CLINICAL TRIAL LIABILITY INSURANCE

- ***R.Qaiser, Faculty Member, NIA, Pune***

With the opening of insurance sector and the demise of tariff regime, suddenly the Competition has become very fierce and we are witnessing the price war of the worst kind. To sustain over a period of time, there is a limit to which you can bring down the prices. What then is the alternative to achieve sustained growth? One of the alternatives is to tap the untapped market. Liability Insurance is one area where there are potential and insurance companies are eyeing the same.

Because of globalization and rapid progress made on technological front specially Information Technology, the world has become a global village. Whatever is happening in one part of the world has its own impact in other parts. Liability Insurance is a growing business area is USA and other advanced countries. This is because the people out there are very conscious of their right and remedies, the laws are becoming more and more victim friendly and so is the judiciary. The prevailing attitude of the people is -- "If I suffer because of somebody's negligence, let's find that somebody, sue him and get compensation." The same kind of mindset is developing in India also. This is getting further fillip from judicial activism and the roles being played by advocates coupled with strong consumer movement. Nothing is seen wrong in making fortune out of somebody's misfortune. Pollution is a world wide concern and so is the liability associated with it. The polluter must pay is now an accepted principle. Cyber-liability is another area of concern which is now engaging the attention of General Insurance Companies. It is felt that whatever we are witnessing happening in USA and Western Counties, the same is very likely to happen in India and other developing countries very soon. Hence growth in Liability Insurance is visualized.

One such potential areas as far as liability insurance is concerned is "clinical trial" and the liability associated with it and the insurance coverage for the same. But before understanding the liability associated with clinical trial, and the insurance part of it, let us

first see what is a clinical trial, how it is conducted and who conducts it? We shall also see how and when the liability comes in the picture. We shall then examine the nature of such liability and how as a part of sound risk management policy the liability insurance can play its role as a risk transfer mechanism.

Whenever any new medicine/therapy is to be launched, it must first be tested in lab on animal or human cell. If the results are encouraging, then it is tested on human being in different phases. Each phase is designed to answer specific questions. Basically there are four phases of testing or trial. It should be understood that a clinical trial is a trial of some medicine on human being to know the efficacy of medicine as also to understand its side effect.

Phase-I

His phase of the trial is meant to answer the question ----

Is the medicine/treatment safe? It tests the safety of the product, safe dosage and identification of side effects. This being the first trial on human beings, it is conducted on a small group of 20-50 volunteers.

Phase-II

It answers the questions --- Does it work? The experiment is carried out on a larger group of people (100 to 300) to further measure the efficacy, effectiveness and safety.

Phase-III

It answers the question – Is it better than what is already available? --The trial demonstrate large scale efficacy of medicine and is conducted on more than 1000 individuals across the countries / world. It is only after the drug is found suitable at phase-III that it is given license to be marketed.

Phase-IV

The testing continues even after the drug is launched (post marketing) in the market to provide additional evidence of efficacy, effect on different segment of population, effect after long term use, etc. This phase designed to answer --- What else do we need to know?

A clinical trial can be:-

(i) Treatment trials – new drugs, combination of drugs, new approach for treatment of disease.

(ii) Prevention trials – better ways to prevent disease in people.

(iii) Diagnostic trials – better test for diagnosing disease.

(iv) Screening trials – best ways to detect certain disease.

(v) Quality of life trials – ways to improve comfort and quality of life of patients with chronic illness.

Everybody understand & appreciate that clinical trials are vital and important for finding new, better and more effective medicine / therapy or procedure for treating disease and for improvement of health and quality of life. There is tremendous commercial advantage to the firm that produces the first approved drug for a disease. That being the position, there is dramatic increase of clinical trials. These have hither to been mostly confined to USA and other Western countries. Every country has got its own rules and regulations vis-à-vis drugs & foods and the clinical trials must comply with those rules. Testing new drugs in USA and other Western countries is becoming increasingly difficult for variety of reasons the chief being strict rules and regulations, getting research subject, elaborate safety norms requirement, judicial environment, etc. So these trials are now being outsourced to countries that are high on "country attractiveness index for clinical trial." India has now become a favourable destination for clinical trial because of availability of expertise and infrastructure, availability of patient / research subject, low cost and not much legal / regulatory restriction.

