*i*notes Newsletter from India's Leading Insurance Broking House
October 2010

Summary

India Insure The risk managers

Message from the Editor

Dear Readers,

After all the controversies and muck that surrounded the Common Wealth Games, the spectacular opening ceremony did give each of us a reason to be proud of! Continuing on the same note, post a slowdown in the industry since the past two years, it is heartening to note the remarkable growth rate of the general insurance industry too. For the first time after the commencement of detariffication in early 2007, has the industry seen this kind of growth – an over 22% growth rate in the first five months. With this kind of a consistent growth rate being maintained, the industry appears poised to end the fiscal with an over 25% growth rate! The Private insurers in particular have been rather aggressive clocking an over 24% growth rate. Well, could this be early indications of the market hardening in some lines of business?

With India emerging as the global hub for Clinical Research, we thought it appropriate to dwell upon this topic and in this issue we have focussed upon Understanding the Clinical Trials business as well as insurance. In our interview section we have Mr. T A Ramalingam, Head Underwriter, Bajaj Allianz & Mr. P. Sashidharan Nair, National Manager - Liability Claims, HDFC ERGO expressing their views on the liability market in India. Our sincere thanks to them for sharing their valuable insights with our readers.

With the festive season round the corner, greetings to all of you!

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

Understanding Clinical Trials Insurance

- *Clinical drug-test claims volunteer's life in Hyderabad- DNA India*
- *49 babies die in AIIMS clinical trials – Times of India*
- *Wyeth's Prevenar vaccine trials suspended in India after reports of infant death – Live Mint*
- *Unending queue of unethical drug trials in India – Express Health care*
- *Centre Admits Deaths in Clinical Trial of GE Drugs- The Hindu*
- *Multinational clinical research company shuts unit at Rajkot hospital following allegations of illegal trial*

The last few years have witnessed a dramatic increase in the number of clinical trials in India. As per the Indian Council of Medical Research's (ICMR) Clinical Trials Registry-India (www.ctri.in), 1279 trials are currently registered in India. India is viewed as a favored global hub for international clinical trials of drugs. According to the Drugs Controller General of India (DCGI), "India will be a preferred site for clinical trials because, in addition to its medical infrastructure and trained, English speaking manpower, it has a large, diverse and treatment-naïve [untreated] population with six out of the seven genetic varieties of the human race; a pool of patients with both acute and chronic diseases, an increase in the number of patients with lifestyle disorders and the highest recruitment rates for such trials internationally". Data also suggests a 60-70% cost saving associated with conducting clinical trials in India compared to the same being conducted in USA/ Western Europe.

Introduction to Clinical Trials

Pharmaceutical companies invest a lot into research to find solutions or cures to large scale diseases or degenerative conditions. Presently, nearly two thirds of R&D costs go into drug development, of which clinical research accounts for 70 per cent of time and resources spent. Before a new drug is being released in the market, it needs to be tested for its safety and effectiveness on human subjects who volunteer to participate. The human subject can either be healthy volunteers or patients suffering from a disease for which the medicine is being tested. The test is intended to provide adequate information on drug use - on its safety, efficacy and possible adverse effects. This process is known as clinical trial or bio-equivalence test, based on the kind of trial conducted.

Clinical trials follow a pre-defined protocol that describes the process followed by the clinical experts in the study; what types of people may participate in the trial; the schedule of tests, procedures, medications, dosages and the length of the study. To protect the interests of the trial participants, they require signing a consent document that details the nature of the study, the risks involved and the potential benefits before the recruitment. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Absence of informed consent in the process of Clinical Trials in India has been a cause of concern. Language and cultural background of socio-economically backward patients come in the way of understanding the drawbacks/ side-effects of some trials. Low literacy levels and poverty in India when added to the pressure from the sponsors for early completion of patient enrollment do at times lead to unethical recruitment.

Stakeholders in Clinical Trials

A trial involves multiple stakeholders: the sponsor whose product is being tested, the CRO (Contract Research Organization) that monitors the trial and the principal investigator or doctor who conducts the trial and the hospital where the trial is conducted. There are also ethics committees — mostly affiliated to hospitals — that approves a trial and carries the onus of ensuring subject safety.

CRO's

Drug companies /Sponsors conduct clinical trials through contract research organizations (CROs), whose job is to get the research done. There has been an unprecedented growth in CROs in India with most Indian and major multinationals setting up operations in India either directly or as joint ventures.

CROs may handle some or all aspects of a sponsor's project including: regulatory approvals for trials, identifying recruiting sites and investigators, monitoring sites, data entry and management, submitting data for marketing approval and drafting study reports for submission to journals. These activities may also be split up and handled by different organizations.

(Contd... 02)

Phases of a Clinical Trial

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help researchers answer different questions.

Phase I trials test an experimental drug or treatment on a small number of healthy volunteers (20-80) for the first time to evaluate its safety, determine a safe dosage range and identify side effects.

Phase II trials: The experimental drug/treatment is given to a large group of patients (100-300) to see its efficacy and to further evaluate its safety. These are conducted on persons having the disease or medical condition to determine whether the drug has some level of therapeutic effect. It gives Indication for use depending on the type of patient, severity of disease, dose range, nature of side effects & severity.

