i-notes
Newsletter from India's Leading Insurance Broking House
July 09

## Summary

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- Claims Case Study: *Understanding the complexities of B I Coverage*
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- Higher Deductibles- *as a Risk Management tool*

india insure
The risk managers

# Message from the Editor

Dear Readers,

We, at India Insure recently celebrated our 10th anniversary and it was with a sense of satisfaction that we reflected upon the past decade. With our growing customer base and commitment towards servicing we look to having lot more reasons to celebrate.

Over the past several issues we have been dwelling upon various insurance related topics and this time around decided to spend time in understanding the risks related to an industry in particular. The choice of industry was rather unanimous – the Pharma industry since this happens to be one industry where there is a huge variety in the nature of risks that the industry is exposed to.

While there was no mention of the FDI hike in the insurance industry by the FM in the Union budget we anticipate this change coming in shortly and with it probably many more new players too.

The general insurance industry has had a slow start off the starting block, with the present growth rate being less than 4%. While there have been reports of some insurers hardening in specific lines of business, no uniform pattern has emerged as yet.

We also have, in this issue, the views expressed by the pioneers in the pharma sector. Our sincere thanks to Ms. Anisha Udeshi, Head – Insurance & Risk Management, Cipla Ltd for sharing her valuable insights with our readers.

We trust you will find this issue interesting!

**V Ramakrishna**
Editor – *i-notes* & Chairman – India Insure

# Risk Exposures in a Pharma Company

**At a glance**

- 49 babies die in AIIMS clinical trials
- FDA issues warnings to Ranbaxy on 25 generic prescription drugs for observing inadequate quality controls
- Fire at Siris Pharma claims the lives of 5 employees including VP
- Toxic chemical fumes kill 1, 22 take ill in Hyderabad
- Vioxx recalled by Merck as it gets linked to thousands of deaths
- Ahmedabad-based Zydus Cadila and Israeli generic major Teva end their patent disputes
- Cultures Contaminated, Months of Research Lost
- Organization Pays $2.5 Million to Settle Data Disclosure Litigation
- UK's Environment agency cleans up river, but sends bill of £700k to polluting company

These headlines reflect the myriad array of risks being faced by pharmaceutical companies today. Though the industry is one of the world's most thriving sectors, it is not immune to the multitude of risks that can threaten its ability to compete. The pharmaceutical industry is characterized by a highly risky and lengthy R&D process, intense competition for intellectual property, stringent government regulation and powerful purchaser pressures. On one hand, pharma companies face similar risks like others - fire, explosion, machinery breakdown, natural catastrophes, business interruption, liability etc. On the other hand, the huge exposure to product liability risks, widespread counterfeiting of prescription drugs, ongoing industry consolidation, a lengthy and costly approval process for new medications, patent expirations and growing litigation issues continue to daunt the pharmaceutical industry on a daily basis. A KPMG report has revealed that the pharmaceutical industry is 50 percent riskier than the S&P's 500 and the risk profile of this industry has changed dramatically in the past decade.

This article dwells upon the risk exposures generally faced by a pharma company.

### Procurement & Supply chain Risks:

As organizations gravitate towards a "build anywhere, source from anywhere" mindset, the risks associated with procurement and managing supply lines assume greater proportions. Pharma companies have faced public scrutiny in the past following supply chain security incidents that highlighted the challenge of managing networks that span the globe and the disparity of quality standards and controls across those networks. While new sources of raw materials and labor offer cost advantages, they need to be evaluated carefully in terms of potential risk and reward.

Supply disruptions may also be the result of supply/capacity constraints, excessive dependence on one geography or supplier, strikes, lockouts, terrorism, regulatory requirements, supplier bankruptcies or unexpected logistics challenges. As the level of sensitivity surrounding procurement activities continues to escalate, procurement managers should start taking proactive steps to prepare for rainy day supply-disrupting events and move on to mitigate the risk of compromised supply.

### Product development Risks

Pharmaceutical companies make some of the biggest gambles of any industry: multi-million dollar investments on a new drug can take a decade or more to play out, as scientific and technical barriers produce a high failure rate. Pharma companies devote substantial resources to R&D since sales and earnings depend significantly on the development of commercially viable new products and production technologies. But because of the lengthy development process involved, technological challenges, regulatory requirements and intense competition, all of the products being developed may not actually reach the market in time or achieve commercial success. Therefore, the need to improve the productivity of drug research and development is an increasingly urgent challenge for the industry.

### Production Risks

Manufacturing efficiency plays a critical role in the pharmaceutical industry and hence the huge production lines and complex nature of machinery requires diligent quality standards across the organization.

(Contd... 02)

## Risk Exposures in a Pharma Company..... Contd. # 1

Quality needs to be controlled using a risk-based approach that identifies critical risk factors in the production process and minimizes or eliminates them. Production could also be adversely affected by occurrences such as technical failures, natural calamities, fire, explosion, theft etc. So, maintaining quality and minimizing production risks is especially crucial in the pharmaceutical industry given that a production error could mean the difference between life and death.

### Price Controls

Perhaps the biggest strategic risk faced by the pharma industry concerns pricing since it is heavily regulated in many markets as governments intervene directly in setting prices. Most of the global pharmaceutical companies earn at least 50% of their income from the US as a market-based approach still rules there allowing them to recoup their significant research and marketing costs. The biggest risk to the industry is when the US brings in a change to the current system which would result in the whole business model for the industry unraveling.

