

India probes charges of violations by drugs regulator

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India's Health Ministry said Thursday it was examining charges that the government's top drug regulatory agency had colluded with pharmaceutical firms to approve drugs without proper clinical trials.

The accusations were levelled in a parliamentary panel report that said officials in the Central Drugs Standard Control Organization (CDSCO) were operating in wilful violation of regulatory practices.

The report, which named a number of international drug majors, said the CDSCO had approved a number of medicines without mandatory final trials, including drugs that are banned in some developing countries.

"There is sufficient evidence on record to conclude that there is a collusive nexus between [drug manufacturers](#), some functionaries of CDSCO and some [medical experts](#)," the report said.

"Such irregular approvals spare drug producers the cost and efforts but put Indian patients at risk," it added.

India's pharmaceutical market has grown by an annual 14 percent in the past five years and, according to PricewaterhouseCoopers, could be worth up to \$50 billion by 2020.

As Indian and international drug makers rush to get their products into the market, the parliamentary report suggested "expert" reports on [drug safety](#) were actually the work of the manufacturers.

"There is adequate documentary evidence to come to the conclusion that many opinions were actually written by invisible hands of drug manufacturers and experts merely obliged by putting their signatures," the panel said.

In a statement Thursday, the [Health Ministry](#) said the panel's findings were being "examined" and promised that "appropriate action would be taken ... wherever required".

The CDSCO is responsible for the licensing, marketing and trials of drugs in India.

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