IMPLEMENT THE SCHEDULE Y-1 AND DRUGS AND COSMETICS (FOURTH AMENDMENT) RULES, 2011

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Implement the Schedule Y-1 and Drugs and Cosmetics (Fourth Amendment) Rules, 2011

Recently, two cases about the trial of drug Tadalafil in a hospital at Indore and the trial of an anti-cancer drug by Axis Clinical Research, Hyderabad, came to the notice of the DCGI that allegedly flouted the clinical trial norms. In the first case, the DCGI initiated action at Maharaja Yashwant Rao Hospital and Mahatma Gandhi Memorial College, Indore where the drug Tadalafil was used for clinical trial for Pulmonary Arterial Hypertension (**PAH**). The study with Tadalafil was initiated on September 18, 2005 when the drug was not approved for the said indication but for male erectile dysfunction on June 10, 2003. In view of this, the clinical trial of Tadalafil in Pulmonary Arterial Hypertension was stopped and the doctors were restricted to conduct any clinical trial for a period of six months. The trial of an anti-cancer drug by Axis Clinical Research on poor people was initiated without procuring proper informed consent. The investigations revealed that the firm conducted bioequivalence study on an already approved anticancer drug and there were certain irregularities with respect to informed consent process, review and decision making process of Ethics Committee.

PSA view – To strengthen the clinical trials regulations the amendment to the Drugs and Cosmetics Rules, 1945 was approved by Drug Technical Advisory Board and a draft notification was released to incorporate effective provisions for providing financial compensation to the trial subjects in case of trial related injury or death. Also, the responsibilities of Ethics Committee, Sponsor & Investigator were fixed to ensure that the subject is adequately compensated financially and with medical care in the event of a trial related injury or death. In light of the increasing episodes of clinical trial deaths, it has become necessary that Schedule Y-1 and the Drugs and Cosmetics (Fourth Amendment) Rules, 2011 is brought into effect. Interestingly, now, although Schedule Y of the Drugs and Cosmetics Act calls for compensation, Clinical Research Organizations are taking up insurance policies to protect the patient in the wake of an adversity. Both informed consent and compensation to victims are the two key factors which can potentially give the Indian patients the necessary confidence to participate in a clinical trial. While the former helps the volunteer or patient to understand the risks of the human study, the latter provides the much needed financial and medical support if the medicine turns fatal or reports an adverse drug reaction. However, as there is no basis on which the compensation can be based, clarity on the method of calculating the compensation is also pertinent.

National Policy on Narcotic Drugs and Psychotropic Substances released

The NDPS Policy has been released by the government thereby allowing the private sector companies to produce alkaloids from opium which so far was produced only in GOAFs. This step will surely ensure that India regains its lost status of a traditional supplier of opiate raw material to the rest of world even while remaining competitive. The policy attempts to curb the menace of drug abuse and contains provisions for treatment, rehabilitation and social re-integration of victims of drug abuse. Therefore, non-intrusive methods of regulating the manufacture, trade and use of such psychotropic substances will be introduced, and emphasis will be laid on adequate access to morphine and other opioids necessary for palliative care, a strategy to address street peddlers of drugs, periodic surveys of drug abuse to gauge the extent, pattern and nature of drug abuse in the country, recognition of de-addiction centers. There will be a time bound plan of action, detailing the steps to be taken by different ministries, departments and agencies, in response to the recommendations of the International Narcotics Control Board. The NDPS Policy recommends production of concentrate of poppy straw in India by a company or body corporate. Overall, the crucial elements of the policy includes (**i**) the private companies getting license to manufacture codiene etc; (**ii**) psychotropic substance control via online tracking on pharma trade; (**iii**) tracking of opium cultivation via satellite; and (**iv**) India becoming a safe and legal producer of opium.

PSA view – Definitely, NDPS Policy is a welcome step that intends to put a curb on the illicit cultivation of poppy and cannabis. The NDPS Policy emphasizes use of satellite imageries for detection of illicit crop and its subsequent eradication and development of alternate means of livelihood in respect of cultivators in pockets of traditional illicit cultivation. NDPS Policy will re-assert India's commitment to combat the drug menace in a holistic manner.

CDSCO plans to set up sophisticated Pharma Research Laboratory at INR 500 million

A detailed proposal has been prepared by the CDSCO for setting up of a Pharma Research Laboratory with sophisticated facilities and has sought INR 500 million (*US$ 10 million*) for this purpose from the Planning Commission so that it can be set up during the next five year plan period. According to the detailed proposal, the lab will require INR 45 million (*US$ 900,000*) for civil construction and another INR 300 million (*US$ 6 million*) for latest equipment and instruments. About INR 10 million (*US$ 200,000*) is expected to be the annual costs for reagents and chemicals. Excluding the land cost and manpower, the proposal has put a cost of INR 500 million (*US$ 10 million*) for the lab.

PSA view – Many Central Drugs Laboratories across have adequate facilities for testing of quality of drugs as per the prescribed standards; however, they are not well equipped to test foreign (*contaminated*) substance in drugs. Hence, if the Planning Commission grants the funds, it would be beneficial to have a state-of-the-art Pharma Research Laboratory to carry out sophisticated analysis of drugs to detect such substances.

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