Regulatory compliance places a greater burden on pharma companies because they span the full pharma product life cycle — from invention to testing, manufacturing and marketing.

Indian Government's intervention into the determination of drug prices is sometimes justified by the fact that it is a key public policy measure for the health of India's teeming masses. However, the increase in existing controls, pressures or restrictions / introduction of new controls will reduce the industry's margins or affect adversely its ability to introduce new products profitably.

### Distribution, Storage, Contamination and Counterfeit Risks

Pharmaceutical companies have faced many issues in their delivery process because of contaminated/ counterfeit drugs being circulated in the market. Contamination in pharmaceutical products creates potential nightmares for drug manufacturers and causes a ripple effect that magnifies costs exponentially. Recent industry events such as the contamination of batches of heparin demonstrate that a small oversight can lead to patient harm and death, product recalls, loss of integrity and significant financial liability for a company.

Since many of the pharma products are temperature sensitive commodities, great care & caution needs to be exercised during transportation, distribution and storage so that the integrity of the product is not adversely affected. Products should be packed in such a way to minimize the risk of tampering, theft and fraud e.g. by using locked containers or by shrink-wrapping entire pallets in plastic.

According to the Mashelkar committee report, the pharma industry faces a loss of around INR 40 billion due to substandard drugs

Pharmaceutical counterfeiting and fraud also pose an immense problem for the pharmaceutical industry. According to the Mashelkar committee report, the pharma industry faces a loss of around INR 40 billion due to substandard drugs and a WHO report suggests that 35 percent of spurious drugs of the world are being produced in India.

### Patent Risks

The pharmaceutical industry is facing a perfect storm of change. Within the next five years, an estimated additional $60 billion in blockbuster drugs will go off patent and face competition from generic drug manufacturers as the world's leading pharma companies struggle to replenish depleted drug pipelines.

- **Patent infringement litigation**

  Pharma companies may need to get involved in lawsuits to enforce patent rights when generic drug manufacturers may seek marketing approval for products currently under patent protection by challenging the validity or enforceability of a patent or with assertions that their generic product does not infringe the patent. If the company is not successful in defending an attack on its patents and maintaining exclusive rights to market its product, then its turnover and margins would be adversely affected. Pharma companies may also be required to defend themselves against charges of infringement of patent or proprietary rights of third parties.

- **Potential changes in intellectual property laws and regulations**

  Enactment of proposals to change existing patent laws and regulations in major markets in which a company sells its products could have an adverse impact on future sales and profits. Examples include making registration of patents for new products more difficult and time-consuming or proposals on decreasing the patented life of a product adversely affecting its exclusivity period.

- **Weakness of intellectual property protection in certain countries**

  Even though India has witnessed significant improvements in its regulatory environment, particularly with regards to patent protection, some concerns however still remain, especially around stringent implementation of patent protection laws. A survey commissioned by E&Y revealed that patent protection was still the most significant issue for a majority of pharmaceutical companies doing business in China and India. The trend of outsourcing R&D and manufacturing to low-cost destinations also entails the critical risk of intellectual property (IP) infringement, leading to counterfeiting.

### Regulatory Risk

Regulatory compliance places a greater burden on pharma companies because they span the full pharma product life cycle — from invention to testing, manufacturing and marketing. Firms that fail to comply with regulations — will face shutdowns, product withdrawals, fines, lawsuits, revenue loss and tarnished reputations.

Regulations vary from country to country, so any company operating in more than one, needs to make sure that it is aware of the legal requirements and liabilities. As pharma companies move parts of their businesses to multiple locations, they may become exposed to varying and in some cases, contradictory regulations. Over the past few years, many of the top global pharmaceutical companies have had to pay billions of dollars to settle legal issues related to transfer pricing in various geographies. In June 2008, GlaxoSmithKline (GSK) Canada lost a transfer pricing case that is likely to cost the company millions of dollars in back taxes, penalties and interest. Ranbaxy Laboratories is also currently in the middle of a transfer pricing dispute with the Income Tax Appellate Tribunal (ITAT) of India.

### Product Liability Risk

Product failures can devastate firms' reputations, brand identities, financial performances and some of the spectacular product recalls undertaken by the pharmaceutical industry in recent years has proven that beyond doubt. Even though, the average time between a drug's introduction to the market and its recall is becoming shorter and shorter, often several years go by until the side effects of a drug are reasonably well known.

(Contd... 07)

## Interview – *Corporate*

*{Views expressed herein are purely personal and does not reflect the views of the company}*

To succeed in a highly competitive and rapidly evolving environment, pharma companies must find ways to enhance shareholder value, increase efficiency, contain costs and manage risk. The fast paced changes within the industry call for a unique approach to risk management to successfully achieve corporate objectives. So, in this issue we speak to Ms. Anisha Udeshi, Head - Insurance & Risk Management of Cipla Ltd. on how they manage their risks.

1. What kind of risk is your biggest exposure? How are risks managed at Cipla so that the potential losses are minimized?

   Marine risk – with the help of risk management practices.

