Pharma & Healthcare Update

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GOVERNMENT CONTEMPLATING TO ALLOW PHASE I TRIALS IN INDIA

The Union Health Ministry is in the process of considering the recommendation of the Drug Technical Advisory Board (DTAB) to allow Phase I clinical trials for the drugs discovered abroad. Currently, Phase I trials cannot be initiated in India for new drug substances discovered in other countries unless Phase I data from other countries is made available to Indian authorities. The DCGI, however, gives approval to Phase I trials for drugs developed in India.

In view of the risks involved, Phase I trials have been prohibited by the Indian government. In Phase I trials, the discovered medicine is exposed to the human body after the successful trials on animals. The risk is much more as the drug is experimented on the healthy human being for the first time.

As India refused to give permission for Phase I trials, the drug companies world over have been moving towards other cheap markets like China. If Phase I trials are allowed in India it will have a major impact on the contract research organizations in the country as the Phase I trial has a huge business potential.

However, the clinical trial institutions for the Phase I trials should be equipped with all kinds of emergency services and highly qualified staff to handle any unknown emergency arising out of use of the new drug.

THE CLINICAL ESTABLISHMENTS (REGISTRATION & REGULATION) BILL

The Union Cabinet has approved the Clinical Establishments (Registration & Regulation) Bill for introduction in this monsoon session of the Parliament. The objective of the legislation is to bring a wide range of clinical establishments such as nursing homes, diagnostic centres, pathology labs, doctors' clinics, spread across the country under a regulatory umbrella. Currently, several establishments are run without any ethics or accountability. The fast growth of diagnostic centres for sex determination in northern states of India coupled with pathology labs run by persons without any medical qualifications have also concerned the government. Therefore, to plug the regulatory vacuum that exists now, this Bill has been proposed. The proposed bill will also cover establishments from all alternative systems of medicine such as homeopathy, *unani, siddha and ayurveda*.

The Bill contemplates, *inter alia*, (i) establishment of a national registry of clinical establishments, and (ii) compulsory registration for all the clinical establishments with the registry, (iii) creation of a National Council of Standards that will prescribe minimum standards for healthcare services. The Council, to be headed by the Director General of Health Services, will have representatives from medical, dental, nursing and pharmacy councils, Indian Medical Association, and the Bureau of the Indian Standards. It would classify the clinical establishments into different categories and also conduct periodic review of the standards for healthcare services. Clinical establishments will be monitored by the Council which will have powers to impose penalties on the establishments for violation of norms prescribed by it.

For the enforcement of this Bill, the States of India will have to concur with the proposed legislation. Some of the northeastern states like Arunachal Pradesh, Mizoram, Nagaland and Manipur have already concurred with the proposed legislation.

PROPOSED - AMENDMENTS TO SCHEDULE Y

The rapid expansion of the Clinical Research Organizations ("**CROs**") in India has made the Union Ministry of Health and Family Welfare consider amending Schedule Y to the Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940. This decision has come after the Drugs Technical Advisory Board, officially gave its consent to take this proposal forward.

Schedule Y stipulates guidelines on approvals for import and manufacture of new drugs for the purpose of sale or undertaking clinical trials for such new drugs in India. It was previously amended in January 2005 to regulate the quality of services provided by the growing number of contract research organizations. Schedule Y requires that Good Clinical Practice Guidelines ("**GCP Guidelines**") issued by Central Drugs Standard Control Organization ("**CDSCO**") have to be followed while conducting clinical trials. The GCP Guidelines are based on the ICH Guidelines.

The ICH Guidelines prescribe a unified standard for the European Union, Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. Schedule Y, however, in order to raise the bar to be at par with the ICH Guidelines, requires further revisions for stricter implementation and maintenance of the international quality standards by the CROs due to lack on their part to meet the required international standards.

What seems to be missing from the present Schedule Y are the detailed obligations and responsibilities of individuals, including the doctors at clinical trial site and the Ethics Committee, involved in clinical research, documenting and monitoring during and post the entire process of the clinical trials. India is a global hub for clinical

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trials and the foreign companies outsourcing the clinical trials to India require assurance of the quality of clinical trial data to enable them to submit such data to the global regulatory authorities.

It is now up to the Indian drug regulatory authorities to consider the concerns in this segment on a priority basis to maintain international standards for various MNCs. With the implementation of more stringent provisions and streamlining the Schedule Y guidelines, the Indian Pharma Industry will certainly attract more clinical trials from MNCs across the world.

- Anurag Dubey, Khushboo Baxi & Gowree Gokhale

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