There are four parties involved in clinical trials and we will examine their role to understand their exposure to clinical liability suits and hence the need for clinical liability insurance. The four parties are:-

i) The sponsor company testing the new products / procedure. Basically the sponsoring company finances the entire trial.

ii) The Clinical Research Organization (CRO) that helps the sponsor manage the study

iii) The institution where the study is actually carried out

iv) The professionals (clinicians) who actually conduct and monitor the study on behalf of the sponsor.

The sensitivity of the clinical trial in view of the involvement of human subject can be well understood and appreciated. The human subject can either be healthy volunteers or patients suffering from disease for which the medicine is being tested. Each party involved in conducting the trial have moral and legal responsibilities towards the human subject. They all have real and significant exposure to liability. Generally the target for litigation are the clinical investigators and the research institute involved. The company that sponsors the trial is also exposed to the risk of liability on account of improper disclosure, conflict of interest, violation of good clinical practices, etc. In any case, in today's litigant society, parties are sued regardless of who or what caused injury or death. This being the ground reality insurance must form part of any risk management philosophy of the company interested in clinical trial. Most liability suit arises because of breaches in "informed consent" rules. Informed consent document is required to be signed by every human subject of the clinical trial. It details all known or reasonably foreseeable risk of the study and other relevant factors. Before any trial is started, detailed document with all the rules, procedures & formalities is prepared and submitted to the authority (Food and Drug Administration (FDA) in case of USA) which after due examination gives the go-ahead signal of actually starting the trial as outlined in the document. This document is called clinical tests protocol. Each trial has got its own individual protocol. Every aspect of the clinical trial including the protocol is further reviewed by IRB (Institutional Review Board) of the organization where this is carried out. Again the clinical trial has to pass through the Ethics Committee which examines it on various relevant parameters relating to the trial. So we can see that there are elaborate system & procedure to be followed so as to ensure that due care and diligence has been exercised at every stage of the trial. There is real danger of adverse reaction to the drugs and the resulting morbidity under trial is not very uncommon. As part of any clinical trial, therefore, this needs proper monitoring and a proper insurance cover for the same can be

useful. Even then, in spite of all precaution being there, liability will arise because of the human elements and other factors and hence the need for insurance.

Clinical Trial Liability Insurance (CTLI) basically covers legal liability arising out of lack of care, negligence resulting in injury or death of the subject. Insufficient/improper disclosure and conflict of interest may also become subject matter of suit. This policy generally covers legal expenses also. Territorial limit is prescribed in the policy. The policy can be single trial policy or it may be multi-trial policy covering several trial of the policyholder. The policy is on "Claim made" basis. Cover can be extended for post trial liabilities upto 60 months. For the purpose of rating the most important aspect to look 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. Parties to the clinical trial must sign clinical trial agreement for strict adherence to the protocol and to take care of other concerns.

Apart from standard exclusions (e.g. war risk, radiation, fines and penalties, deliberate contravention of instruction, etc.), the exclusion under CTLI are basically meant to exclude from the scope of the cover all eventualities that can not be attributed to and not resulting from the participation in the clinical trial.

Government of India is coming out with a comprehensive legislation called Central Drug Authority (CDA) bill --- that envisages imprisonment of five years, and fine of Rs. 20 lacs for those found violating norms of clinical trial. As of to-day there is no act or law to monitor the clinical research and drug trial in the country. Such a bill is necessary to ensure that the people who undergo clinical trials are not exploited and should be well informed about risk. Indian Chapter of Association of Clinical Research Professionals (ACRP) has been launched. There is need to enhance capacity building to handle trials in a more scientific and rational way. The likely enactment of law and launching of the chapter will bring in more professionalism and hence more of insurance support will be required There is thus a good market for this class of business in India. Though the

insurance is not mandatory but since most of the sponsoring organization are big multinational drug companies and they are governed by strict statutory / regulatory norms in their respective counties, they insist for insurance to be taken by Clinical Research Organisation (CRO) and other associated with the clinical trial in places where it is actually being carried out. But this being a new emerging field, lot of marketing effort is required coupled with creation of awareness. In fact in India, there is need to make such insurance mandatory under the proposed Central Drug Authority (CDA) bill which is to be debated in parliament very soon so as to boost the clinical trial process for medical advancement and to compulsorily protect the interest of the trial subjects.

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