Pharma & Healthcare Update

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CLINICAL TRIALS - ADDED STRINGENT MEASURES ON THEIR WAY!

The clinical trial framework in India is all set to get a facelift. The Ministry of Health and Family Welfare is soon going to amend the Drugs and Cosmetics Rules, 1945, by inserting an added schedule to the already existing Schedule Y (which deals with the requirements and guidelines for permission to undertake clinical trials in India) as well as a new Rule 122DAB. The proposed amendments, which have already been approved by the Drug Technical Advisory Board ("**DTAB**") and the Drugs Control Committee, and now await notification, is intended to be brought about in view of India's rapid growth in the pharmaceutical sector and it being one of the prime clinical trial markets, which has attracted multinationals globally who have their eyes set on India for the next few years at the least.

The proposed new Schedule 'Y1' will contain rules relating to clinical trials including regulations for registration of clinical trials and Contract Research Organizations ("**CROs**"), penalty provisions for violations committed, registration of the ethics committees and on-site audits of trials.

Until now, the regulations dealing with clinical trials did not specifically cover penalty related provisions in instances where clinical trials were not being conducted in accordance with the required regulations nor have there been adequate provisions dealing with compensation of the clinical study subjects at the time of an injury arising to a particular study subject. However, with the new Schedule Y1, it is intended to impose penalty in the form of ten years of imprisonment for violating clinical trial norms. Moreover, mandatory conduct of audits of the clinical trials are also proposed which may come as a timely relief to most multinational companies who enter into arrangements with CROs and where they find it cumbersome to monitor and ensure appropriate safeguards are in place including adherence to quality norms while conducting the trials.

Another essential aspect is that of registration of the CROs for the conduct of clinical trials, which is expected to be made mandatory from June 2009, as soon as the proposed amendments are notified. Registration will ensure that the minimum requirements for a CRO to be able to conduct a clinical trial are adhered to. Once an effective mechanism is put in place for the registration of CROs, the Drug Controller General of India ("**DCGI**") also aims at slowly getting applicants who wish to conduct clinical trials to register themselves online with the Clinical Trials Registry-India ("**CTRI**") which was launched in July 2007 by the National Institute of Medical Statistics, Indian Council of Medical Research. However, registration at the CTRI is currently only voluntary. It is proposed to be made mandatory sometime in June this year in order to publicly make available, from a single source, information about ongoing trials in the country, thereby streamlining and enhancing the accountability and transparency of clinical trials in India, thereby reducing the loopholes in each and every clinical trial.

Considering India is one of the preferred destinations for clinical trials and the rapid rise in the number of trials being conducted in India, bringing about changes in the regulations for effective implementation of the clinical trials is the need of the hour to make sure India continues to enjoy its strong position in the clinical trial market and where there is a possibility of greater expansion on an even larger scale!

- Khushboo Baxi, Dr. Milind Antani & Gowree Gokhale

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