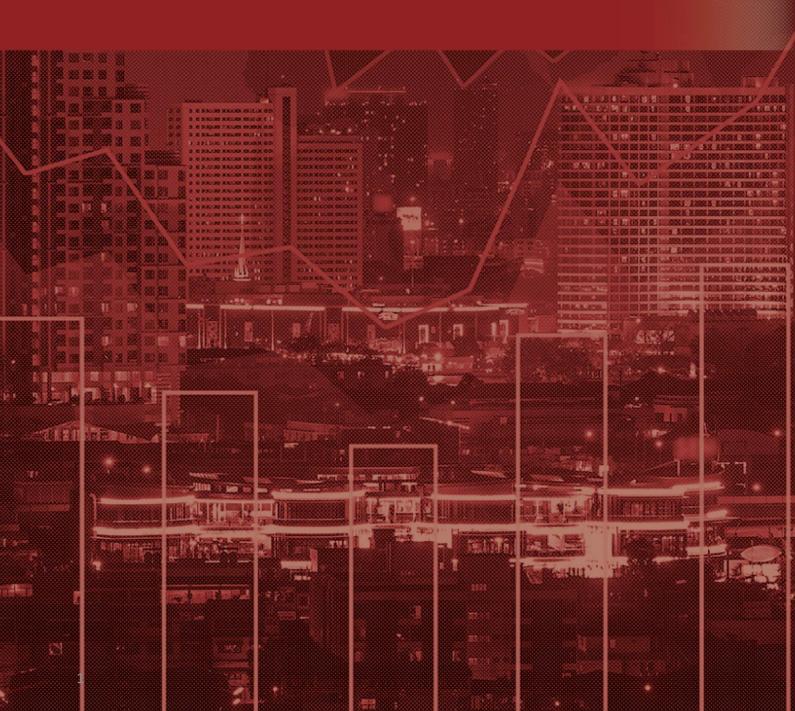


## **Sector: Pharmaceuticals & Biotech**





#### **ICICI Lombard Corporate India Risk Index - Introduction**

- ICICI Lombard Corporate India Risk Index is the first ever unified, credible, standardised corporate Risk Index that spans over the country level, the industry level and the company level
- This index maps the risk to a company on the basis of awareness, preparedness, probability and criticality across 15 sectors in India
- It will help the companies understand the level of risk that their business is facing and assist them in developing a successful risk aversion plan

#### **ICICI Lombard Corporate India Risk Index - Sector List**

- IT/ITeS
- BFSI
- Healthcare
- Pharmaceuticals & Biotech
- Energy

- Automotive & ancillary
- Hospitality/Tourism
- Manufacturing
- FMCG/Retail
- Infrastructure & Realty
- Metals & Mining
- Transportation & Logistics
- Media & Telecommunications
- Chemicals & Petrochemicals
- E-commerce/New-age



## **ICICI Lombard Corporate India Risk Index - Risk Framework**

 Disruptive technology · Intellectual property

· Data compromise

The ICICI Lombard Corporate India Risk Framework comprises of 32 risk elements across 6 broad dimensions:

- Inflation
- Taxation
- · Regulatory Risks
- · Foreign Exchange Risk
- Geo-political Risks

· Accidents/Fire Safety

· Supply Chain Risk · Environmental Risk

Strikes/Closure/Unrest

Competitive Risk

#### Market and **Economy**



- · Counterfeiting R&D / Innovation failure • Infringement / violation

#### **Technology**



- · Natural Hazards like flood, drought, famine, earthquake, landslide, etc.
- Pandemic (e.g. COVID)

**Operational and Physical** 

 Terrorism and Insurgency Equipment Malfunction



**Natural Hazard** and Event



- Cybercrimes
- · Counterfeiting
- · Harassment/Bribing
- Executive threat/
- Impresonation
- · Physical violence/ abuse

Crime and Security



- · Resources scarcity and/or misutilization
- Public sentiment
- · Failed/Hostile M&A