2. Recent events in the global pharmaceutical market have moved product liability insurance to the spotlight. Losses continue to occur with increasing frequency and severity & hence insurers decline to provide cover or even if it is available, the premiums have shot through the roof. How do you view the situation in India, is getting the cover comfortable?

   Yes - for us so far the programme is very competitive. We are working on Liability Risk Management programme with the insurers to enable them to get our risk written comfortably in the overseas or through GIC. Not only Product liability insurance, it is clinical and bio-equivalence that have first come to the spot light.

3. The withdrawal of a product from the market due to the risk of severe side effects usually has very serious implications for the company concerned, frequently involving a loss of image and a dramatic fall in its share price. What does the pharmaceutical industry do to prevent such risks?

   Effective Recall procedure

4. Does Cipla use self-insurance alternatives while dealing with risk? How much percentage is self insured?

   Various policies have different % of self insurance technique – this is decided upon the risk appetite and risk transfer mechanism is also used.

5. What according to you are the emerging risks likely to hit the pharmaceutical industry?

   Liability risk

6. Even after 10 years of liberalization, price continues to be the main driver when it comes to purchasing insurance. What role do you think can brokers play in pushing the market in the right direction so that clients start looking at differentiators other than price?

   Value add to the client, delivery of the product and especially services as agreed upon.

7. What would you like to see improve in the insurance industry in order to help the Pharma industry?

   Better understanding of Pharma and Chemical Risk

## News TitBits

**SC awards techie Rs 1cr damages for medical negligence**

*Source: Livemint*

In the highest compensation ordered by an Indian court in a medical negligence case, a techie who found himself paralyzed waist down after a surgeon damaged his spinal chord during an operation to remove a tumour in the chest, was awarded Rs 1 crore in damages by the Supreme Court on Thursday. The victim, Prashant S Dhananka, 39, who spiritedly argued his case from a wheelchair he has been confined to since the operation 19 years ago, had sought a compensation of Rs 7 crore. The court, however, settled for an almost seven-fold increase in the Rs 15 lakh amount awarded by the Andhra Pradesh high court. In September 1990, he had been admitted to Nims after tests showed that he had a tumour in his chest. A surgery was conducted on him to remove a sample of the tumour to examine if it was malignant. Dhananka alleged that the surgeon found the tumour to be benign, but without consulting a neurosurgeon, he went ahead and removed the tumour, damaging blood vessels connected to the spine, leaving him paralysed below the waist. The large award may now spur the demand for professional indemnity cover or error and omissions cover for doctors and hospitals.

## News TitBits

**Investment norms for New Pension Scheme finalized**

*Source: IBEF*

Paving the way for the New Pension Scheme (NPS) from 1st May, the Pension Fund Regulatory and Development Authority (PFRDA) On Wednesday announced investment guidelines for contributory plans. Following recommendations from the Deepak Parekh-headed Expert Group and taking into account comments from the public, PFRDA has categorised NPS investments into three asset classes – E (equity), C (corporate paper) and G (government securities).

**Our comments:**

On May 1, 2009, the Pension Fund and Regulatory Development Authority (PFRDA) threw open the New Pension Scheme (NPS) to all Indian citizens. The NPS has been mainly designed to fill in the gap of old age income security of the unorganized sector. It is a pure defined-contribution product in which an individual needs to invest a certain amount every year. On retirement at 60 years, you get the corpus – part of which is in the form of a lump sum. The other part compulsorily needs to be used to purchase annuity from an insurer to ensure the regular flow of income post retirement.

Investors have 3 options while deciding the investment pattern in NPS – Equity, Government bonds and Corporate bonds. The **PFRDA** has made a strict limit of investment of only 50% in equities of the pension funds.

NPS begins with a mandatory Tier I account and an annual contribution of at least Rs 6,000. NPS has two sets of charges — flat and variable. You would need to pay about Rs 470 as flat charges every year, but this is expected to come down as volumes go up. The variable charges are custodian charge of 0.0075-0.05 per cent of the fund value per annum and fund management charge of 0.0009 per cent of the fund value per annum. These are the lowest in the industry.

Though NPS scores in terms of cost and ease of handling, it loses out in terms of taxability. The present tax treatment of NPS where the final corpus is taxable as per each individual's tax slab puts subscribers at a clear disadvantage vis-a-vis insurance and non-government PFs. NPS needs a tax treatment similar to that enjoyed by EPF and PPF where the final corpus is also non-taxable. Also, the current flat annual service charges of nearly Rs 700 will crowd out lower income (and more vulnerable) workers.

All in all, NPS is undoubtedly an important reform but one that needs improvement.

## Readers Speak

**To how many brokers should an organization issue a mandate to source quotes?**

One school of thought is that a mandate for a particular coverage should be issued to only one broker. The brokers should be evaluated first by presentations on their servicing capabilities, insurance markets represented and experience with similar risks to assess their competence and then finally issue an exclusive mandate to the broker that seems fit. But another school of thought is that mandates should be issued to all brokers who approach them in order to introduce an element of competition into insurance purchasing. So what do you think is the right choice and why? What is your rationale? Is it best to let one broker approach the marketplace for a particular coverage line or have two or more bid against each other?

Your opinion is solicited.

