PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Hindu, Delhi
Wednesday 30th October 2013, Page: 10
Width: 8.36 cms, Height: 22.33 cms, a4, Ref: pmin.2013-10-30.38.57

Cleansing the system

One hundred and fifty-seven human clinical trials were approved last year while just five managed to pass muster this year. The differentiating factor was this: the trials cleared last year by the Drug Controller General of India were on the recommendation of only the New Drug Advisory Committee, while the five cleared this year went through the new three-tier regulatory regime that came into effect this January following the Supreme Court's directive. If any, the huge difference in the number of approved trials clearly reflects how a radical shift in priority — placing the well-being of volunteers and benefits to the medical needs of the country much higher than the interests of pharmaceutical companies — has drastically cut down the number of eligible trials. There can be no better proof that till the court intervened, permission to conduct clinical trials was granted with scant regard to volunteers' welfare or the real benefits to people at large. Also, no regulation worth the name existed in checking the clinical trials "racket" that was creating "havoc" in the country. Therefore, the court's directive to reassess the 157 trials using the stringent regulatory norms should be welcomed. It should not come as a surprise if only a fraction of these trials approved last year passes scrutiny.

Even if the directive is seen as increasing the regulatory uncertainty and furthering losses to the clinical trials business, there can be no question of compromising human safety, and treating poor, illiterate people as guinea pigs. The clinical trials business in India is estimated to be worth around Rs.3,000 crore and is expected to double in the next few years. With its huge population, diversity, medical expertise and low cost, India may be a hub for trials. Tragically, it is the huge financial potential that the industry promises and other gains that have led to this unsatisfactory state and the refusal by the government to clean up its act. For instance, the Drugs and Cosmetics Rules of 1945 were only recently amended to compensate participants in case of injury or death. As a result, only a fraction of those who died or had an injury were compensated. Nearly 2,650 people died during clinical trials between 2005 and 2012; about 80 deaths were directly attributable to them. Similarly, nearly 12,000 serious adverse events (excluding death) were reported during the same period, and around 500 were directly caused by the trials. Conducting human clinical trials is absolutely necessary even if animal trial results are promising. But human safety is supreme, and the apex court has rightly ensured that it would remain so.

Clinical Trials.