**Nestle violates India’s law on infant milk substitutes**

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Nestle India Ltd, one of the biggest players in fast-moving consumer goods (FMCG) segment, is engaged in the food business of milk products, nutrition, beverages, prepared dishes, cooking aids, chocolates and confectionery. The company manufactures and markets branded products of daily consumption and use, such as coffee, milk, ghee, curd, and raita. Nestle India is a subsidiary of Nestle S.A. of Switzerland.1

In 2004, Nestle India Ltd initiated a project to upgrade the production technology for infant nutrition products and the company launched NESTLE NAN 3, a follow-up formula for older infants. 2

**Nestle under scanner**

In May 2015, food safety regulators reported that samples of its Maggi 2 Minute Noodles had unexpectedly high levels of monosodium glutamate, and 17 times the permissible limit of lead. 3

In August 2019 the news appeared that Nestle conducted clinical trials in five hospitals on substitutes for breast milk in complete contravention of the Infant Milk Substitutes Act. The Breastfeeding Promotion Network of India (BPNI) found on screening the trial registry of Indian Council of Medical Research (ICMR) that Nestle has sponsored a research titled “Multicentric Observational Study to Observe Growth in Preterm hospitalised infants”.

This trial was conducted on 75 premature babies between the age of 28-34 weeks. The objective of the study was to assess the growth and feeding intolerance in preterm infants. One of the exclusions was that the infant could not be fed milk substitute within 48 hours of birth, but from the third day onwards, the trial suggested that the infant could be given a milk substitute instead of breast milk. 4

On 17 July 2019 the BPNI complained to Union Health Minister, Govt of India that the company had violated Section 9(2) of the IMS Act (The Infant Milk Substitutes, Feeding Bottles and Infant Foods). Allowing the complaint, Union Health Secretary on August 2, directed ICMR Director to “get the trial examined and take necessary action to comply with the provisions of the IMS Act”. She directed that trials be first screened for infringement of the IMS Act in future.

Dr Monjori Mitra of Medclin Research Pvt Ltd. is the trial coordinator and research director of the clinical trial number — CTRI/2018/12/016715 — registered under the Clinical Trial Registry of India (CTRI). The five hospitals which participated in this research were Cloudnine Hospital (Bengaluru), Institute of Child Health (Kolkata), Manipal Hospital (Bengaluru), Sir Ganga Ram Hospital (New Delhi) and Calcutta Medical Research Institute (Kolkata), all private institutions.4

**What is IMS act?**

It is the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003. It provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breastfeeding and ensuring the proper use of infant foods and for matters connected therewith or incidental thereto.

It states that no person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods shall offer or give, directly or indirectly, any financial inducements or gifts to a health worker or to any member of his family for the purpose of promoting the use of such substitutes or bottles or foods. No producer, supplier or distributor shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminars, meetings, conferences, educational course, contest, fellowship, research work or sponsorship. 5

**Nestle’s response**

Responding to the allegations, Nestle India emphasized that the company always complied with all laws and regulations including the IMS Act. It said that the objective of the clinical study was to encourage science-based research and all Institutional Ethics Committee approvals had been obtained from the participating sites. Nestlé India assured to provide all its support on this issue to ICMR, claiming that they were confident of their position. 6

**ICMR history with clinical trials 4**

Since 2007, ICMR has been monitoring the clinical trials for administration of anti-cervical cancer HPV vaccines to prevent cervical cancer in 24,000 girls in the tribal belts of Andhra Pradesh and Gujarat. In 2010, six tribal girls from Gujarat and Andhra Pradesh involved in these trials died.

The vaccines, produced by Merck and GlaxoSmithKline, were given under an “observational study” conducted under the aegis of Programme for Appropriate Technology in Health (Path), an organisation funded by the Bill and Melinda Gates Foundation. These programmes were conducted in 2007 while the vaccines were approved later.

Under rules, a firm interested in trial is supposed to approach the Drug Controller with a protocol to get approvals, but in India there have been several evidences of weak monitoring.

The government had in 2010 stated that 1,725 persons lost their lives to drug trials in four years from 2007 to 2010.

A Parliamentary committee report in 2010 found that ICMR had signed a memorandum of understanding to provide technical support to the project in 2006 even before the Drugs Controller General of India (DGCI) approved its use in the country, which actually happened in 2008. An ICMR official was implicated in this for favouring this project.

The Ministry directed ICMR to regulate a trial that is already underway. The question was how are such trials were happening under the watch of ICMR? It can not regulate a trial retrospectively. It has to be done before the trials begin.

**ICMR panel calls for end to Nestle-sponsored medical study 7**

On receiving the complaint, union health secretary directed ICMR Director to “get the trial examined and take necessary action to comply with the provisions of the IMS ACT”. The committee constituted by the ICMR concluded that the company’s sponsorship of a five-hospital study violates India’s law on infant milk substitutes. The committee recommended immediate termination of the study and prosecution of the violators (researchers and company). Two more instances of [Nestle](http://timesofindia.indiatimes.com/topic/Nestle) sponsored clinical trials have been brought to the attention of [ICMR](https://m.timesofindia.com/topic/ICMR). These are a multi-country observational study on infant feeding registered in December 2018 that lists Societe des Produits Nestle of Switzerland as its primary sponsor and another observational study on composition of milk of nourished and under-nourished mothers with funding and sponsorship of Nestec Ltd of Switzerland, which was registered in 2014. Both studies included several hospitals such as Apollo Children's Hospital, Chennai; Sir Ganga Ram Hospital, Delhi; Hiranandani Hospital, Thane; and a Bangalore hospital of the Narayana Health Group. The ICMR is requested to take appropriate action against such studies also and follow up of action also must be done.

**CONCLUSION**

The ICMR constituted a committee, which stated that “the complaint is well founded” and that “the study is violative of section 9(2) of the IMS Act” and that it was “funded and sponsored by Nestle India, which is a producer/supplier/distributor on infant milk substitutes as defined under the Act”. Section 9(2) of the Act states: “No producer, supplier or distributor shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminars, meeting, conference, educational course, contest, fellowship, research work or sponsorship.”

The ICMR committee recommended termination of the study and for its status in the CTRI to show the reasons for termination. It further stated that the Drug Controller General of India (DCGI) should examine whether the respective institutional ethics committees that permitted the studies were constituted in accordance with existing regulations. It said “the respective ethics committees may be directed to explain how they permitted such study in violation of the IMS Act”. The committee recommended the prosecution of violators to serve as a deterrent. Nestle has been arguing that its sponsorship of such studies does not amount to violating the IMS Act.7

The ICMR is paramount moral, ethical and disciplinary body in India and hence needs to control, correct and administer such acts of unethical promotion of infant milk substitutes which violates the law of the land. It is hoped that Nestle India will learn from this sad happening and desist from such acts of violating the laws of the land in future.

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Conflict of Interest

There is no conflict of interest for the authors.