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Title : Need to regulate and register the global pharmaceutical companies conducting clinical trial research in India.

SHRI B. MAHTAB (CUTTACK): Sir, I would like to draw your attention to the alarming situation prevailing in this country. It has come to light that taking advantage of a large population, diverse gene pool, prevalence of many diseases and low cost, global pharmaceutical companies have made our country an attractive destination for testing their new molecules. Less talked about is the scope for unethical trials arising from the large number of poor and uneducated poor. The pharmaceutical companies are carrying out such trials in India and other developing countries in devious ways which underline the need for a mechanism to protect the poor from being exploited. "Access to information is especially important for people in the developing world where the potential for exploitation is the greatest." notes an editorial published in the British Medical Journal. A survey conducted by ICMR earlier this year brought out the scant regard Indian Institutional Committees have for the guidelines on ethics and only 40 out of 179 committees were found to follow the guidelines.

There is a need therefore to start a registry. Apart from bringing about order and transparency, registration will help in strengthening clinical trial research. While human clinical trials are crucial to assess the safety of drugs, it is

* Not Recorded.

imperative that the issue of safeguarding the interests of people who knowingly or unwittingly become involved in such studies is accorded the highest priority.

Therefore, registering trials will help in making available information about their positive and negative outcomes. Today, even children below the age of ten months are being provided drugs of foreign pharmaceuticals and the information is not being shared with anyone in this country. It is prevalent in many States. This is very alarming. I urge upon the Government to regulate it and start a registry at the earliest and take stringent action against those who are treating our people as guinea pigs.

Accountability of clinical trials is necessary. Would Government take steps in this regard immediately?