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DGCI curbs doctors' role in clearing new drugs

ABANTIKA GHOSH
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AFTER damaging revelations in a parliamentary panel report about collusion of doctors with pharma firms in helping new drugs bypass mandatory clinical trial regulations in May, the Drug Controller General of India (DGCI) has done away with the regulatory rules that made discretionary approvals possible.

A decision on whether a certain drug can be granted an exemption from the mandatory clinical trial regulations is now the exclusive domain of the New Drug Advisory Committees (NDAC) formed by the Central Drugs and Standards Control Organisation, meetings of which, are diligently documented.

The need to furnish certificates from doctors vouching for the safety and efficacy of a drug does not exist any more because the decision of the NDAC is final, with or without letters from doctors. All members of the NDAC are required to furnish disclosures about any ties they may have with pharmaceutical firms.

"We have stopped the practice of giving clearances to drugs on the basis of letters of recommendation from doctors. It is now mandatory for all new drugs to be cleared by the NDAC whose deliberations are a transparent affair so that there are no considerations others than those of science in reaching a decision. The experts on the NDAC have to give disclosures about their own links with pharma companies," said Drug Controller General of India Dr G N Singh.

In May, the 59th report of the Parliamentary Standing Committee on Health and Family Welfare had delved deep into the drug regulation morass to come up with shocking details about how doctors submitted identical letters of recommendation for drugs and other irregularities to reach the conclusion that a "nexus... exists between drug manufacturers and many experts whose opinion matters so much in the decision making process of the CDSCO..." On an average, the report said, one drug is approved every month through this route, without necessary trials.

The changes in the new drug approval norms are among a series of reforms that CDSCO has undertaken over the last few months, including some crucial ones on clinical trials after controversial reports on deaths during drug trials, lack of compensation and questionable means of obtaining consent.

Regulatory