PROCEDURES AND QUANTUM OF COMPENSATION TO VICTIMS OF TRIALS

June 2012

Procedures and quantum of compensation to victims of trials

The Health Ministry is all set to formally notify the procedures and amount of compensation to be paid by the sponsors, if a volunteer dies or gets injured during a clinical trial. The draft rules for the new schedule Y1 under the Drugs and Cosmetic Rules, 1945 were already published and with a view to tighten the norms on clinical trials, several sections of the amendment have already been implemented. However, the detailed procedures and amount of compensation to be payable is yet to be completed and is expected to be notified in a couple of months. The Drug Technical Advisory Board has provided its go ahead to CDSCO to prepare a "compensation chart" or extensive guidelines that will specify the amount to be paid. Ethical committees of the company will have to decide the quantum of compensation on the basis of these guidelines. The Indian Council of Medical Research recently framed draft guidelines for compensation to participants for research-related injury. With the notification, these guidelines will be made effective as rules.

Twelve New Drug Advisory Committees and Six Medical Device Advisory Committees have been constituted to evaluate clinical trials proposals. These committees consist of leading experts from Central and State Government medical institutions. The draft notification provides for medical treatment and financial compensation to the trial subjects in case of trial related injury or death and procedure for payment of financial compensation.

PSA view – Though it has already been delayed, yet the proposed regulation and compensation policy is a much needed step. During our past posts we have noted the crucial aspects of the plausible proposed regulations. Owing to increasing number of severe adverse events or adverse events that have been notified in the past year, it has become crucial to enhance the responsibilities of ethics committee, sponsor & investigator to ensure that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths.

FIPB starts clearing investments in pharma sector again

In October 2011, an inter-ministerial group headed by the Prime Minister decided to make the CCI the approving body for all foreign investments in the sector, ending a decade-long policy of automatic FDI approval in the sector. The change was triggered by concerns that if foreign firms dominated the Indian pharma sector, it could lead to a steep rise in prices of medicine in the country. It was also decided that the

in the earlier FIPB meeting on March 30, 2012 mainly on grounds of lack of clarity in new regulations. It is to be noted that even after eight months of the announcement by the Prime Minister, CCI doesn't have the necessary legal mandate to control FDI in this sector.

To avoid further inconvenience to investors, FIPB has resumed clearing investment proposals in Indian drug companies and has cleared four proposals of foreign financial investors. However, the FIPB again deferred a decision on stake buys by multinational drug companies, extending uncertainty over new rules to check rising cases of brownfield investments.

PSA view – The uncertainty over new rules has led to proposed investment being stalled. As has been reiterated by us in our April and May flash, an authority which has been specifically created for promoting and regulating foreign investment in India, namely the FIPB, already exists. There is no requirement to assign the task to a body that is responsible for enforcement of fair trade. The move to authorize CCI to approve brownfield investments is causing unnecessary confusion and hindrance to investments. Again, it is reiterated that it is best advised to let the FIPB handle the entire FDI regulation in the pharmaceutical sector.

Food Business License

The Food Safety and Standards Authority of India has issued a licensing alert for all categories of food business and manufacturing & processing units asking them to convert their existing food business licenses to new licenses under the Food Safety and Standards (Licensing and Registration) Regulation 2011 ("Regulations"). This process has been asked to be completed on or before August 4, 2012. The Regulations came into force after August 5, 2011 with the aim to regulate the licensing of all the food manufacturing and processing units.

PSA view – It is essential that the unregulated and widespread food sector is regulated under one licensing authority and uniformly licensed under the Regulations. Creation of the FSSAI had this as one of the mandates. In view of the licensing alert being issued, it seems that sooner the food units, whether manufacturing and processing will be brought under one regulatory regime and governed uniformly.

By:
Neeraj Dubey
Divij Kumar