

**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