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Indian expert panel to probe drugs regulator

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India's Health Ministry said Friday it had set up an expert panel to review the operations of its drug regulatory agency, accused of colluding with pharmaceutical firms to approve drugs without 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 countries.

In a statement Friday, Health Minister Ghulam Nabi Azad announced the creation of a three-member panel, comprising medical experts and academics, to look into the workings of the CDSCO.

The panel will examine the "validity" of any scientific and statutory basis for approving new drugs without clinical trials and recommend measures to bring about "systemic improvements" in the approval procedure, Azad said.

The parliamentary report had concluded there was sufficient evidence to suggest the existence of a "collusive nexus" between drug manufacturers and CDSCO officials to push some medicines onto the market.

"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 drugmakers rush for a slice of the market, the parliamentary report suggested some "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.

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