**Emerging** 

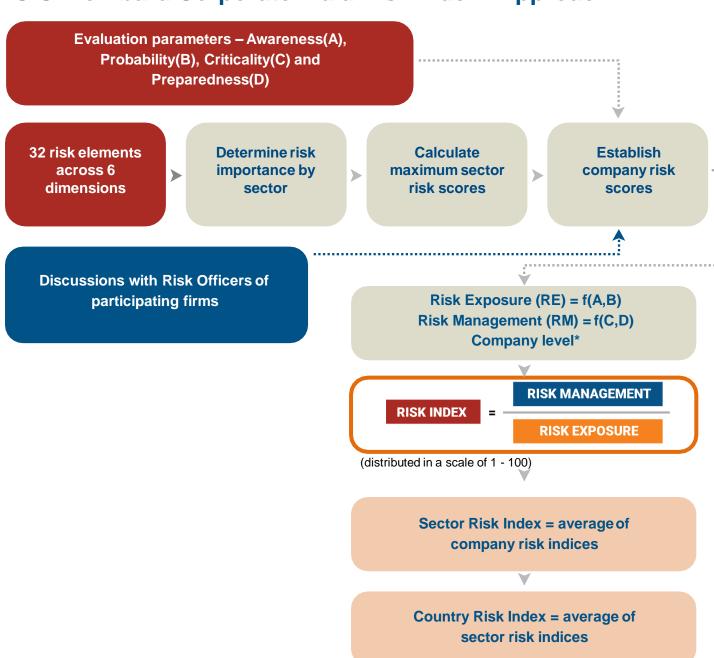




### **ICICI Lombard Corporate India Risk Index - Methodology**

- ICICI Lombard Corporate Risk Index is based on the principles of Lean and Six Sigma that qualify business processes by measuring Effectiveness and Efficiency
- Corporate Risk Index score measures the risk mitigation practices undertaken by a company relative to its Risk Exposure
- The Corporate Risk Index for 2020 is based on published business performance reports, assessments, and insightful discussions with key executives of 150 companies in India across the key 15 sectors

#### **ICICI Lombard Corporate India Risk Index - Approach**





## **ICICI Lombard Corporate Risk Index – Formulation**

The Risk Framework comprises of 32 risk elements across 6 broad dimensions

Measured across 4 parameters spanning exposure and management

**Probability** 



**RISK MANAGEMENT** 

**RISK EXPOSURE** 

## **ICICI Lombard Corporate Risk Index – Scale**

**RISK INDEX** 

Score	< 30	30 - 50	<b>50 – 60</b>	60 - 80	> 80
	Ineffective	Sub-optimal	Optimal	Superior	Over- prepared
Category	The corporate has very high exposure or very poor risk management practices or both	Not all risks are handled effectively. Risk management practices are likely dated or inefficient.	Most current risks are being handled effectively. Emerging risks associated with strategic initiatives need more diligence.	Very effective and efficient risk management practices. Well positioned to handle current and future risks across dimensions.	High investment in risk mitigation practices. Likely over-investment in one or more risk dimensions. Difficult to justify ROI



#### **Corporate India Risk Profile**

# Risk Exposure Score: 66 Risk Management Score: 64



Corporate India's Risk Exposure and Risk Management scores are 66 and 64 respectively; this indicates the country's marginally inferior risk management abilities and mitigation strategies for risk aversion.

The Corporate India Risk Index for Market & Economic Risk is low owing to a high exposure to geopolitical tensions and competition faced from MNCs. Technological Risk is also a matter of concern as India predominantly uses outdated technologies which are less effective and reduce productivity and thereby profitability. Another area of concern is Crime and Security Risk due to the existence of corruption in the system along with poor government regulations.

Various sectors namely Automotive, Manufacturing, Metals & Mining, Healthcare, IT-ITES, BFSI, and Media & Telecommunication have risk indices above the country's risk index.

Sectors with risk indices lower than India's risk index are Chemicals, Hospitality, Pharmaceuticals, New Age, Energy, Realty & Infra,, FMCG, and Logistics.