Phase III trials: The experimental drug/treatment is given to larger groups of patients (1000-3000) at multiple sites/centers to confirm its effectiveness, monitor side effects, compare it to commonly used treatments (therapeutic benefits) and collect information towards obtaining marketing approval for the drug.

Phase IV trials are conducted after a drug obtains marketing approval. They are conducted for various purposes including monitoring for drug interactions over a much larger patient population and longer time period. No fixed time and population.

Regulation of Clinical Trials

The major regulatory body involved in the drug approval process in India is the Drug Controller General of India (DCGI). The trial sponsor must obtain approval from the DCGI before starting a trial. Trials also require clearance from the Institutional ethics review committee (IEC) at each site.

Clinical trials in India are regulated by Schedule Y of the Drugs and Cosmetics Rules. The Rules are enforced by the office of the DCGI who is also responsible for monitoring all clinical trials submitted for approval. DCGI was not equipped to monitor existing clinical trials but a recent health ministry statement mentions that it is planning to conduct regular inspections of trial sites from September 2010. For new drugs being developed in India, clinical trials have to be conducted in India from Phase I. Till January 2005, clinical trials of new drugs being developed outside India were permitted only with a "phase lag": a phase 2 trial could be conducted in India only after phase 3 trials were completed elsewhere. Phase 1 trials of foreign drugs are not permitted, except for drugs of special relevance to India. As of January 2005, an amendment of Schedule Y of the Drugs and Cosmetics Rules did away with the phase lag in international clinical trials conducted by foreign sponsors. There are no longer any restrictions on "concurrent phase" clinical trials in India. Phase 2 and phase 3 trials of drugs discovered abroad may now be conducted in India in the same phase and at the same time as they are conducted in other parts of the world.

Clinical trials Registry: A central online registry for clinical trials has been set up and w.e.f. 15th June 2009, mandatory registration of clinical trials in the registry **(www.ctri.in)** is required. As per DCGI decision, trial registration before the enrollment of the first patient has become mandatory and all registered trials are made publicly available to ensure transparency and accountability.

Institutional Ethics Committee (IEC)

Though ethics is an important part of medical research, it is very often neglected. The Indian Council of Medical Research (ICMR) guidelines for clinical trials insist on the setting up of ethics committees at the institutional levels. IEC's are specially constituted review bodies established or designated to protect the welfare of human subjects recruited to participate in research studies. An IEC, is charged with the responsibility to scrutinize and approve the clinical trial before the study begins and also to conduct periodic reviews of the progress of the trial. Revised ICMR guidelines for biomedical research published in 2006 state that the ethics review committee is also responsible for monitoring trials. A draft bill to make the guidelines legally binding is pending with the ministry of health. Once passed, the law will require that all IECs register with a Biomedical Research Authority who will evaluate the functioning of IECs.

However, ethics review in India is far from adequate. Not all IECs are established as per legal provisions; and neither are the members sufficiently trained for this work.

Where the liability is

The conduct of clinical trials, involving the participation of human beings, implicates a variety of concerns creating numerous challenges for the different stakeholders who are involved. Prime legal issues in the arena of clinical trials are: conflict of interest, consent, confidentiality, jurisdiction, scope of acceptable research, justice in recruitment of subjects and remedy mechanism in case of negligence. Specifically, an organization engaged in any aspect of clinical research is subject to the threat of claims alleging misstatements, claims challenging the veracity of its information, or allegations that a breach in protocol by staff members has caused a research subject to suffer bodily injury.

As per the Indian Council of Medical Research (ICMR) Ethical Guidelines / Good Clinical Practice (GCP) framework, it is obligatory for the pharma company, sponsor or the institution conducting trials to compensate research subjects for serious adverse reactions, disability or death. ICMR guidelines of 2006 inter alia states that: *'Each research (study) should include an in-built mechanism for compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment. With respect to any effect that the conduct of research or experimentation may have on the human participant and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.'*

Sponsor / Pharma Company

The commercial advantage to the company that produces the first approved drug for a disease that affects a large patient population can be enormous. But also, the liabilities associated with such trials can be significant as drugs being tested may produce effects that were not envisaged causing injury to the trial participant. This can create large liabilities and the companies sponsoring such trials may find themselves entangled in legal suits.

CRO

These entities have an errors and omissions (E&O) exposure related to the collection and management of research data, and they may also have a professional indemnity exposure if they employ or contract with the research professionals who have direct patient contact or manage the trial. This was illustrated recently when CRO Parexel was at the centre of a drug trial disaster after six out of eight men it carried out Phase I trials on - under contract on behalf of small German biotech firm TeGenero - experienced a severe and systemic adverse reaction and were admitted to intensive care within hours of taking the experimental drug. TeGenero had taken out an insurance policy of only £3m, to cover the trial and went bust shortly after the tragedy, while Parexel is currently in compensation negotiations with the lawyers of the victims.

(Contd... 03)

Understanding Clinical Trials Insurance .... Contd. # 2

E&O and Professional Indemnity exposure exists when a CRO:

- Manages the trial
- Develops the trial protocol and consent forms
- Has direct patient contact (dosing patients with study drug, drawing blood, etc.)
- Recruits patients

Ethics Committee

IECs are at risk of approving improperly developed protocols or inappropriate/misleading consent forms. A vicarious professional indemnity/ bodily injury exposure also exists due to an improperly developed protocol approved by the IEC, which results in an injury to a trial subject.

