REGULATING CLINICAL TRIALS

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The Supreme Court has asked the government to discuss with states all facets of a legal framework to regulate and monitor clinical trials of new drugs by foreign firms across India. The court also asked the petitioner Swasthya Adhikar Manch, the National Human Rights Commission, NGOs and other organizations to submit their suggestions before the next hearing on Sept 24, for strengthening the legal regime to regulate clinical trials so as to minimize the harm to the patients upon whom the new drugs were being tested. Meanwhile, the Drug Controller General of India ("DCGI") has reacted very strongly to the various complaints regarding the independent ECs attached to hospitals and CROs, which continue to review and approve new clinical trials in violation of norms as these ECs are permitted only to conduct periodic review of the ongoing clinical trials already approved by them only. They have been warned of stern action. DCGI is also awaiting the enactment of the amendments to the Drugs and Cosmetics Act, which would bring all medical devices under the regulatory mechanism helping to raise the standard of this niche products.

PSA view – The aforesaid Bill would strengthen the regulatory mechanism for the medical device sector in the country so as to ensure that it is on par with the regulatory standards followed internationally. The Central Drugs Standard Control Organization is plagued with inadequate infrastructure and shortage of staff and the new drugs are being approved for marketing by short-circuiting the clinical trials and in some cases, not conducting them on Indian patients. Even the report of the Parliamentary Standing Committee on Health and Family Welfare which had examined CDSCO's functioning had taken a dim view of its working. The committee favoured a non-discretionary, well laid down written guidelines on the selection process of outside experts as it feels that there is sufficient evidence on record to conclude that there is collusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts. Amendment to laws and new authorities would certainly help improve the situation.

2. LSIO offers incentives to boost India's life sciences sector

India, which is gradually becoming a leading destination for healthcare solutions, has been offered certain funding and tax incentive schemes by UK Trade and Investment (UKTI) LSIO to boost Indian companies for effective translation and commercialization of life science projects. Dr. Adam M Hill, Healthcare and Medical Technology Specialist, LSIO explained, "Healthcare systems are struggling with increasing costs globally. The rapidly growing UK medical technology sector is capable of offering solutions despite a difficult economic climate. Looking beyond the domestic British market, UK offers the ideal gateway to other markets by virtue of strong trade links with Europe and beyond. Besides this, gaining regulatory approval and adoption in the UK can also help get approval within other healthcare systems as well."

PSA view – In the wake of increasingly expanding global medical technology market these incentives must be availed. They should prove useful for life science companies to commercialize medical innovation at a global level and that too in the times when costs are inflating and research and development is becoming complicated day by day.

3. Bill for creation of CDA in current session

The Health Ministry wants to table The amending Bill, i.e. The Drugs and Cosmetics (Amendment) Bill, 2013 ("Bill") in the current session of parliament. The Bill seeks to establish a Medical Devices Technical Advisory Board, which would enable medical devices to be regulated under it. It will also have separate chapters on clinical trials, medical devices and specific penal provisions in case of any violation. The primary object of the Bill is creation of CDA, a centralized licensing authority for drugs. The CDA will act as an appellate body for central and state drug controllers and it will also review the issuance of licenses for manufacture and sale of drugs. Amongst other aspects, the Bill also seeks to bring export of drugs and cosmetics under the purview of the Drugs and Cosmetics Act, 1940. The government plans to withdraw the pending Drugs and Cosmetics Bill, 2007 which was originally planned to create CDA as the Bill has been modified.

PSA view – The Health Ministry is back with the revised Bill on drugs and cosmetics after 6 long years. However, with the way things are going on in the parliament where even important legislations like the food bill is pending, one wonders whether the government will seriously look to discuss and pass any change to the existing drug and cosmetic regime. Also, enhanced checks and balances may dissuade foreign companies and investors from investing in the Pharma sector.

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