#### **Corporate India Risk Index at Glance**

Sectors	Risk Exposure	Risk Management	Risk Index
Automotive	72	72	59
Chemicals	68	66	55
Pharma	69	65	52
New-Age	65	61	51
Energy	69	66	52
Manufacturing	65	64	57
Metals and Mining	54	54	60
Realty and Infra	63	62	57
Hospitality	68	64	50
FMCG	72	69	54
Logistics	71	65	47
Healthcare	55	59	70
IT-ITES	57	58	64
BFSI	73	76	65
Media-Telecommunication	64	64	60
Overall Score	66	64	57



#### Pharmaceuticals & Biotech Sector Risk Profile

Risk Exposure Score: 69

Risk Management Score: 66

Risk Index 52

#### **Sector Risk Index - Six Risk Dimensions**



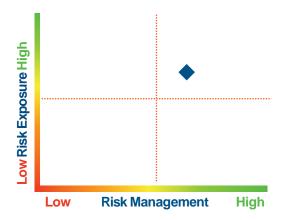
The Indian Pharmaceutical and Biotechnology sector's Risk Exposure score is 69 mainly due to its high exposure to Operational risk and Market & Economic conditions. While the Risk Exposure of most companies is majorly due to internal factors, the external factors have a limited impact on the business performance.

The overall Risk Management score is 66. The companies in Pharmaceuticals sector have high class mitigation strategies implemented for bulk of the risk, however there is still a need for companies to improve their Operational Risk Management practices especially the risks associated with portfolio, commodity pricing, and environmental hazards.



#### **Risk Dimension Analysis: Market and Economy**

## Risk Exposure Score: 67.3 Risk Management Score: 65.8



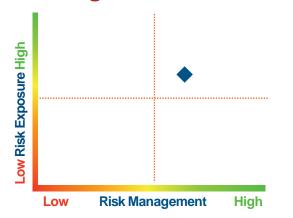
Having multi-geography focus, companies are prone to risk owing to regulatory uncertainty

- There have been rapid technological advancements in the pharmaceutical industry, and the companies are facing fierce competition from competing products, generics and biosimilars indicating high competition risk
- All the pharma companies are exposed to regulatory risks with all the plants always under scanners of FDA and Indian regulations.
   Companies are continuously monitoring regulatory landscape and proactively mitigate risks posed by evolving regulations
- Owing to high international exposure the sector has medium to high exposure to geo-political risk

Recommendation:
No company can be risk-averse with regard to regulations; companies could develop stringent checklist and internal mechanism to keep a watch on regulatory reforms and adherence to it. To mitigate geo-political risk companies could do In-depth follow-up of country risk and response measures to protect their assets, employees and other local stakeholders.

## **Risk Dimension Analysis: Technology**

## Risk Exposure Score: 65.4 Risk Management Score: 61.6



# Niche industry driven by knowledge intensive products can limit innovation risk

- The time period for developing a new product is longest in the pharmaceutical industry and the risk of the product failing to reach the market at the end of that period is still substantial, with a high attrition rate present throughout the R&D process
- To mitigate this risk, companies are reducing time to reach market by expediting the process and parallel run multiple phases of testing



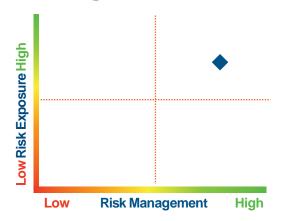
#### Recommendation:

Large companies can consider consolidating or doing collaborative R&D to ensure pipeline competence and timely delivery to market in priority diseases



#### **Risk Dimension Analysis: Operational and Physical**

Risk Exposure Score: 77.6
Risk Management Score: 70.7



Companies with focus on single drug class have risk of business continuity in long run

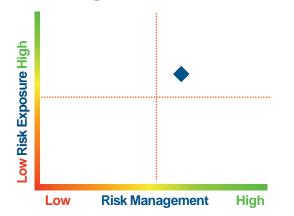
- Financial and profitability risk owing to pressure on margins and volume growth due to commoditization and hyper-competition in select therapies.
- Companies operating in different spheres of pharmaceutical industry face risks associated with that particular segment. For example, API manufacturers face pricing pressure on account of commoditization whereas formulators face high competitive intensity and entry barriers.
- Quite many Pharma companies are focused on one class of drug which leads to business continuity risk when that drug class is out of use

# **Recommendation:**

The companies could consider to put eggs in different baskets thereby helping companies to better withstand segment specific risks by shielding them from sharp revenue volatility by way of reducing dependence on the performance of one segment.