Each party involved in conducting the trial has moral and legal responsibilities towards the human subject. They all have real and significant exposure to liability.

Litigation trends

The Indian trend in the clinical trial litigations is unique till now. Media and NGOs appear as the flag raisers rather than the participants in the trials. Few PILs and writs occupy the case domain, with very little judicial interpretation, but the spat of litigations abroad serve as a stern warning, making future litigations by the participants a certainty.

Clinical Trials Insurance

Participation in clinical trials always carries some risk, such as injuries resulting from the research procedure, injuries caused by the administration of medication or medical procedures or an investigator's failure to follow the protocol or to perform the procedures correctly. These potential liabilities have created the need for Clinical Trials Liability Insurance since Products Liability Insurance does not normally include the liability of an unproven, unregulated product in its testing stages.

Clinical trial insurance (CTI) pays for the sums which the Insured shall be liable to pay as damages / compensation (including claimants costs and expenses) arising out of claims which are made by research subjects alleging death, bodily injury or any other adverse reaction in the body causing harm or disability to the body as a result of participation in a clinical trial. The term 'insured' includes a wide group of people involved in the clinical trial, from the sponsor to the investigators & the hospitals, to the contract research organization and even to the ethics committee that approves the trial. The policy can be single trial policy or it may be multi-trial policy covering several trials of the policyholder.

No Fault Compensation

The Clinical trials insurance policy is based on a no-fault principle which is intended to provide compensation to clinical trial subjects, without proof of fault of the insured, in the event of their suffering an injury which is directly attributable to their involvement in the trial.

At the time of a claim, the Insured by way of agreement offers the Trial Subject the option of having the Claim determined in accordance with the Conditions of Compensation laid out in the policy wording. The Trial Subject must agree within three months to the amount of compensation offered. If the Trial Subject does not accept the compensation offered, then he can pursue his rights in a Court of Law and the insurance policy will indemnify the insured all sums which he shall become legally liable to pay to the trial subject in accordance to the law applicable in the country in which the trial took place subject to the policy limits.

Claims -made policy

The most commonly accepted form of insurance available for most types of products in human clinical trials is that which is written on a "claims made" basis, as opposed to being written on an "occurrence" basis. A claims-made form provides coverage only if the claim is filed during the policy period. As long as the claim is registered within the agreed-upon coverage dates, the insurance carrier is responsible; if, however, the claim is filed at any time after the coverage period even if the accident occurred during that coverage period, the insurer is not responsible.

Even with a claims-made policy, a company can still ensure that it is covered for claims filed after the policy has expired. Whenever the company buys a new policy or renews its current one, it is imperative that the retroactive date be exactly the same as it was on the original policy. This makes the insurer responsible for any incidents that occurred while the company was under coverage, regardless of when the claim was filed.

In a single trial policy it is imperative that the insured purchase an "extended Discovery Period" under the policy. On completion of a clinical trial, the insured has an option of either discontinuing the policy or renewing the policy for another 12 months. If the insured discontinues the policy, then the policy will provide for a 3 to 6 months discovery period in which the insured can notify a claim, discovered to a subject after the policy expiry. In certain countries there is a regulation of buying a discovery period for a specified no. of months which can range from 6 months to 3 years.

In India there is no such regulation with respect to the discovery period.

Premium Rating

For the purpose of premium rating, the most important aspect that is looked into is the track record of the sponsoring company and others involved in conducting the trial. The company must establish and maintain a policy of adherence to the required clinical trials protocol and must not stray from safety norms. Fulfillment of informed consent rules must be ensured.

The rates of premium are dependent on the type & phase of trial, the drug being tested, the number of trial subjects, age of the subjects and the outcome of the trial.

Limits of Coverage

There is no set rule for establishing coverage limits or minimums, but the consensus in the insurance community is that a clinical trials liability policy should carry a minimum limit of $1 million and can have upper limits of $10 million through $20 million or more. Of course, a company's specific needs and sometimes the needs of the testing facility and its risk levels will dictate an acceptable range for these limits.

The Policy also provides various extensions like Professional Indemnity extension and Manslaughter Defense cost for the Ethics Committee. Clinical trial insurance products are now available in India and are being provided by several general insurers.

Conclusion

The value of clinical trials outsourced to India is estimated at USD 350 mn in 2009 and expected to reach USD 1 billion by 2012. India is clearly on course to become a major global center for clinical trials. Considering the fact that clinical trial is a new form of business in India and with reports of failure rates, it poses a lot of challenges to all the stakeholders, including the sponsors and the service providers. Although companies face continuing pressure to reduce clinical development timelines and costs, it is important that these factors do not encourage staff to let standards slip since one adverse event can cause catastrophic losses.

Conducting clinical trials can be risky business. However, with a holistic risk management approach that includes contractual protection and tailored insurance coverage, firms can move with confidence into this exciting and necessary arena. It is in the pharmaceutical industry's interest to have a properly designed risk management and insurance program to ensure compliance, protect trial subjects and safeguard the viability of companies involved in the business of seeking out new ways to improve human lives.

The inherent activity of a clinical trial understandably brings with it the risk of litigation and loss.