In the last issue of inotes, we had asked

**Will the increased focus on company directors and thrust on corporate governance boost the demand for D&O liability insurance?**

Below are some of the responses we received

**Mr. Shasi Gangadharan,** VP, Chubb Specialty Insurance Manager, Asia Pacific Zone

The topic makes reference to "increased focus" and "thrust on corporate governance" as reasons for increase in demand for D&O insurance. Historically and today , demand for D&O is primarily driven by a) increase in exposure (private) and b) rise in rules, regulations in the governance of conduct of directors and the company (public or regulatory) . As you are aware the product came about in the US due to both aspects. So if you mean these in the use of the phrase "increased focus", I agree.

On the second one, "thrust on corporate governance", this take it to mean a) rules and regulation on transparency and b) increase in awareness of risk management . If you see a number of markets in Asia, these factors have been the primary motivator for demand in liability products. Others include globalization, rising consumerism and the role of media.

In India, Satyam's case should be treated as a inflection point in history of D&O in India. Others major points such as (a) rise of corporate India in the mid 1990 (b) introduction of Rule 404 (c) amendments to the Comp.s' Act (d) changes to the accounting rules - therefore each of these inflection points have brought about a set of results.

Mandating D&O- there are numerous examples of various mechanism that have mandated the purchase of liability insurance (incl state mandated terrorism insurance) through contractual, advisory (through codes) and regulatory requirements. So while mandatory purchase of insurance may not be new, the purchases of D&O insurance is. The problem with compulsory insurance is not new - for example - sanctions if not complied, what limits, what form, what if not commercially available etc.

**Mr. Nikhil Modak,** Sr Underwriter, Bajaj Allianz

The Satyam Saga, had an enlightening effect on the Indian Corporates, as several directors on the company's Board started running for D&O cover. Is India Inc in a position to fight it out in the Court of Law for the 'Wrongful Acts' of its Directors and Officers? The provision of Section 201 of the Indian Companies Act, mentions that the Company will not indemnify its Directors for their wrong doings for breach of duty, breach of trust etc., has caught attention of many Corporates, although proving such an 'Act' revolves around the intention of those committing this 'Act'. Moreover regardless of the stipulations of company's Act in the event of insolvency there will be no prospect of the company indemnifying its Directors & Officers.

Moreover, the proposed New Companies Amendment Bill which is waiting to be passed in the Parliament, makes a specific mention of 'Class Action Law Suits' in India, which if implemented will see good Corporate Legal Firms venturing into India as we expect to see increased transparency in the Corporate Legal Affairs and also Fast Redressal, since there will be more people joining the Law Suit (s), thus also leading to less pressure on Judiciary.

**Hemant Raj Johri, Deputy Manager, Oriental Insurance Company**

I am of the opinion that the the increased focus on Corporate Governance will lead to the need for greater DISCLOSURE by the corporates. What is of utmost importance is gaining, sharing and disseminating information. This requires a proper MIS and also proper strategies for dissemination of information to be in place. while the demand for D&O liability insurance cover is expected to increase, there will be other new dimensions also which will acquire significance.

*{Views expressed herein are purely personal and does not reflect the views of the company}*

## Claims Case Study: *Understanding the*

**Background:** In the years preceding September 11, 2001, a company called XYZ operated and maintained the buildings which comprised the World Trade Center. XYZ also had contracts with individual tenants to perform maintenance work & provide various janitorial, electrical, and engineering services within the individually leased spaces. In order to efficiently perform these functions, XYZ had office and storage space within the WTC complex and had sole access to janitorial closets and other facilities and equipment on every floor. At the time of the attacks, it employed more than 800 people at the WTC, and its exclusive and significant presence at the complex allowed it to secure service contracts with nearly all of the WTC's tenants. Thus, XYZ was intensely involved in a building that it did not own or lease.

XYZ procured insurance coverage from Unity Insurance Co. for property damage, business interruption and contingent business interruption. XYZ's claims under the policy arose out of the complete destruction of the WTC. XYZ declares it has lost, as a result of these events, all income that it derived from its operations at the WTC. Specifically, it asserts that it should be compensated for **its lost income** resulting from the destruction of:

(1) Its equipment, offices and warehouses
(2) The common areas in the WTC; and
(3) The spaces occupied by the tenants with whom XYZ had contracts to provide services.

Unity argued that XYZ was entitled only to a $10 million per-occurrence limit of liability under Contingent Business Interruption (CBI) clause since XYZ's claim arose from damage and destruction of the premises of XYZ's customers. XYZ contested the applicability of the CBI provision and insisted instead that the relevant clause which would apply is the Business Interruption clause, invoked by XYZ's extensive relationship with the World Trade Center complex and not the CBI clause.

The matter then went to Court.

## complexities of BI Coverage

### XYZ's Business Interruption Coverage

XYZ's basic insurance coverage for business interruption covered losses *resulting directly from the necessary interruption of business caused by direct physical loss or damage to insured property at an insured location.*

For any property insurance claim, the insured must have an "insurable interest" in the real or personal property for which it seeks coverage. XYZ's policy defined insurable interest as "*the interest of the Insured in all real and personal property including but not limited to property owned, controlled, used, leased or intended for use by the Insured*".

