CLINICAL TRIALS ON MINORS

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Clinical trials on minors

Recently a team of pharmacologist in Andhra Pradesh conducted a study on the clinical trials on paediatric subjects. More than 500 clinical trials were examined by the team. They concluded that a majority of pharma companies and hospitals conducting clinical trials in the country fail to observe ethical aspects like consent from minors involved in the clinical and post-trial obligation. Essentially, Schedule Y of the Drugs and Cosmetics Rules ("**Rules**") provide that the paediatric subjects are legally unable to provide written informed consent and are dependent on their parents/legal guardian to assume responsibility for their participation in the clinical studies. Therefore, the consent to participate in the clinical trials has to come from the parent or legal guardian and they sign the written informed consent for the paediatric subjects. The Rules further provide that mature minors and adolescents should personally sign and date a separately designed written assent form. However, which age group shall constitute mature minors is not defined. The study team suggested that consent should be taken from children if they are above seven years of age. As the companies conducting trails prefer to conduct trial on illiterate and poor patients, which can be assumed as exploiting the situation of the poor, it also observed that disease to be explored in clinical trials by pharmaceutical companies was not based on healthcare need of that particular region. The team noted that informed consent was taken in 67.5% clinical trials. Assent taken from children was not mentioned in any clinical trial although 8.6% clinical trials studied related to childhood diseases.

PSA view – In trials, resorting to "selective reporting" to the Clinical Trials Registry of India should be avoided. In selective reporting companies tend to report only the positive results while adverse results are often kept under cover. Post-trial obligations requires that research sponsors should provide successfully tested drug to research participants, who took part in the clinical trials after the trials. Procuring consent from children above seven years of age for participating in the clinical trial should be actively encouraged. However, this does not mean that Informed Consent should not be procured from the parent or legal guardian of the paediatric subject.

Phyto Pharmacueticals to be governed by the DCA soon

The newly formed DTAB at its first ever meeting has directed the DCGI to make provisions for the applicability of the DCA to phyto pharmaceuticals. The DTAB met on October 10, 2011 which was presided over by the Director General of Health Services and was attended by the DGCI, Director of the Central Drugs

Laboratory, Director of the Central Research Institute, Director of the Indian Veterinary Research Institute, President of the Medical Council of India, President of the Pharmacy Council of India and the Director of Central Drug Research Institute. According to media reports, the decision for inclusion of phyto pharmaceuticals under the purview of the DCA was the consistent demand from the phyto pharma industry for a regulation to streamline the sector and bring in regulation for governing the same. The DCGI is likely to make an announcement soon, expanding the applicability of the DCA to this sector.

PSA view – While the demand of the industry has been paid due attention and adhered to, it is noteworthy that the applicability of the provisions of the DCA as they stand on the phyto pharma sector may be full of obstacles. As is the case with specialized technology and drugs, the generic provisions of the DCA may be inadequate to address the issues of safety and distribution of such drugs. Phyto pharmaceuticals are essentially drugs which are primarily derived from plants. Since the nature of manufacturing, storing and using the drug will be different from conventional factory manufactured drugs, the same needs to be factored in before making a generic law applicable to the same. It may be a better idea to hold talks and discussions with the industry members to find out what the exact issues being faced are, and the intricacies involved therein to be able to regulate the same in a much more coherent manner.

DCGI to issue guidelines on compensation to clinical trial victims

Due to ambiguity on the law on compensation to clinical trial victims, the DCGI has announced that they will soon be issuing guidelines on providing proper compensation to the victims of the trials. Though the Indian Council for Medical Research (“ICMR”) Ethical Guidelines for Biomedical Research on Human participants, 2006 have specified the need for provision of compensation of participants for research related injuries, due to a lack of clear guidelines in this regard, the sponsors of the trials very often exploit the participants by simply providing some treatments. In absence of a binding law for providing compensation to such victims and due to a public outcry on the same, the issue has caught the attention of the drug authorities in the country.

PSA view – In November 2008, the ICMR issued a draft guideline for compensation to participants for research related injury. The draft guideline would bring uniformity in giving compensation to the participants and apply to all clinical research uniformly. However, the draft is still to be released. It is sad that even after 22 trial related deaths in 2010, no concrete guidelines exist on compensation to trial victims. There is a lot of expectation from the DCGI and it is hoped that these guidelines are enforced and made mandatory.

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