu Marg, Off Veer Savarkar Road, Near Siddhi Vinayak Temple, Prabhadevi, Mumbai 400025. Toll Free: 1800 2666 Fax No: 022 61961323 IRDA Reg. No. 115 CIN: L67200MH2000PLC129408

Customer Support Email Id: customersupport@icicilombard.com

Website Address: www.icicilombard.com

37 | Pharmaceutical Sector Risk Report 2022



Notes:





Now accessible at

www.icicilombard.com/corporate-india-risk-index



Please send a mail to <u>ciri@icicilombard.com</u> to get your customized ICICI Lombard Corporate India Risk Index Report





