GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA UNSTARRED QUESTION No. 4351 TO BE ANSWERED ON THE 20th DECEMBER, 2024

Ethical Standards in Clinical Trials

4351. Dr. T Sumathy Alias Thamizhachi Thangapandian:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government has taken appropriate steps to check, monitor and control the conduct of Clinical trials by Pharma companies without following the proper ethical standards;(b) if so the details thereof including the total list of Pharma companies reprimanded by the Government for adopting such unethical practices in clinical trials in the last seven years;(c) whether it is true that certain pharmaceutical companies which have purchased electoral bonds were also found to be involved in unethical practices in conducting clinical trials; and(d) if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (d): There is a system of monitoring clinical trials. Companies that are found to be in non-compliance with the regulations are issued show cause notice and various actions such as issuing of warning letter, continuation of trial after corrective action, not permitting use of the clinical trial data, and debarring from conducting clinical trials for some time, etc. are taken under the provisions of the New Drugs and Clinical Trials Rules, 2019.