Unity argued successfully to the District court that XYZ needed to establish the existence of a "legally cognizable interest" in the property. The court noted that XYZ neither "used" nor "controlled" the common or tenanted areas of the WTC in a manner that sufficed for the creation of a "legally cognizable interest" in the property. Its insurable interest was confined to those locations which XYZ itself occupied, and not those locations which were the means through which its work was accomplished. By so finding, the District Court concluded that XYZ cannot recover under the policy for any business interruption loss from their destruction.

Unhappy with the judgment, XYZ went for appeal.

The Court of Appeals held that the District Court erroneously held that XYZ's usage was confined to the offices that XYZ itself occupied. Since XYZ is not engaged in predominantly mental labor and thus is prevented from working solely within the confines of its own offices; its "usage" necessarily extends beyond those boundaries.

Thus, the Court of Appeals by reversing the judgment in favor of XYZ, held that since these portions of the buildings were the means by which XYZ derived its income and were essential to completing its job functions, it "used" the WTC property and therefore had an insurable interest as that term was defined.

So, XYZ has Business Income coverage for its loss from destruction of the WTC's tenanted space and common areas. Accordingly, XYZ is entitled to claim its loss of profits as Business Income.

### XYZ's Contingent Business Interruption Coverage

Contingent business interruption coverage generally insures against a disruption of income resulting from damage to a third-party or a property upon which the insured relies. XYZ's contingent business interruption provision insured against "*actual losses sustained due to the necessary interruption of business as the result of direct physical loss or damage of the type insured against to properties* ***not operated by the insured*** *which wholly or partially prevents any direct supplier of goods and/or services to the insured from rendering their goods and/or services, or property that wholly or partially prevents any direct receiver of goods and/or services from the Insured from accepting the insured's goods and/or services*".

The Court of Appeals held that XYZ essentially managed and operated the WTC infrastructure as well as the common areas and physical space used by WTC tenants and the public at large. The court found that the tenants of the WTC were the customers of XYZ and therefore direct receivers of XYZ's services. XYZ argued that the inability of these tenants to conduct business with it, resulting from the destruction of their leased spaces, was covered under this contingent business interruption coverage. However, the Court of Appeals found XYZ's contingent business interruption coverage to be inapplicable because XYZ's customers were tenants in the same building that XYZ operated and from which it supplied services to the tenants. Since the case involved a unique set of circumstances where the insured's customers occupied a building that the insured itself operated, it rendered the CBI provision inapplicable.

### Our Learnings

The issues before the court demonstrate the importance of understanding the nature and extent of business interruption coverage prior to its purchase. Depending upon the subtle differences in the specific nature of the interruption, the language of the insurance policy, and the court's interpretation of that language, you may not be covered. It is therefore incumbent upon every policyholder to work with its insurance broker or consultant to design business interruption coverage that is responsive to the particular risks that the business faces.



## News TitBits

### Cancellation of group mediclaim policies increases by 30%

*Source: Business Standard*

Internal audits have forced insurance companies to ask for higher premium after issuing policies, leading to an increase in cancellation of mediclaim covers. According to the industry estimates, cancellation of group mediclaim policy midway has gone up by 30 per cent. Insurers, mostly private ones, are opting to cancel mediclaim, marine and cargo cover at a later stage due to adverse claims ratio. In order to grab market share, they have not been pricing the product correctly. "Private insurers are cancelling group health policies with a 30-day notice. The trend has been continuing post-detariffication, but has gained momentum this year with the increase in internal audits of these companies," said Boda Insurance Broker Executive Director K Ramachandran.

### India among top 10 world life insurance markets

*Source: Economic Times*

The life insurance industry might have turned in a poor show in FY09 with almost flat growth, but with the rest of the world shrinking during this period India has for the first time moved up the ranking to be among the top 10 life insurance markets worldwide. According to the latest sigma report on world insurance markets, India recorded an inflation adjusted growth of 0.2% in USD terms while the world market shrunk 3.5% in '08 thanks to the global financial crisis. While '08-09 was an exception on account of the crisis, the average growth of the Indian life industry post liberalization has been very impressive. India was at No 20 at the time of liberalization in 2000 but had moved up to No 17 two years back and was at number 11 position last year.

### Swiss Re, Religare in JV talks

*Source: Economic Times*

Swiss Re, the world's second-largest reinsurer, is in talks with New Delhi-based Religare Enterprises to form a joint venture to launch a health insurance company in India, an executive of the Indian company said. Discussions for the venture are in advanced stages, said the executive, who requested anonymity.

