DTAB PROPOSES TO WAIVE LOCAL DRUG TRIALS FOR NEW DRUGS

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The DTAB, the apex drug safety authority, has proposed amendment to the D&C Rules to permit exemption for New Drugs already marketed in well-regulated countries like United States of America, European Union etc. through credible PMS mechanism, from local clinical trials in India. As a result, the existing requirement under D&C Rules to conduct Phase III clinical trial for the new drugs approved in other countries stand modified. Further, DTAB has opined that the experts in the specific therapeutic area must evaluate the safety, efficiency and efficacy of the new drugs.

The recommendation by DTAB is in line with the Prof. Ranjit Choudhury committee report which suggested that drugs marketed in well-regulated countries for a period of 4 years may be granted marketing license subject to strict PMS for 4-6 years. However, the DTAB panel opined that the period of 4 years may be waived subject to the condition as to availability of alternative therapy or in national health care emergencies. In consonance to DTAB recommendation, the Union Health Ministry may amend the D& C Rules and it is decided that the period of 4 years may be waived only in cases of national emergency, epidemic and for orphan drugs for rare diseases and for which no alternate therapy is available.

PSA view: The exemption proposed by DTAB is a step in the right direction for the drug manufacturers as it does away with the additional formality of repeating drug trials However, keeping in mind the rationale behind conducting Phase III trial for new drugs i.e., to assess the efficacy of drug when administered to people of different ethnicities, it is recommended that DTAB and the policy-makers must mandate a mechanism to ensure that the new drugs introduced are effective and favorable to the Indian population.

Finally guidelines for PCV system are in the offing

Currently, there is no specific legislation regulating PCV activities in India. In many countries, it is mandatory for the pharmaceutical company to have such a system in place to monitor drug safety.

In order to formally set up PCV system for collection, processing and forwarding of Adverse Drug Reaction reports (“ADRs”), Government has formed a high level committee to prepare guidelines for manufacturers on the same to effectively monitor drug safety.

Setting up of a PCV system was recommended in a recent meeting with officials from the Pharmacy Council of India (“PCI”) and Indian Council of Medical Research (“ICMR”). It was suggested that the manufacturer or applicant should have a PCV system in place for collection, processing and forwarding of the ADR report.

This, according to official sources, has been done in consideration of the proposal to amend provisions relating to post marketing surveillance under Schedule Y.

The existing law pertaining to post-marketing surveillance requires that the applicant must furnish Periodic Safety Update Reports (PSUR) to the Central Drugs Standard Control Organization ("CDSCO"). However, it does not specify that the applicant should have a PCV system in place to monitor the clinical safety of new drugs after it is introduced for marketing in the country.

PSA view: The CDSCO equivalent to the European Medicines Agency of the European Union, DGHS, in collaboration with Indian Pharmacopeia Commission ("IPC") runs a nation-wide Pharmacovigilance Programme ("PVPI"). IPC monitors the execution of the PVPI related activities in India. CDSCO is vested with the powers to approve new drugs and clinical trials in the country. It also lays down the standards for drugs, controls the quality of imported drugs, coordinates with state drug control organizations and provides expert advice to bring about uniformity in the enforcement of the Drugs and Cosmetics Act, 1940 and Rules 1945. Several Indian drug manufacturers conduct PCV of their drugs and CDSCO has its designated centers across the country which conduct PCV; however, the private players hardly report PCV to these centers as the same is not yet mandatory. With new PCV mandate in the pipeline, we can only expect better vigilance of drugs!

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