MANDATORY TO REGISTER ETHICS COMMITTEE

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Mandatory to register Ethics Committee

The CDSCO has issued the Draft thereby making the registration of ethics committees mandatory in India, which shall come into effect after publication in the official gazette. Under the existing regulations, registration is mandatory only for the clinical trials and not for the ethics committees. However, now it shall be mandatory for the ethics committee to be registered as well. The registration shall be valid for a period of 5 years from the date of issue, unless not cancelled or suspended before.

The Draft provides that for registration of the ethics committee an application should be made to the licensing authority pursuant to the requirements in Schedule Y-I. The licensing authority may grant registration subject to certain conditions and as per Schedule Y, the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding rights, safety and well being of the trial subjects. If the licensing authority is not satisfied, it can reject the application with reasons and specify the conditions which must be satisfied before the registration can be granted. If the ethics committee fails to comply with any of the conditions of registration, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons thereof, can suspend or cancel the registration of the ethics committee for such period considered necessary.

PSA view – In 2011, the Drug Technical Advisory Board had come up with this suggestion in the wake of widespread complaints that the ethics committees at most of the clinical trial sites are not independent. Most of the ethics committees are active with no monitoring of the trials by the authorities. In wake of this, this is a welcome step and what needs to be desired now is its effective implementation.

Guidelines for determining quantum of financial compensation to be paid in case of clinical trial related injury or death

The CDSCO has come up with a guideline for determining quantum of financial compensation to be paid in case of clinical trial related injury or death. Presently there is no specific provision under Drugs and Cosmetics Rules for payment of compensation in case of clinical trial related injury or death of the subject. However, the Good Clinical Practice Guidelines for Clinical Trials of India (under paragraph 2.4.7) provides that the subjects that suffer injury during clinical trials are entitled to medical care and financial assistance as compensation for any temporary or permanent injury. In case of death, their dependents are entitled to

material compensation. Guidelines further provide that it is the obligation of the sponsor to pay the compensation.

For assessing compensation in the case of trial related injury or death following parameters needs to taken into consideration: (a) Age of the deceased; (b) Income of the deceased; (c) Seriousness and severity of the disease, the subject was suffering at the time of his/her participation into the trial; and (d) Percentage of permanent disability. To determine the compensation in case of trial related death following formula should be used: C1 = A x B (1 – F/100). The various methods of reaching to the value of A (ascertaining multiplier A factoring income), B (ascertaining multiplier B factoring age) and F (risk factor) has been provided elaborately in the draft. Upon calculation of all the multipliers, the amount of compensation to be paid shall be determined by using following formula: C2 = A x B (1 – F/100) x D/100, where D is percentage disability caused to the subject due to clinical trial.

PSA view – There was always a need for a simple and expeditious procedure for payment of compensation and criteria for determining the amount of financial/material compensation to be paid in the cases of study related injury to the subject or in case of death to his/her nominee(s). Injuries can be physical or psychological/emotional. The above formula based compensation seems more apt than simple determination by the ethics committee. The proposed draft rule 122 DAB in clause (1) and (2) provides that in case of trial related injury or death financial compensation will be provided in accordance with the recommendations of the ethics committee as per the guidelines prescribed for the purpose. By the time the amended rules come into force, the guidelines should be in place for the purpose of implementation of the rules.

Draft rules for inspection of clinical trial sites

In order to further streamline the clinical trials in India, the CDSCO has issued Drugs and Cosmetics (3rd Amendment) Rules, 2012 regarding the inspection of premises of clinical trial sites by the regulatory officials with or without prior notice. The new amendment provides that: (a) the clinical trials should be conducted in compliance to the approved protocols, requirements of Schedule Y, good clinical practices and other applicable regulations; (b) Approval of the ethics committee should be taken before initiating the study; (c) Ethical aspects of the trial should be followed as prescribed in Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research; (d) Clinical trial should be registered with the Clinical Trial Registry; (e) Annual status report on the trials should be submitted to the licensing authority; (f) Any suspected unexpected serious adverse reaction should be communicated with 14 days to the licensing authority; (g) For study related death or injury, compensation or medical care should be provided; (h) The sponsor/CRO, investigators shall allow CDSCO officer who may be accompanied by an officer of the concerned State Drug Control Authority to enter, with or without prior notice, any premises of sponsor/CRO and clinical trial site to inspect, search, seize any record, data, document, books, investigational drugs etc. related to clinical trials and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of the trial; and (i) The premises of sponsor/clinical research organization and clinical trials shall be open to inspection by the officer of the CDSCO, who may be accompanied by an officer of the concerned state drug control authority to verify compliance. Upon inspection, the CDSCO inspecting office may (a) issue warning letter giving details of deficiency; (b) recommend that the study may be rejected; (c) suspend/cancel the clinical trial permission; (d) restriction of an investigator/sponsor/CRO to conduct future trials.

PSA view – There was an urgent need for such a regulation providing more teeth to the regulator. It would be interesting to see how this will be implemented. Incidentally, on August 16, 2012, the Drugs Controller General, Dr. G. N. Singh issued a notice for all parties engaged in clinical trials and asking them to strictly comply with the existing regulations and take sufficient care while dealing with the subjects (protecting their rights, safety and well-being).

India to claim exemption from Bio-Equivalence tests

The Ministry of Commerce is contemplating speaking to various governments of foreign nations where Indian drugs are facing difficulty in seeking registration for marketing due to the Bio-Equivalence tests. This effort is in tandem with the government's contemplation of fiscal support to companies for registration and BE studies. Industry representatives have made several appeals to the government stating that small and medium sized companies are facing several hurdles in marketing their drugs due to the study as well as facing delays due to the foreign governments putting in place rigorous procedures for the registration.

PSA view – Government intervention in this regard is highly welcome since various hurdles are being put in front of small and medium sized firms restricting access to foreign markets. It will be important for such small and medium scale firms to have access to international markets in order to develop the Indian pharma sector. It will also be beneficial for foreign markets and public to have access to cheaper drugs without compromising on safety since the manufacturing protocols and processes being implemented in India are in conformity with global standards. It is natural for foreign governments and regulators to be wary of drugs manufactured in other nations, not only due to quality issues but also as a challenge to its domestic industry. It will be extremely challenging for the government to seek some sort of relief of mid-way for domestic manufacturers and it will be interesting to watch the developments and efforts of the Indian government in this regard.

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