With the increase in the number of trials being conducted in India, demand for appropriate risk management measures and clinical trial liability insurance is also increasing. In this issue we speak to Mr. T A Ramalingam, Head Underwriter, Bajaj Allianz & Mr. Sashidharan Nair, National Manager - Liability Claims, HDFC ERGO on how the insurance industry in India is supporting Pharma companies and Clinical research organizations with insurance & risk management solutions.

Can you briefly describe the current conditions in the liability landscape in India? How have exposures increased over the past year for insurers and reinsurers writing this line of business?

Mr. T A Ramalingam: The awareness towards Liability has been increasing in India in the past couple of years what with more media coverage in respect of cases like Satyam, Taj Terror attacks etc. Hence the consumers have become much more aware of the exposures they face on day to day basis. This of course presents both an opportunity as well as a threat to the Insurers and Reinsurers who are willing to write this risk.

Mr. P Sashidharan Nair: Liability scenario has changed in India in line with the Industrial growth and globalization of Indian Industry, especially the IT Industry which has been the trendsetter. We have seen increase of claims mainly in EPLI related issues in IT Industry from US and other countries. Indian companies have got listed in NASDAQ and this has resulted in suits against some of these companies by shareholders, investors and statutory bodies. This has also created a scenario by which the Indian investors who were not litigation conscious becoming one.

Another area where we have seen increase in litigation is Media Liability cases in view of changed approach by Producers and deep pockets of these producers attracting litigation by complainants. There would also be more cases coming up in Product Liability and General Liability in future when the awareness grows.

What reasons would you attribute to the Indian market not being as litigious as other countries, particularly in the West? Do you foresee any changes in this tendency in the near future in India?

TAR: The backlog of cases pending with the courts and the time it normally takes for any case to be heard and finally adjudicated could be some of the reason why India is not as litigious as other countries. However considering the awareness and the increased standards of living this could change in a couple of years time.

PSN: The main reason is the lack of confidence in the Indian courts that the case will come to a logical conclusion in a short time. This is the case of most of the Litigations and also to some extent lack of specialist lawyers who will educate the affected public like we have in other developed nations. The Customers/ investors are not fully aware of their rights under various laws and statutory provisions which can be the real contributor for such Litigations against Companies/ Corporations.

The above aspect will definitely change with the advent of RTI, Publicity through media, Advocates getting into specialized area of corporate laws / investor rights etc. After Satyam episode there was a move by SEBI to ensure that all listed companies mandatorily take a D&O cover. This would have increased liability business in India and resultant awareness by common public about their rights against Companies and corporation. However, we have not seen this happening like all such Reactions when a calamity occurs.

What are the critical parameters considered in arriving at the premium for clinical trials liability insurance and how are the prevailing market conditions in following 'strict underwriting practices' as far as Clinical trials insurance is considered?

TAR: Various parameters like characteristics of the drug, method of administration of drug, subject profile, trial period, trial phase, number of subjects, etc are considered for the rating of clinical trial policies. Considering the nature of cover being offered in Clinical Trials Strict underwriting practices need to be followed for each and every proposal.

Different trials have different levels of risk. Is there a distinction made between clinical trials involving patients with life threatening disease and trials involving healthy volunteers as study participants? How do insurers deal with this?

TAR: Yes. There is clear distinction between trials based on the subject profile. This is a very important factor while underwriting clinical trial insurance policies. The premium rating would differ accordingly.

What are the areas of concern that the insurance industry has with clinical trials and how do those concerns influence or shape the solutions that are provided?

TAR: The main concern is lack of data being submitted by the clients. This could be because the trial protocols are confidential in nature. To mitigate this, we are willing to offer to sign a mutual Non-disclosure agreement with our client which offers much more confidence to share the required data with us. The other concern is that for most of the clients have been opting for very low Indemnity limits. We have been constantly educating our clients to buy reasonable Insurance limits especially considering the significant rise in clinical trial claims in India.

PSN: Claims as such has not been in large numbers and hence it is difficult to have a trend which will enable one to develop concerns. What has been seen is that like other litigation cases, probably the research subjects are still not that educated about their rights and consequently not aggressive enough to seek larger compensation. There have not been enough case studies in India which has made the Industry to sit up and review the Policy coverage. However, the fact that India is catching up with being one of the top Pharma Research centres in the world may attract more stringent rules and awareness amongst the subjects. Most of the Insurers restrict the coverage by not giving Medical benefits extension or have a higher deductible for such claims. This is a good approach since as stated earlier Trial Drug related complications are few.

Presently the Organization specifies an agreed amount payable to a Trial Subject in the event of Drug related complications and Insurer would pick up only those liabilities which an Insured becomes legally liable other than agreed amount as per contract. This happens only when a Research subject does not agree to the compensation offered and demands for more.

Have you seen an uptick in the past few years from Pharma companies/ Contract Research Organizations enquiring about insurance coverage for clinical trials? What percentage of clinical trials conducted in India do you think opt for this cover?

TAR: Yes, there has been significant rise in the enquiry as well as the purchase of Clinical trial policies. However, the penetration on this product has been quite low with not more than 10% of the clinical trials conducted in India being insured.