# Report Card - May 2009

**Gross premium underwritten by non life industry for and up to the month of May 2009 (Rs. In crores)**

| INSURER | MAY 2009-10 | MAY 2008-09 | GROWTH OVER THE SAME PERIOD OF PREVIOUS YEAR | APRIL - MAY 2009-10 | APRIL - MAY 2008-09 | GROWTH OVER THE SAME PERIOD OF PREVIOUS YEAR |
|---|---|---|---|---|---|---|
| New India | 421.45 | 411.54 | 2.41% | 1177.47 | 1095.48 | 7.48% |
| United India | 404.92 | 359.62 | 12.60% | 898.05 | 797.64 | 12.59% |
| Oriental | 345.29 | 304.85 | 13.27% | 836.43 | 731.93 | 14.28% |
| National | 334.69 | 363.07 | -7.82% | 773.46 | 819.54 | -5.62% |
| ICICI-lombard | 206.71 | 257.56 | -19.74% | 631.37 | 800.84 | -21.16% |
| Bajaj Allianz | 192.35 | 232.71 | -17.34% | 424.60 | 508.85 | -16.56% |
| Reliance General | 169.23 | 152.27 | 11.14% | 385.62 | 426.22 | -9.53% |
| IFFCO-Tokio | 114.59 | 132.11 | -13.26% | 284.18 | 274.33 | 3.59% |
| Royal Sundaram | 64.50 | 56.90 | 13.36% | 142.66 | 131.05 | 8.86% |
| Cholamandalam | 62.15 | 52.42 | 18.56% | 166.86 | 147.46 | 13.16% |
| Tata-AIG | 59.51 | 74.08 | -19.67% | 206.95 | 222.05 | -6.80% |
| HDFC ERGO | 46.75 | 16.61 | 181.46% | 136.17 | 31.22 | 336.16% |
| Future Generali | 28.70 | 9.19 | 212.30% | 62.49 | 19.55 | 219.64% |
| Shriram General | 17.18 | 0.00 | - | 44.34 | 0.00 | - |
| Bharti AXA | 12.49 | 0.00 | - | 28.33 | 0.00 | - |
| Universal Sompo | 8.60 | 0.05 | - | 27.24 | 0.18 | - |
| Raheja QBE | 0.00 | 0.00 | - | 0.01 | 0.00 | - |
| PRIVATE TOTAL | 982.76 | 983.90 | -0.12% | 2540.80 | 2561.74 | -0.82% |
| PUBLIC TOTAL | 1506.35 | 1439.08 | 4.67% | 3685.41 | 3444.59 | 6.99% |
| **GRAND TOTAL** | **2489.10** | **2422.98** | **2.73%** | **6226.21** | **6006.33** | **3.66%** |
| **SPECIALISED INSTITUTIONS:** | | | | | | |
| **1.Credit Insurance** | | | | | | |
| ECGC | 67.07 | 57.53 | 16.58% | 124.14 | 104.59 | 18.69% |
| **2.Health Insurance** | | | | | | |
| Star Health | 9.98 | 4.47 | 123.27% | 151.16 | 62.68 | 141.16% |
| Apollo DKV | 9.57 | 3.94 | 142.89% | 14.71 | 5.44 | 170.40% |
| **Health Total** | **19.54** | **8.41** | **132.34%** | **165.87** | **68.12** | **143.50%** |
| **3.Agriculture Insurance** | | | | | | |
| AIC | 34.42 | 19.56 | 75.97% | 80.24 | 43.24 | 85.57% |

## Observations on Line –wise premium growth for FY 08-09

As at the end of FY 08-09, motor insurance continues to dominate with 44% of the market share, followed by health and fire with 20% and 11% respectively.

### 1. Health Insurance

- The growth in the health insurance sector has been stupendous in the past 2 years with the contribution from the health insurance portfolio being highest with an accretion of 1500 crs.
- The size of the health insurance market has grown from Rs.5125 crs in FY 07-08 to Rs.6625 crs in FY 08-09 registering a growth rate of 29.65%
- Health insurance occupies a market share of 21.28% at the end of FY 09 compared to 18.08% a year ago.
- The private players have grown at a rate of 23.67% compared to 22% of the PSU's. But when the stand alone health insurers- Star Health & Apollo DKV are also included, the picture changes with the private players recording a growth rate of 41.3%.

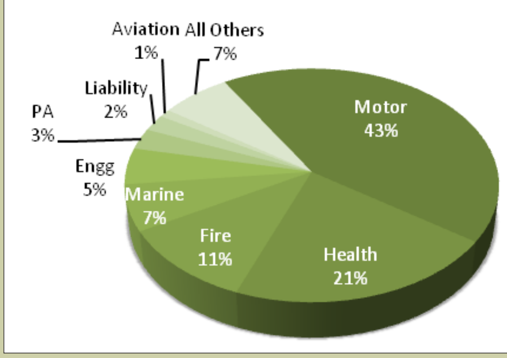
### 2. Fire Insurance

- The premiums from fire insurance have dropped from 3517 crs in FY 07-08 to 3420 crores in FY 08-09 registering a negative growth of 2.42%.
- Fire insurance now occupies a market share of 11% compared to 12.44% a year ago.
- Private sector seems to be more affected by the free fall in fire premiums than the public sector. While the PSU's have recorded a positive growth of 2.56%, the private players have registered a negative growth of 10%.

### 3. Motor Insurance

- The market size of motor insurance portfolio at the end of FY 09 stands at 13458 crs compared to 12804 crs a year ago. The motor insurance premiums have grown by 5.11% in FY 09, with OD contributing 2.41% & TP contributing 9.90%.

**Line-wise market share as on 31 Mar 09**




- The market share of the motor portfolio has declined from 45.3% to 43.2% in FY 08-09.
- The motor premiums of the public sector in fact registered a decline of 0.48% while the private sector grew by 12.48%.

### 4. Engineering Insurance

- Coming to engineering insurance, premium collections have to grown to 1573 crs in FY 08-09 compared to 1432 crs a year ago registering a growth of 9.82%.
- The market share of the engineering insurance portfolio more or less remains the same at 5.07% at the end of FY 09 compared to 5.05% during the corresponding period last year.
- PSU's seem to be going strong with a growth rate of 15.3% while the private sector could manage a growth rate of only 2.78%.

