Two private hospitals in Bengaluru are under a cloud for participating in clinical trials concerning infants sponsored by a company making infant milk substitutes.

The Breastfeeding Promotion Network of India (BPNI) — a body notified by the Government of India to monitor the implementation of Infant Milk Substitutes Act — has named five hospitals, including Bengaluru’s Manipal Hospital and Cloudnine Hospital as being part of the study sponsored by Nestle India Ltd.

According to the BPNI, Dr Monjoni Mitra of Medclin Research is the trial co-ordinator of the study, which has been registered under the ICMR.

"On examining the ICMR Clinical Trial Registry maintained by the Indian Council of Medical Research (ICMR), BPNI confirmed that Nestle India Limited, a producer of infant milk substitutes and infant foods, is sponsoring research titled ‘Multicentric Observational Study to Observe Growth in Preterm hospitalized infants’,” said an official from the BPNI.

Alleging violations of the IMS Act, the BPNI wrote to the Ministry of Health and Family Welfare (MOHWF) following which the MOHWF shot off a letter (a copy of which is with DH) to the director-general of the Indian Council for Medical Research (ICMR) to initiate action.

In the letter, the MOHWF asks that the complaint from the BPNI be examined at the ICMR. “Please get this examined and take necessary action at your end to comply with the provision of the IMS Act and also ensure that all the trials in future are screened for any infringement of the IMS Act,” the letter states.

Although the hospitals deny wrongdoing, the BPNI, citing ICMR documents, said the research had been approved by ethical committees which are not independent.
Responding to this, Dr Anoop Amarnath, chief of clinical services, Manipal Hospital said, “There are absolutely no such nutritional studies being approved or carried out at any of our hospitals. We encourage breastfeeding and are one of the few centres who have specialists dedicated exclusively to promote breastfeeding.”

A Cloudnine spokesperson also denied breaking rules. “We at Cloudnine Group of Hospitals have been actively working towards data collection and research publication and we have constituted our Institutional Independent Ethics Committee as per ICMR guidelines which approves all our research studies. Our clinical research is done as per Indian and international guidelines and we don’t break any rules while conducting any research,” said the hospital.

**Nestle reacts**

Reacting to the news, Nestle said “clinical study for the purpose of scientific information is not prohibited under the IMS Act”.

“The IMS Act does not discourage or prohibit the dissemination of scientific information. A mere reading of Section 9 will clearly show that the Act prohibits financial inducement to health workers or any contribution or pecuniary benefit including the funding of seminar, conference etc., only if these are for the purpose of promoting the use of infant milk substitutes, feeding bottles and infant foods,” said a company spokesperson.

The objective of the clinical study, said Nestle, was to “encourage science-based research”. “This study is an institution based study, all Institutional Ethics Committee approvals have been obtained from the participating sites,” said the company.

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