

## Pharma & Healthcare Update

December 15, 2005

### NEW BILL TO REGULATE SCIENTIFIC RESEARCH ON HUMANS

A new Bill titled as - "The Biomedical Research on Human Subjects (Promotion & Regulation) Bill", has been proposed by the Government to regulate and enforce ethical practices in scientific research on humans. It is likely to be introduced in the next session of Parliament.

The need for the Bill arose as currently only the commercial aspects of research on humans through clinical trials was being regulated under the Drugs and Cosmetics Act, 1945, more specifically Schedule Y. Further, concerns were being raised as to the unethical practices in the industry. The current bill which relies heavily on the "ethical guidelines for biomedical research on human subjects" issued by the Indian Council of Medical Research (ICMR), aims to plug the holes and encompass all kinds of research on humans. This would include clinical trials - both commercial and academic, as well as the entire range of research, including genomics, gene mapping, foetal tissue transplant, and stem cell research.

The Bill is driven by "ethical considerations" in research and its schedules contain the principles and processes, such as:

- ethical considerations
- ethical review procedures
- clinical trials
- clinical evaluation of devices
- diagnostics
- vaccines
- epidemiological studies
- stem cell research (including human genetics research)
- transplant research
- assisted reproductive technologies

It also covers stem cell research, a very controversial area of research which has been opposed in many countries. A further need to regulate this kind of research in India was felt as there are many cases of forced informed consents and clinical research on the illiterate and poor, which could lead to unregulated abortions, and the general flouting of medical ethics and scientific principles by doctors.

Currently the only regulator on human research in India is the Drug Controller-General of India who regulates commercially conducted clinical trials. The Bill proposes that the ethics committee of ICMR be designated as the national ethics committee, which will also be the technical adviser to the biomedical regulator. It also prescribes fines up to Rs 1 lakh and imprisonment of up to a year for norm violations.

Though, the Bill has been seen by some as a right move in the direction of bringing in more regulation into a much needed space, others feel that it would be causing a multiplicity of regulation, as there is the Drugs and Cosmetics Act already regulating clinical trials. Hence, it is felt that such a move would actually hinder the burgeoning market for clinical trials in India.

- Nithya Reddy & Dr. Milind Antani

Source: Business Standard (December 15, 2005)

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