MINISTRY AMENDED THE RULES

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The Ministry has amended the Rules and now, in Schedule Y of the Drugs and Cosmetics Rules, 1945, in paragraph 2(2)(iv) relating to responsibilities of Sponsor, the clause will read "(iv) Any report of the serious adverse event, after due analysis shall be forwarded by the sponsor to the Licensing Authority as referred to in clause (b) of rule 21, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within fourteen calendar days of the occurrence of the serious adverse event." In case the investigator fails to report any SAE within the stipulated period, he will have to furnish sufficient reason for the delay to the satisfaction of the licensing authority. The SAE report should be sent to the licensing authority, chairman of the EC and the head of the institution where the trial has been conducted within 14 days of the occurrence of the SAE. For EC, the amendment says that "In case of serious adverse event occurring to the clinical trial subjects, the Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as referred to in clause (b) of rule 21 for conducting the clinical trial, to the Licensing Authority within thirty calendar days of the occurrence of the serious adverse event." The amended Rule 122-DAB says that the injured subject shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. And in case there is no permanent injury, the quantum of compensation shall commensurate with the nature of the non-permanent injury, loss of wages and transportation. The ministry has invited objections and suggestions to the amendment from the stakeholders within 45 days.

PSA view – The changes made by the Ministry are in sync with the demands from different quarters. The proposed regulations on clinical trials had also suggested similar provisions and now it seems that the course of change is here to stay with this amendment, if this finally comes into effect.

Ministry frames rules to ban import of cosmetics tested on animals abroad

Last year, Ministry had drafted the rules to prohibit the testing of cosmetics in India (The final notification is yet to come to put the ban in force) and now, after consultation with the Drugs Technical Advisory Board, it has drafted another set of rules to amend the Rules to ban the import of cosmetics tested on animals abroad. The following new rule 135-B will be inserted after Rule 135-A "Import of cosmetics tested on animals prohibited—No cosmetic tested on animals shall be imported." The draft has been released inviting comments from the stakeholders.

PSA view – This new move has been welcomed by NGOs working towards cruelty against animals.

FDA Nagpur cancels drug licenses of retailers & wholesalers

The Maharashtra Food and Drugs Administration's ("FDA") Nagpur Division recently cancelled 364 drug licenses of retailers and 12 drug licenses of wholesalers for non-compliances under the Drugs and Cosmetics Act. The FDA conducted annual inspections of 4,190 retailers and 1,265 wholesalers in Nagpur Division last year and found 84 sub standards samples out of the total of 521 samples of medicines collected. Nine cases were filed on sub-standard medicines and eight cases were filed under other categories. FDA has given show cause notices to 23 units and canceled licenses of five units, six licenses were suspended, warnings were issued to five units while eight cases are pending.

Further, FDA also took action against two firms for violation of the provisions of Drugs Price Control Order and seized stock of medicines worth Rs. 1,48,675 and registered 10 FIRs under Drugs and Magic Remedies Act. Two firms were also fined Rs. 1,20,000 for selling sub-standard medicines and ayurvedic medicines worth Rs. 50,000 were also seized.

PSA view – On one hand where the implementation of pharma laws and regulations is getting stringent day-by-day, on the other hand it is unfortunate to know that sub-standard drugs are so blatantly sold in our markets. Recently, US regulator of drugs had imposed ban on India's Sun Pharma's drugs which had sent out a negative message worldwide. So, it's good that such raids are conducted. We are of the opinion that more periodical raids should be conducted at drug stores and whole-sellers godowns, especially in small towns and cities. However, law enforcement agencies cannot plug every such non-compliance before the damage is actually caused.

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