(Contd... 07)

inotes Newsletter from India's Leading Insurance Broking House
October 2010

Report Card - August 2010

Gross premium underwritten by non life industry for and up to the month of August 2010* (Rs. In crores)

INSURER	AUGUST		GROWTH OVER THE SAME PERIOD OF PREVIOUS YEAR	APRIL - AUGUST		GROWTH OVER THE SAME PERIOD OF PREVIOUS YEAR
	2010-11	2009-10		2010-11	2009-10	
New India	456	383	19.19%	3052	2541	20.11%
United India	512	414	23.75%	2571	2073	24.03%
National	441	332	32.79%	2376	1847	28.62%
Oriental	413	360	14.88%	2226	1957	13.74%
ICICI-Lombard	358	263	36.14%	1755	1375	27.61%
Bajaj Allianz	230	190	21.00%	1198	1040	15.26%
IFFCO-Tokio	128	91	40.80%	769	644	19.45%
Reliance	125	149	-15.82%	690	877	-21.34%
Tata-AIG	89	58	52.38%	529	398	32.87%
HDFC ERGO General	111	70	58.46%	544	361	50.60%
Royal Sundaram	88	74	18.97%	443	360	22.99%
Cholamandalam	73	58	26.52%	399	354	12.68%
Future Generali	55	28	100.27%	261	147	78.27%
Shriram General	56	31	79.34%	254	111	128.22%
Bharti AXA General	40	18	125.98%	220	80	175.67%
Universal Sompo	23	10	138.38%	127	54	133.70%
SBI General	0	0		7	0	
Raheja QBE	1	0		3	0	
PRIVATE TOTAL	**1378**	**1039**	**32.56%**	**7199**	**5801**	**24.09%**
PUBLIC TOTAL	**1823**	**1489**	**22.45%**	**10225**	**8418**	**21.46%**
GRAND TOTAL	**3201**	**2528**	**26.61%**	**17424**	**14219**	**22.53%**
SPECIALISED INSTITUTIONS:						
1.Credit Insurance						
ECGC	70	67		338	327	3.54%
2.Health Insurance						
Star Health	27	16		555	420	32.20%
Apollo MUNICH	13	8		69	35	97.87%
Max BUPA	2	0		6	0	
Health Total	**41**	**23**		**629**	**455**	**38.48%**
3.Agriculture Insurance						
AIC	431.55	234.65		710	468	51.76%

* Source : IRDA

Performance for Apr-August 2010 Period

- The industry (incl stand alone health insurers) have collected premiums of Rs.18053 crores recording a growth rate of 23% during Apr-August 2010 compared to Rs. 14674 crores during the same period last year.
- The private players have registered an impressive growth of 24.09% during this period compared to last year's dismal 4.41%.
- The PSU's have registered a growth rate of 21.46% during this period compared to last year's 10%.
- The accretion achieved by the PSU's during this period is Rs.1807 crores; the private players: Rs.1398 crores and stand-alone health insurers: Rs.175 crores towards the overall market accretion of Rs.3379 crore.
- The major contributors for the performance in the period Apr- August 2010 have been National with an accretion of 529 crores (National has overtaken Oriental to be the 3rd largest general insurer), New India with an accretion of 511 crores, United India with an accretion of 498 crores and ICICI Lombard with an accretion of 380 crores.
- Reliance has recorded a negative growth of 21.34% during this period.
- At the end of this period, the private players have collectively increased their market share to 41.32% from 40.80% during the same period last year.

News TitBits

ICICI Lombard insures Nacils fleet for $ 9.1bn

Source: Economic Times

ICICI Lombard General Insurance has won the bid to insure NACIL's aircraft fleet for USD 9.1 billion, the first time as the lead insurer for the national air-carrier. The UK's Chartis is the lead reinsurer for the deal.

Insurance cos to make mediclaims time-bound

Source: Economic Times

To check fraud in the reimbursement of mediclaim policy, public sector insurance companies have decided to deny claims to policy holders if they fail to submit their papers post-discharge within the stipulated timeframe. Insurance companies have so far taken a lenient approach on this aspect. A TPA official said: "The United India Insurance Company has issued a circular as per which claim documents have to be submitted within seven days from the discharge date".

Banks ask Oriental to pay Rs 400 Cr on Paramount Default

Source: Financial Express

The state-owned Oriental Insurance has been saddled with claims of Rs 400 crore from five banks. The banks are looking to recover the money paid to the oil companies on behalf of Paramount Airways which had failed to clear its dues involved in the bank guarantee. Disturbed by the development, IRDA has banned the sale of credit insurance by general insurance companies to banks, except state-owned Export Credit Guarantee Corporation (ECGC).

LIC earns premium of Rs 4853 cr from BSNL

Source: Economic Times

Life Insurance Corporation (LIC) has earned premium of Rs 4,853 crore from BSNL under a group scheme, which is the largest sum got by a life insurer from a single company. The policy is of BSNL Employees Leave Encashment Scheme which is the corpus towards earned leave encashment to be paid to employees of BSNL at the time of retirement.

Swiss Re to exit TTK Healthcare TPA

Source: Economic Times

Re-insurance firm Swiss Re said it will sell its entire 26% stake in third party administration firm TTK Healthcare TPA to Vidal Healthcare Services so that it can focus on the re-insurance business in India.

Reinsurance reform next on IRDA agenda

Source: Hindu Business Line

After a spate of reforms in Unit-Linked Insurance Plans (ULIPs), the Insurance Regulatory and Development Authority (IRDA) wants to streamline reinsurance segment.

