CCI RESTRAINS AIOCD

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In a matter between Peeveear Medical Agencies in Kerala and the Mumbai based multinational company Janssen Cilag Pharmaceuticals, while passing an interim order under section 33 of the Competition Act, 2002, in favour of Peeveear on August 23, 2011, the CCI restrained AIOCD from issuing any direction or threat to Janssen to terminate its distributorship with Peeveear. The CCI passed the interim order and also instructed Janssen not to discontinue its distributorship with Peeveear. In the petition filed by Peeveear, it was alleged that AIOCD was exercising complete and absolute control over individual stockiest of drugs and medicines in the country bypassing from the power vested with it as per its Memorandum of Association which is essentially related to protection and promotion of the interests of persons engaged in drug trading industry and allied lines. Peeveear was appointed as the distributor of Janssen from March 2011 and it started sale of their products immediately after it. But, on April 26 the agency received an e-mail that supplies from Janssen would not be made to it for want of authentic documents to support the appointment of distributorship.

PSA view – Under the pretext of protecting the interests of its members, the AIOCD has been abusing its dominant position and has been regularly involved in anti-competitive agreements which have the result of limiting and controlling the supply and marketing of pharmaceutical products, and thus directly influencing the purchase and sale price of the drugs throughout India. The AIOCD is controlling the trading policies of different manufacturing companies, controlling the profit margins, regulating the stockiest/distributor agreements of each manufacturing company, recommending all its members and stockiest the profit margins with respect to various companies and collecting Rs. 2000 per product from every manufacturer in each state for giving permission to launch their new medicines in the name of Product Information Service. In May this year the CCI had restrained the AIOCD for the same reason in a case with Cuttack based C&F Agency, Santuka Associates Pvt Ltd. The decision is laudable.

Health ministry plans to notify Schedule Y1 after NHRC sends notice about trial-related deaths

The NHRC has taken up the issue of deaths occurring during the course of clinical trials. This has put pressure on the drug control authorities to officially notify the proposed Schedule Y1. The draft notification on Schedule Y1 was introduced in January 2011; however, due to the increase in deaths caused during clinical trials, the Health Ministry has decided to finalize the Schedule Y1 by accommodating the relevant suggestions from the stakeholders. As many as 22 cases of trial-reported deaths were reported in 2010. It

has been proposed that to further strengthen the regulation on clinical trials provisions should be made under the Drugs and Cosmetics Rules for providing financial compensation to relatives of trials subjects in case of trial related deaths. Further, the responsibilities of the Ethics Committee, Sponsor & Investigators could be further enhanced to ensure that the financial care and medical care are provided to trial subjects who suffer trial related injury or death.

PSA view – There have been numerous trial related deaths in the past three years; however, still the Health Ministry has not provided a date by when the Schedule Y1 would be notified. It will be interesting to see what responsibilities would be vested in the Ethics Committee to ensure timely payment of compensation.

Health ministry to finalize legislation to regulate fertility clinics

Based on the guidelines and norms set by the Indian Council of Medical Research ("ICMR"), the Health Ministry is in the process of finalizing a legislation to regulate the growing number of fertility clinics in the country.

The government has accepted the national guidelines for accreditation, supervision and regulation of Assisted Reproductive Technology ("Art") clinics in the country, developed and announced by the ICMR. To effectively implement the guidelines, the Health Ministry is finalizing the Assisted Reproductive Technology (Regulation) Bill ("Bill"), which has been published for the comments from the stakeholders. The Bill details procedures for accreditation and supervision of infertility clinics (and related organizations such as semen banks) handling spermatozoa or oocytes outside of the body, or dealing with gamete donors and surrogacy, ensuring that the rights of all concerned are protected, with maximum benefit to the infertile couples/individuals within a recognized framework of ethics and good medical practice.

PSA view – The last nearly 20 years have seen a rapid growth of infertility clinics that use techniques requiring handling of spermatozoa or the oocytes outside the body, or the use of a surrogate mother. As of today, anyone can open infertility or ART clinic as no permission is required for the same. Keeping in mind the popularity of the fertility clinics and the interest of the public it is important to regulate the functioning of such clinics to ensure that the services provided are ethical and that the medical, social and legal rights of all those concerned are protected.

By:
Neeraj Dubey
Divij Kumar