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Banning clinical trials not a solution to avoid deaths

30 April 2013 | News | By BioSpectrum Bureau

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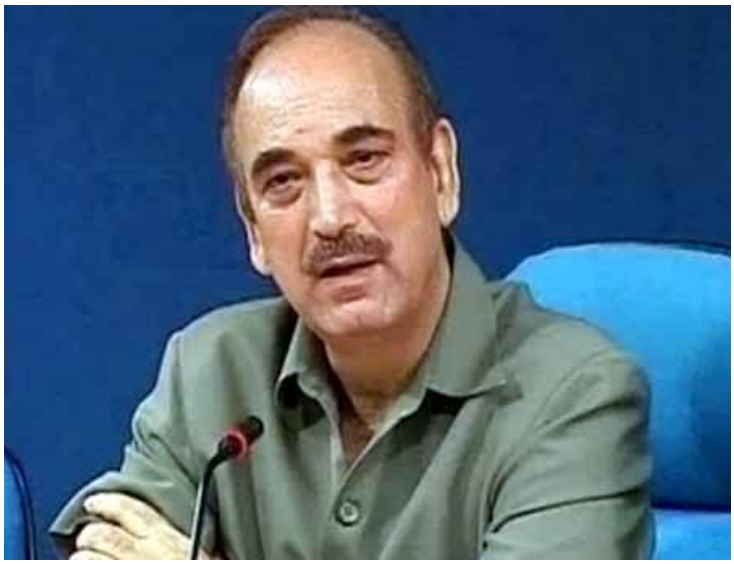

The minister for health and family welfare, Ghulam Nabi Azad emphasized in the parliament on April 30, 2013, that the research in the area of drug discovery leads to newer, safer and more efficacious drugs being made available in the country. â€œClinical trials are the only way of establishing the safety and efficacy of any new drug before its introduction in the market for human use. Clinical trials (with safeguards) are necessary for introduction of new drugs for a country like India, considering its disease burden and emergence of new variants of disease. The trials in the long run benefit the country and its patients. However, lesser number of clinical trials are taking place in the country as compared to the trials in other countries,â€? mentioned Azad.

â€œAs on March 20, 2013, and as per the information available in www.clinicaltrials.gov of National Institute of Health, United States of America (USA), a total number of 1,42,239 clinical trials of different countries worldwide were registered. Out of these, 67,881 are from USA, 38,473 from Europe, 10,702 from Canada, 2,645 from Japan, etc. Only 2,178 clinical trials were registered from India,â€? he added further.

â€œBanning clinical trials, whether local or global, will not be in the interest of drug discovery and research in the country. However, there is a need to effectively monitor these trials so as to avoid irregularities therein. The government has been continuously making efforts at strengthening the regulatory provisions and the monitoring mechanism of clinical trials in the country and to avoid irregularities therein,â€? said Azad.

The minister cited the amendments of various provisions in the Drugs and Cosmetics Rules, 1945 relating to clinical trials. These included the amendment vide Gazette Notification G.S.R. 53 (E) dated January 30, 2013, specifying procedures to analyse the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines. Apart from that the amendment vide Gazette Notification G.S.R. 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial

inspections and actions in case of non-compliance. The third amendment he read out was on the registration of the Ethics Committees has been made mandatory in the Drugs & Cosmetics Rules vide Gazette Notification G.S.R No. 72(E) dated February 08, 2013, specifying requirements and guidelines for registration of Ethics Committee.

The minister also trashed the news reports that clinical trials were being conducted on new born babies at Safdarjung hospital at New Delhi. â€œThere is no report regarding the conduct of clinical trials on children particularly on new borns by foreign pharmaceutical firms at Safdarjung hospital,â€? he said.