Avantha inks pact with ERGO to discuss life JV

HDFC Standard Life awarded India's Most Trusted Private Life Insurance Brand 2010

United India Insurance Company has been selected as the best 'Non-Life Insurance Company' in the country by NDTV Profit – Business Leadership Award Committee for the year 2010.

ICICI Lombard awarded NASSCOM - CNBC TV 18 IT User Award 2010

Readers Speak - *The Future of TPA*

In the last issue of inotes, we had asked

"What actually went wrong with the TPA concept that started with very high expectations? Who is to blame? Did TPA's fail in achieving their responsibilities? How do TPA's enforce standardization without any kind of regulation on healthcare rates? Are customers & Insurance companies better off without TPA's? Is it the end of the road for TPA's in India or is there a bright future awaiting them? How do they move forward?

Below are some of the responses we received

Response from **Ms. K Radhika, Business Head, Iffco Tokio General Insurance**

TPAs are in nascent stage in India. The TPAs operate as Managed Care Organizations who play a vital role in bringing all components of Health care such as physicians, clinics, hospitals, long term facilities, insurance companies and pharmacies together. The role of TPAs has been defined to control costs of health care and ensure appropriate quality of care. It is perceived that hospitals tend to charge patients covered with insurance more. In the absence of monitoring and control mechanisms, it is difficult to handle fraudulent claims. The effectiveness of the TPAs in managing claims depends on their bargaining power with the health care providers such as the hospitals. The growing health insurance and the unregulated health care market are only going to result in the costs of healthcare going up.

The fact that the healthcare providers are fragmented and unregulated offers a huge challenge to the TPAs in controlling and managing the claims. Lack of management competencies and capabilities can also be a serious issue for the functioning of the TPAs. The TPAs today are not able to attract quality Medical Doctors to work for them for various reasons which in turn denies them the chance to negotiate better with both the hospitals and the insurance companies. Quality manpower and consistency in operations need to be the focus areas for the success of TPAs. With the growth of health insurance in the rural areas of India, TPAs need to expand their infrastructural capabilities to serve the rural health insurance schemes. The investment in Technology will help TPAs improve standards of service and render better analysis of medical trends. TPAs will continue to play an important role in the growth and development of managed health care system in India.

Response from **Ms. Malti Jaswal, CEO, E-Meditek TPA Services**

From initial days of 2002 when the concept of TPA was introduced for the first time in India to 2010, the role of TPAs has undergone a sea change. It is no more restricted to organizing cashless for health insurance customers but extends to provider network management, managing claims and containing cost, checking fraud and leakages, and value added services like analytics for insurers, wellness programs for insureds etc, all delivered in seamless fashion. While the expectations of the industry from TPAs have grown multi fold, one witnesses the challenges of the TPA industry to meet the same, especially given the inherent conflicts between 3 key stake holders in health insurance – insured, insurer and healthcare provider and also due to limitation to servicing capability imposed by prevailing low TPA fee.

This has led to a question mark on future of TPAs. While TPA industry is rising to meet the challenge by improving services, investing in technology and people, offering end to end solutions, adopting best practices, however the answer to the question also lies in the evolution of health insurance, to the necessity of a reasonable level of trust and understanding between stakeholders. Whether the customer is served by an in-house claims team or a TPA, the delivery of services also depends on – simple products with clearly explained exclusions, healthcare provider ethical practices, customer awareness and education. As for the TPAs future, so long as a TPA can help keep claims cost low and customer experience high, it would not go out of business.

"Views expressed herein are purely personal and do not reflect the views of the Company"

Claims Case Study: *Spontaneous Combustion*

Background: Suryakanti Oil Mills had taken a fire insurance policy from ABC Insurance Company for the period 1st Jan - 31st Dec 2008 in respect of the stocks of mustard seeds during their storage in the silo installed near the oil mill inside the factory premises of the insured. The sum insured under the policy was Rs. 1.25 crore and premium was charged for covering the perils specified in the policy, including "spontaneous combustion".

On 7th August 2008, the workers in the complex reportedly observed flames & smoke emanating from the top of the silo in which mustard seeds were stored. The workers immediately went to the top of the silo and removed the lid with a view to releasing the pungent fumes from the silo. Simultaneously, the air circulation fan was reportedly switched off. Thereafter the outlet hatch at the bottom of the silo was opened, with a view to letting out the stocks of mustard seeds. It was reported that the initial seeds that came out were undamaged but thereafter heat affected mustard seeds started pouring out.

The insured reportedly informed the insurer on the same day that 8952 quintals of mustard seeds stored in the silo had been affected due to self "spontaneous combustion" and requested to depute a surveyor for assessment of claim. The insured also mentioned that they did not report the matter to the fire brigade on the ground that the fire brigade would pour water into the silo and cause further damage to the stocks.

The surveyor appointed by the Insurer, after verification, arrived at the conclusion that though the insured stocks were damaged

Next Issue - PSU Cartelization for TPA

In order to bring down the high claims ratio in health insurance, public sector insurance companies have decided to float their own third-party administrator (TPA) for management of health claims. They have also invited proposals from companies to form a joint venture for their yet-to-be-floated TPA. Third-party administrators (TPAs) have complained to the Competition Commission of India (CCI) against the 4 PSU's forming a cartel and abusing their dominant market position in planning a TPA outfit of their own. TPA's feel the move will put them out of business and sound the death knell for the fledgling industry.