### 5. Liability Insurance

- On the liability front, premiums grew from 583 crs to 713 crs at the end of FY 09 registering a growth rate of 17.74%.
- The market share of liability insurance portfolio increased from 2.06% to 2.29% in FY 08-09.
- Private players have registered a growth rate of 22.29%, almost double the growth rate of public players at 12.78%.

# Risk Exposures in a Pharma Company .... Contd. # 2

This time lag involves a major risk for pharmaceutical companies, because it means that many patients will be harmed in the meantime. In recent years, several drug companies have been targeted in lawsuits based on alleged misrepresentations / omissions regarding product safety, product efficacy, clinical trial results, the quality or safety of the company's manufacturing processes, the commercialization or marketing of the company's product, the company's description of its product etc.

## Environmental Risks

Perhaps more than in any other sector, environmental issues in the pharmaceutical industry pose a complex challenge to management and have the potential to significantly impact profitability. Pharmaceutical companies are at great risk from environmental exposures due to the nature of the bulk manufacturing process, which has a low ratio of finished product to raw material and produces a high volume of waste. In recent years, pharma companies have attracted significant media attention—not to mention lawsuits - for air, water and soil contamination.

So, safeguarding the environment needs to be considered as a governance obligation that makes complete sense from a business perspective. Organizations also need to be aware that in many instances, their liability insurance policies will not cover them for pollution liabilities.

## Business Interruption risks

Pharmaceutical companies face a huge potential business interruption risk. A typical pharma company's property exposure is 75-80% business interruption, with the remainder related to actual physical damage.

Although pharma companies undertake business continuity planning - single sourcing for certain components creates a risk of failure of supply in the event of regulatory non-compliance or physical disruption at the manufacturing sites. Since the industry is moving towards much more complex business models with significant outsourcing, it is not only important that pharma companies have their business continuity plans, but it is also important that the people that they are dealing with have their business continuity plans as well.

## Risks associated with Clinical trials

Clinical trials are another area of significant concern for pharmaceutical and biotech companies. Clinical trials are conducted during the development of potential products to determine their safety and efficacy for use by humans. Issues of particular concern are the informed consent process, clinical trial design and controls, monitoring of clinical trials, failing to disclose the full results of clinical trials and manipulating trial data to maximize sales.

**Privacy issues:** With the growth of online pharmacies, global clinical trials and electronic medical records, pharma firms also face an increased risk of inadvertently exposing patient information. The bulk of privacy concerns today centers on clinical trial information — who participated in which types of trials.

## Insurance Solutions

All business is the undertaking of risk for reward, however where there is uncertainty in risk, many pharma companies look to transfer that risk to insurers as much as possible. The dynamic risk profile of most bulk drug and pharmaceutical industries warrant periodic risk identification exercises to be performed to avert major incidents/ accidents.

Below is the risk matrix that identifies the risks exposed to & the availability of an insurance cover.

| Risks associated with | Availability of insurance cover |
|---|---|
| 1) Procurement | Yes |
| 2) Supply chain | Yes |
| 3) Product Development | No |
| 4) Clinical trials | Yes |
| 5) Production | Yes |
| 6) Price controls | No |
| 7) Distribution | Yes |
| 8) Storage | Yes |
| 9) Risks of counterfeiting | No |
| 10) Patent infringement | Yes |
| 11) Changing regulations | No |
| 12) Political turmoil | Yes |
| 13) Trade credit | Yes |
| 14) Product Recall | Yes |
| 15) Business Interruption | Yes |
| 16) Environmental Pollution & Contamination | Yes |
| 17) Third party bodily injury & property damage | Yes |
| 18) Employee Health & Safety | Yes |
| 19) Cash in transit/safe | Yes |
| 20) Employee Dishonesty | Yes |
| 21) Natural calamities | Yes |
| 22) Terrorism | Yes |
| 23) Directors & Officers liability | Yes |

## Conclusion

While pharmaceutical companies have processes and controls in place to manage risk, it is now time to reassess their risk framework and to make any modifications that are needed to stay current with the evolving business model and the changing industry risk profile. Comprehensive risk management plans should be developed for each product in the pipeline or on the market.

The fast paced changes within the industry call for a unique and proactive approach to risk management to successfully achieve corporate objectives. The benefits of a well-understood, well-documented, well-communicated risk-management process go beyond helping a company boost revenue and profitability. Equally important are the benefits that accrue from recognizing and mitigating risks before they have a negative impact on a business. A vigorous risk-management process that enhances management decision making, assigns accountability and alerts a business to risky activities is an asset that can provide a significant competitive advantage in the market.

**Reliance Life Plans IPO**
*Source: Reuters*

Reliance Capital is planning the first-ever initial public offer (IPO) by an insurance company in India by taking its subsidiary - Reliance Life Insurance public. The company is looking to divest up to 26% in its insurance arm through an IPO or selling to a strategic partner or both, Sam Ghosh said.


## Higher Deductibles- *as a Risk Management tool*

***Deductibles -*** those clauses in every insurance policy that makes us - the policyholder, pay the first part of every loss! And if the loss is less than the deductible, the insurer never pays anything leaving us to bear the burden — even though the premiums are regularly paid. This seems unfair and so many of us hostile towards deductibles try and choose the smallest one that an insurer offers.

