

Law for regulating clinical trials on Humans

5059. SHRI T.M. SELVAGANAPATHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government is considering to bring any law to regulate clinical trials on humans;

(b) if so, the details thereof;

(c) whether it is also a fact that India is emerging a safe haven for drug trails on humans; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Clinical trials are necessary to establish the safety and efficacy of any new drug before approving its introduction into the market for human use. These trials are already regulated under the provisions of the Drugs and Cosmetic Act, 1940 and the Drugs and Cosmetic Rules, 1945 made there under.

(c) No.

(d) Does not arise.

Compliance of Tobacco Control Laws

5060. SHRI HUSAIN DALWAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the steps taken by Government to ensure compliance with the provisions of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) (Second Amendment) Rules, 2011;

(b) if so, the details thereof;

(c) whether any violation of the provisions have been observed, recorded or received by the Steering Committee, which were formed at the National, State and District levels for this purpose under the Law; and

(d) if so, the details thereof and the action taken thereon?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) This Ministry has written to Ministry of Information and

Broadcasting for issuing further direction to their subordinate offices for taking appropriate action for implementation of the Rules. In addition, this Ministry has also written to Chairman and CEO of Central Board for Film Certification (CBFC); and Advertising Standards Council of India (ASCI) for implementation and monitoring of the said Rules.

(c) and (d) Earlier, in November 2011 the Ministry of Information and Broadcasting, Government of India, had advised the CBFC and its Regional Board to maintain status quo as it existed before notification of these Rules, citing practical difficulties in implementation. These Rules are at present being followed only to a limited extent. Ministry of Health and Family Welfare is pursuing the matter with Ministry of Information and Broadcasting, for minimizing practical difficulties with a view to ensuring effective implementation of the Rules.

WHO Warning on cell phone radiation

5061. SHRIMATI T. RATNA BAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the WHO has warned that radiation from cell phones is possibly cancerous; and

(b) if so, the details thereof and the steps being taken by Government to face such situation in future?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) The Government is aware about the fact that the World Health Organization (WHO) has classified radio frequency electromagnetic field as possible carcinogenic to humans.

(b) Indian Council of Medical Research has initiated a multi-centric study in Delhi/NCR to address this issue. Under this study efforts are going on to examine whether use of cell phone create risk of neurological, cardiological, cancer, ENT and reproductive disorders. The efforts are also going on the measure specific absorption rate, power density wave length and frequency of Radio Frequency Radiation emitted from various types of cell phones and cell phone towers under this study.

To develop necessary guidelines fixing safe exposure limits of Radios Frequency Radiation along with other necessary measurement and recommendations on this topic in the country, the Department of Telecommunication, Ministry of Communication and Information Technology, Government of India, appointed an