With TPA's currently handling around 80% of the PSU's health insurance business, what will be the impact of the common TPA on consumer and the health insurance industry? Will claims costs come down? Will the service levels improve? Will the lack of competitive spirit after formation of common TPA cause a decline in performance? Who will eventually bear the brunt as the industry pushes for increased efficiency? Will not the lack of regulatory guidelines for providers (hospitals) again act as a roadblock in achieving the very purpose for which the common TPA is created- bring down claims costs?

Your opinion is solicited!

Please send your responses in 200 – 300 words to knowledge @indiainsure.com

due to spontaneous combustion, he could not observe any evidence of fire within the meaning of the policy having occurred inside the silo. If the mustard seeds had really caught fire, the fumes containing oil would cause deposit of oil smear on the inner surfaces of the silo body and the manholes/vents through which the fumes come out. He did not observe any such oil smear. On the ground that there was no "fire" due to the spontaneous combustion, the Insurance Company going by the Survey Report repudiated the claim. The Insured was aggrieved and took the matter to Court.

The Issues

The Court observed that the schedule to the insurance policy specifically provides that ABC Insurance Company had charged additional premium for covering risk due to 'Spontaneous Combustion', that means there was insurance cover for damage due to spontaneous combustion of the stocks. Further, no exception was carved out while covering the risk due to spontaneous combustion.

However, Learned Counsel, on behalf of the Insurance Company submitted that for Spontaneous Combustion an endorsement was also given to the following effect:

*"In consideration of the payment by the insured to the Company of additional premium the Company agrees notwithstanding what is stated in the printed exclusions of this policy to the contrary that the insurance by this policy shall extend to include loss or damage **by fire only of or to the property insured caused by its own fermentation, natural heating or spontaneous combustion.**"*

The Insurance Company vehemently contended that as there was no fire, they are not liable to reimburse the damages.

Conclusion

However, the Commission held that by taking additional premium and giving endorsement for spontaneous combustion, the Insurance Company had covered such peril and recorded the following reasons for the aforesaid judgment.

- *Recovery of additional premium indicates the nature of the contract that subsists between the parties. That contract cannot be of giving insurance coverage only in case of damage by fire. If that contention is accepted, the object and purpose of payment of additional premium is frustrated. Recovery of additional premium indicates acceptance of risk by the Insurance Company for the perils contemplated.*
- *Also, the aforesaid endorsement on 'Spontaneous Combustion' is apparently vague. By a bare reading of this clause, it would be difficult to conclude what it exactly conveys. And if the contract is vague, benefit should be given to the insured.*

In view of the matter, the Court held that the damages are covered the Fire policy taken and directed the Insurance Company to pay the claim to the Insured.

Interview – *Insurers* .... Contd. # 4

How have the claim trends been for liability insurance in general and Clinical trials in particular in India over the past couple of years?

TAR: We have seen an increase in the frequency as well as the quantum of claims under clinical trial policies. This could be attributed to stricter norms enforced by the ethical bodies and governing entities on compensating the injured clinical trial subjects.

PSN: Claim trends have seen increase in General Liability, Media liability and Crime claims. Clinical trials are still an untapped business in India but have seen claims mostly related to medical expenses for treatment of the Trial Subject. This is more due to complications during the trial period and may not be always due to the direct result of Trial Drug.

According to Associated Chambers of Commerce and Industry , an influential national Industry Association, India is set to grab clinical trial business of approx. 1Billion US$ by 2010 end making the subcontinent one of the preferred destination for clinical trials. The Indian Pharma Industry is growing at the rate of 11% whereas the Clinical Research Industry is growing at an annual rate of whopping 84%. However, most of the incidents that result in liability is Uninsured and would go unreported for the Insurance Industry to build up a data base. This Insurance is not mandatory in India and hence most of the Organizations opt for self Insurance. What can change this as in all cases is increase in awareness of rights.

Risk management enjoys exceptional strategic significance in the insurance industry. How do you view the way the pharmaceutical sector deals with the risks associated with clinical trials?

TAR: Insurance has always been a significant risk management tool for all companies and pharma companies are no exception. Product liability still remains their most important exposure, however with stricter regulatory norms and increased consumer awareness, clinical trials exposure is not far behind. Pharma companies have been viewing this quite seriously and hence this has led to increase in enquiries for this product.

PSN: All organizations have a set protocol on the basis of which the trials are conducted and there are many committees and requirements which are to be complied with by the Organization conducting the trials. If I am not mistaken, according to Indian Law a Foreign organization cannot conduct Phase 1 Clinical Trials for a Molecule in India. There are sufficient safeguards set and what is to be ensured by the Drug Controller is that all the written rules are strictly adhered to.

Any risk which is unforeseen and beyond their control resulting in a liability against the research subject can be transferred to an Insurer. However, as stated earlier very few organizations opt for Insurance cover probably due to the fact that no one has faced a serious damage suit till date. There have been stray cases of problems arising due to trial drug related issues but the same have gone unreported at least to common public and media. As Insurers, we always look for the controls and procedures that have been put in place by the organization and various approvals that have been taken, while underwriting a proposal.

What is your strategy for growth of the Liability vertical in 2010-11? Would there be any specific product focus you would be looking at?

TAR: We are looking at growing the liability line of business this year by at least 25%. We are also looking at introducing a couple of new products during 2010-11.

