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Q:- Why India act urgently to curb the problem of counterfeit drugs? Discuss the initiatives taken by government of India to tackle the problem of counterfeit drugs.

India recently alters functioning of drug regulatory including massive reorganisation and mass transfer of officers this year. Its because of drug administration in India itself flawed through many counterfeit drugs. For example:- CBI arrest Deputy drug Controller at the Central Drug Standard Control Organisation (CDSCO) for corrupt practices related to drug approvals.

This kind of issue is not only at Union government, but also state government and many pharma manufacturers. According to the WHO research, one in 10 medical products circulating in low and middle income countries is either substandard or falsified.

A national wide survey in 2014-16 showed that 3% medicines marketed in were substandard, around 0.023% were either spurious or counterfeit. Many of large pharma companies failing in quality test. For ex:- Sun pharma's "Pantocid".

INITIATIVES TAKEN BY GOI → COUNTERFEIT DRUGS

Indian government takes many patient safety initiatives → to control menace

of Counterfeit Drugs:-

1. SURVEYS TO ASSESS THE EXTENT OF IT:-

1.1. CDSCO conducted a survey periodically through testing.

1.1.1 National Institute of Biologicals Under CDSCO is in the process of scrutinizing over 47,000 drugs samples, as reported DCGI in 2015.

2. D & C Act Amendment Bill 2008 for stringent punishment:-

2.1 GoI amended Drugs & Cosmetics Act in 2008 → Introduced stringent punishment and penalties for the manufacturer of spurious drugs, ~~and~~ altered drugs and made the offence non-bailable.

3. Feasibility study for Drug track and trace in domestic market:-

3.1 Ministry of Health and family welfare (MoHFW) initiated → public welfare and consumer empowerment measures.

3.2 Establish drug authentication and secure distribution network of drugs in domestic and international market through 14 digit number in drugs.

3.3 WIPRO ~~used~~ helped for it.

4. Industry initiative Anti-Counterfeiting Measures through technologies → Overt technologies, Covert technologies, Forensic, Serialisation/Track-n-trace technologies.

5. Director general of foreign trade (DGFT) measures through Drug Authentication & Verification Application (DAVA) through bar

codes.

Thus for the public safety, GoI should implement separate task force independently for regulator and proactive engagement. Need a holistic approach to tackle this issue. It needs all sectors and stakeholders to address the overall interest of patient safety first and healthy nation.