## **Risk Dimension Analysis: Crime and Security**

Risk Exposure Score: 60.1 Risk Management Score: 57.6



#### Counterfeiting is a serious public health menace

- Sector is undergoing a rapid digital transformation and more data than ever before is being managed online, resulting in companies being more prominent targets for cyber attacks
- Digital security breach could lead to serious financial loss, business disruption and/or damage to any pharmaceutical company's reputation.
- Counterfeiting is viewed as a serious public health menace which is promoted by criminals with little regard for the health and safety of patients. There is a serious need for anticounterfeit strategy in each of the company



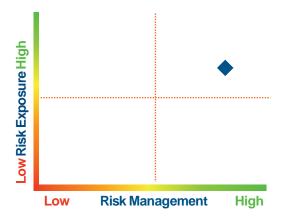
#### Recommendation:

The companies could defined a consistent Cyber Risk Management programme that involves periodic testing and improvement of controls through simulated phishing and penetration testing exercises



#### **Risk Dimension Analysis: Natural Hazard and Event**

Risk Exposure Score: 56.4 Risk Management Score: 66.8



Natural hazards pose huge risks to the pharmaceutical and biotech industry

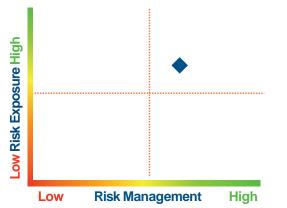
- The pharma companies were highly impacted by Covid-19 and faced many issues with supply chain and vendor management.
- Natural disasters can cause damage to hospitals and pharmacies that make them temporarily inaccessible and/or render stored medications unusable. This can result in pharmaceutical shortages. Unfortunately, substitute drugs are often more expensive than the standard ones.
- Moreover natural disasters increase pressure on healthcare system as more patients are admitted and drug demand also increases. This creates risk on supply chain and product availability

# **Recommendation:**

The companies could develop a cross-functional Business Continuity Team to keep plants and distribution centres operational and also shrink risk arising out of natural hazards and pandemic

## **Risk Dimension Analysis: Emerging Risk**

Risk Exposure Score: 58.6 Risk Management Score: 59.0



M&A is a growing trend across the chemical industry to garner a higher market share

 Mergers & Acquisitions have been playing a critical role in shaping the Indian Pharmaceuticals and Biotech industry landscape in the past and are expected to continue doing so in the future.



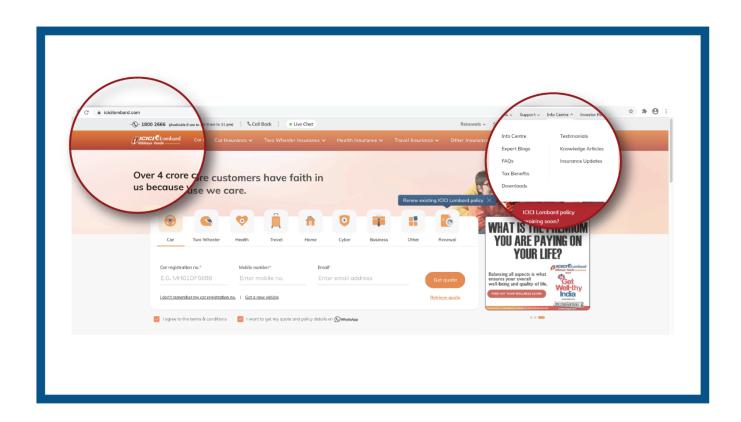
#### Recommendation:

In order to avoid risk of failed acquisitions the companies in the sector can do a detailed study of target company on the approved ANDAs, marketed products and pipeline products for which it expects to get approvals over the next few years. This will help to reduce the risk of failed M&A



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