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

View Point

PRODUCT INNOVATION IN THE INDIAN GENERAL INSURANCE MARKET- *Where are we?*

One of the objectives and expectations when the insurance market got liberalized in the year 2000 was that there would be substantial product innovation to cater to the various segments of the customers. How has the industry fared in the past decade in this aspect? Has the industry succeeded in bridging the gap between the customer needs and his insurance policy? While there have been some innovative variants in the Life and Health sector, it appears that the other lines of business have got a raw deal. Unfortunately, there is a stunning lack of product innovation in the other lines of insurance. Today, the property market is largely governed by the principle of 'One size fits all'. This could probably be because of the regulatory constraints in this line of business.

As the situation stands presently, the very large customer succeeds in getting what he requires either because of the knowledge he has acquired or with the inputs from the insurer or an expert broker. But what about the mid market segment, SMEs and retail customers which forms over 80% of the insurance market? It is this segment which is neglected and an investment by the Insurer in product innovation could pay off to both the Customer as well as the insurer. True, that the investment would pay off only for the lead time of say 6 months or so before the policy is picked up by other insurers too, but then this should not be the reason for an insurer to turn a blind eye to the customer requirement. To begin with, it would require insurers getting to actively take feedback from their field staff. While the entry of the broker has distanced the insurer from the customer, it is for the insurer to set up periodic interactions with the brokers to collect info on the market need. The overseas market has a wide array of products like Carbon credit insurance, weather derivative products, title insurance, latent defects insurance, holiday insurance etc. which have been tried and tested. What requires to be done by insurers in India is to understand and modify the policy to suit the Indian customer.

In response to the regulations permitting insurers to file new Add on covers several insurers have come up with new 'Add on' covers, but has this benefitted the customer? Are customers aware of these new covers? How would customers get to know of these add ons? In view of the weak distribution channels available in the present market, it probably may have been more effective had the Regulator permitted entirely new products in these lines of business and have it mandatory for the policy wordings to be available on public domain. Also, an effective way of reaching out to the customer requirement could probably be achieved by having policies to cater to each industry segment. These policies could have been tailored to have all the relevant add ons forming a part of the policy and the customer having a choice of de-selection of risk (as is presently available for the Flood, storm tempest as well as Riot, Strike, Malicious damage covers in the Standard Fire and Special Perils policy). This could help overcome the lack of knowledge in selling the right add ons by the distribution medium, be it an agent, broker, corporate agent or a bancassurance channel, and also one need not keep referring back to the erstwhile tariff and give discounts. A similar situation exists in the Project insurance segment too where presently there is a standard CAR / EAR/ MCE policy for all projects with a long list of add ons. Having customized products for say the Road, Bridge, Hydel, Thermal power projects etc would have a larger number of satisfied customers. These policies which are All risk policies have several exclusions like the dewatering, desilting expenses etc. which are not listed and come in as a surprise to the customer only when faced with a claim. Insurers need to relook at the age old products and re engineer them to meet the current local system.

The industry is now dealing with Customers who know what they want and what better provocation than this does the insurer require to get on with investing resources on Product innovation. By not investing in product innovation, the point that the insurer is turning a blind eye to is that while each customer is unique, the product is not. With the impetus in place, the crying need is for the Regulator to give Insurers the liberty to design new products thereby giving the customer the flexibility to choose what he requires and not choose from what is available!

–Ms. Meena Nair
AVP, India Insure

Disclaimer

Contact us

India Insure Risk Management & Insurance Broking Services P Ltd.

Ahmedabad 105, Sears Towers,Opp. IIPM, Off C.G. Road, Gulbai Tekra, Ahmedabad- 380006. Gujarat, INDIA. Tel: +91 79 32422007, Fax:+91 79 26406044 (M) +91 98250 66044, +91 97255 04381 Mr. Pawan Kumar Mediratta email : pawan.mediratta@indiainsure.com

Bangalore H M Geneva House, Property No.14, 401, 4th Floor, Cunningham Road, Bangalore - 560001, Ph: 080-41128056-57. Fax: 080-41128597 Contact: Mr. Rajendra Naidu, e-mail : rajendra.naidu@indiainsure.com

Chennai Building No.824,Bhandari Towers, 1st Floor, Opposite to Kilpauk Medical College, E V R Periyar Road, Kilpauk, Chennai – 600 010 Ph: 044-42661540 Fax: 044-42023799, Contact: Mr. V.G. Dhanasekaran, e-mail : dhanasekaran.vg@indiainsure.com

Kolkatta 4th Floor, Larica , 7 Red cross Palace, Kolkatta- 700001 Ph: 033-64602097 / 98 Contact: Mr. Dilip Burman e-mail : dilip.burman@indiainsure.com

Hyderabad # 405, Archana Arcade, St John's Road, Secunderabad - 500025 Ph: 040-27822989/90/91, Fax: 040-27822993 Contact: Mr. B.N. Prasad, email: bn.prasad@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. R. Chandrasekaran, email: chandrasekaran.r@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 Office No.592/2, Deccan Gymkhana, Off J M Road, 2nd Floor, Next to Hotel Central Park, Pune - 411004. Ph: 020-66030713, 020-66016676. Fax: 020-66030713 Contact: Ms. Aparna Ramesh email : aparna.rk@indiainsure.com