The spirit of the deductible actually is to discourage small claims and also to ensure that the insured does not cultivate an indifferent attitude to loss control & safety measures just because he is covered by an insurance policy.

The insured generally tends to think that it is only the insurer who benefits by having a deductible clause. On the contrary, there are definitely advantages to the insured also in adopting deductibles – especially higher ones. Here are some:

- **Encourages Loss Control**

  Emphasizing insurance deductibles to let management and staff know that it is the organization that bears the first part of any loss can act as a strong motivator for loss control. Globally companies with risk retention capabilities have considered the use of higher deductibles that act as a good incentive for effective internal housekeeping. Higher deductibles offers opportunity for insureds to manage their insurance costs by encouraging safety and risk management as part of the organization's "culture" in performing everyday activities.

  When you gravitate to a higher deductible, you also need to think about the retained liability and how would you most appropriately and efficiently fund for that liability. It makes sense in creating a reserve fund to cover deductible amounts on various insurance policies. Integrating your safety and insurance programs will ensure that you have a true risk management program.

- **Reduces Premium costs**

  The deductibles set in the property insurance policies that we have today dates back to the nineties. Although inflation has taken its toll on valuation of property, causing the values to increase manifold, the deductibles still remain the same. In this current detariffed environment, opting for higher deductibles definitely reduces premium because it is this lower layer of the risk that is usually characterized by high frequency and low severity losses that can be easily predicted. Insurance is often not the best solution for this layer of risk since it is a product that spreads the risk of serious, but low-probability, losses among a group.

  Low-deductible insurance causes a large number of small claims to be filed. Claims for small amounts of money require many of the same investigative and paperwork operations as large claims. This results in high administrative costs that must be passed on to the customer. So, by relying on insurance for only those potentially catastrophic events in an organization's life, we can cut down the insurance premiums.

- **Improves Allocation of Insurance Budget**

  Insurance premiums that are saved by choosing substantial deductibles in insurance policies for controllable exposures becomes money that can be put to higher and better risk management uses. Premium not spent to cover fairly routine, reasonably predictable losses usually are better spent to buy higher limits of thorough protection against large, low-probability losses that would be highly disruptive (like Business Interruption / Professional Indemnity).

IRDA has now allowed insurers to file for variations in deductibles under Fire, Engineering, IAR and Motor OD. So, retaining a larger deductible and taking on more of the risk yourself- results in an attractive set of costs and benefits. The premium discounts available for larger deductibles gradually keeps decreasing as the deductible goes higher and so organizations should maintain the optimum balance between the premium cost and how much loss they can comfortably handle. Examining your organization's loss history can help you select the proper deductible for each type of insurance. All in all, deductibles are an elegant way of setting the tone for better risk management practices in an organization.

## Disclaimer



## Contact us

**India Insure Risk Management & Insurance Broking Services P Ltd.**

**Ahmedabad** # 401-402 Aditya Arcade, Near Choice Restaurant, Off C.G Road, Navrangpura, Ahmedabad - 380009
Tel: + 91 79 40018500/40018400, Fax: + 91 79 40018515
Mr. Pawan Kumar Mediratta email : pawan.mediratta@indiainsure.com

**Bangalore** # 34, Royal Park Apartment, 2nd floor, Office No.12, Park Road, Tasker Town, Shivajinagar, Bangalore - 560051.Ph: 080-41128057-58. Fax: 080-41128685
Contact: Ms. Chetna Wasu
e-mail : chetna.wasu@indiainsure.com

**Chennai** Sri Valli Griha, Flat GA, Ground Floor, New # 34, (Old # 26), Raman Street, T Nagar, Chennai-600 017. Ph: 044-4202 3797/98 Fax: 044-42023799
Contact: Mr. V.G. Dhanasekaran
e-mail : dhanasekaran.vg@indiainsure.com

**Kolkatta** 4th Floor, Larica , 7 Redcross Palace, Kolkatta- 700001
Ph: 033-64602097 / 98
Contact: Mr. Deepak Kwatra e-mail : deepak.kwatra@indiainsure.com

**Hyderabad** # 405, Archana Arcade, St John's Road, Secunderabad - 500025
Ph: 040-27822989/90/91, Fax: 040-27822993
Contact: Mr. Vinod Kalevar
email: vinod.kalevar@indiainsure.com

**Mumbai** **Branch & Corporate Office :** Gala # 16,1st floor, Mehta Industrial Estate M & T Studio Compound, A.K.Road, Andheri (E), Mumbai - 400 093
Tel : 022-66791416 /17/18, Fax : 022-66791421
Contact: Mr. Rama Rao email: ramarao@indiainsure.com

**New Delhi** # B-3/6, 2nd Floor, Asaf Ali Road,New Delhi - 110002
Phone No: 011 43538760/61
Contact: Mr. P. Srinivas Rao email: srinivas.rao@indiainsure.com

**Pune** # 101, Premium Point, Opp. Modern High School, J.M. Road, Shivajinagar, Pune - 411005,
Tel : 020-66016676 Fax: 020-66030713
Contact: Ms. Deepali.A.Rao
email : deepali.rao@indiainsure.com