HEALTH-INDIA: Prime Destination for Unethical Clinical Trials

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By Keya Acharya

BANGALORE, Dec 14 (IPS) - Lack of regulation, accountability, low costs of operation and wide availability of target participants are reasons why multinational drug companies, researchers and institutions are increasingly basing their clinical trials in India.

An estimated 40 percent of all clinical trials now take place in Asia, Eastern Europe, central and south America. "There is no compulsory registration system for clinical trials in these countries and many do not follow European directives in their operations", says Dr. Jacob Sijtsma of the Netherlands-based WEMOS, an advocacy health organisation tracking clinical trials in developing countries.

Sijtsma, who was in India for a bioethics conference, held earlier this month at the Bangalore-based National Institute of Mental Health Sciences, said there is a growing concern in India's medical and civil society on the lax regulation and ethicality over clinical trials conducted in this country.

In 2006, WEMOS and the Centre for Research on Multinational Corporations prepared an overview of 22 known examples of unethical clinical trials, eight of which were operating in India.

The Indian examples of illegal and unethical trials involved Sun Pharmaceuticals and Novartis's Letrozole for inducing ovulation when approved only for breast cancer, Novo Nordisk's for diabetes treatment, Solvay Pharmaceuticals' for treating diarrhoea, Johnson and Johnson's for treating acute malaria, Pfizer's for cardiac events, Otsuka's for arterial disease, Indian companies Shantha Biotechnics and Biocon for diabetes and the John Hopkins' University's trials for treating oral cancer.

Other countries with documented illegal trials include Russia, Nepal, Uganda, Peru, China, Nigeria, Argentina and even places like London and New York involving well-known institutes like the U.S. National Institute of Health, Walter Reed Army Institute of Research, Centres for Disease Control and several international pharmaceutical firms.

Dr. Bernard Lo from the University of California at San Francisco, also here for the conference, said even more disturbing questions arise in the field of stem cell research in its newest method called Induced Pluripotent stem cell (iPs cells).

In this system, embryonic stem cells are not used, but virtually any cell is taken to the laboratory, inserted with a human gene and grown into human cells.

"This makes for laboratory manipulation of basic science research, no consent is needed by anyone and the cells can be bought commercially, giving rise to all sorts of ethical questions that need to keep pace with the rapid research in this field," said Lo.

"I am extremely concerned about the conduct of stem cell research in India," said Dr. Pushp Bhargava, a highly respected former director of India's Centre for Molecular Biology at Hyderabad city. "We have no idea where these cells are coming from, whether they have been characterised,'' Bhargava told IPS.

"There is no method of validation or checking," he complained.

WEMOS's Dr. Leontien Laterveer says a lack of transparency and secrecy shrouding all clinical trials, whether in India or other countries, makes it very difficult to obtain information about their operations.

"We are appealing to Indian organisations looking at this issue to come forward and collaborate with us," say both Laterveer and Sjitsma.

More importantly, there are insufficient checks by the European Union in spite of the Helsinki Declaration on a code of ethics for clinical trials, making it easy for drugs to enter the European market, add the two.

"European pharmaceuticals are also not bothered about legal and regulatory aspects,'' said Laterveer. ''They leave it to the countries themselves.'' The Helsinki Declaration is currently under review.

"We need the input of Southern experts to help process the review of the Helsinki Declaration," said Sjitsma.

Media exposés of exploitation in cases such as the U.S. John Hopkins' Hospital's collaboration with the Regional Cancer Treatment Centre in Kerala, in 2000, forced the Indian Council of Medical Research (ICMR) to inquire into the trials.

The results however are still not public and no action has been taken against its then director, while the Johns Hopkins University barred the principal investigator from heading future research with human subjects.

In recent years, India has made some regulatory attempts, amending its drugs and cosmetics act to require compliance by trial conductors with a set of good clinical practices (GCP) guidelines along with the ethics committee that the ICMR formulated.

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But there is still no mandatory compensatory payment, or strong penalty against the defaulting company.

"We need to pin down direct responsibility for monitoring with the ethics committee and measures taken to permanently revoke the licence of the defaulting company,'' says Adarsh Gangadhar, a lawyer attached to the National Academy for Legal Studies and Research in Hyderabad.

Dr. Prathap Tharyan, head of psychiatry at the respected Christian Medical College (CMC), Vellore, and South Asia coordinator of Cochrane, a network of specialists working to improve evidence-based healthcare, averred that ''deception, fraud and structural problems in randomised clinical trials'' are rampant in India.

Tharyan has now helped set up an online Clinical Trials Registry through ICMR. Its implementation, however, remains dependent on wider awareness of the issues involved in India.

''Ethics awareness in India is evolving and the law intervening, but I find a deficiency in working out solutions for implementation,'' said Madhav Menon, one of India's leading legal experts.

The National Institute of AIDS Research (NIAR) at Pune is committed to setting up community advisory bodies (CABs) with participation from field workers, patients and others concerned to disseminate awareness and information on the rights of participants in clinical trials.

However, the entire concept of CABs is still evolving, with insufficient information on rights or ethical principles and no mechanism for redressal of grievances, NIAR's Dr. Sanjay Mehendale told IPS.

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