News

The Supreme Court rejects a PIL that sought a court-monitored investigation into children's hazardous cough syrup deaths.

> Following the alleged deaths of 14 children in Madhya Pradesh from ingesting hazardous cough syrups, the plea demanded a national recall of tainted syrups and a drug-safety reform.

A Public Interest Litigation (PIL) petition asking for an impartial, court-monitored investigation into the deaths of several children, which were purportedly brought on by tainted cough syrup, was denied by the Supreme Court on Friday [Vishal Tiwari v. Union of India].

Advocate Vishal Tiwari's plea was denied by a bench consisting of Justice K Vinod Chandran and Chief Justice of India BR Gavai.

> **"Deaths per day are increasing. This is not the first time that medicine has been tampered with. States are pointing fingers at one another. One agency's investigation is required,**" Tiwari stated, making an in-person appearance.

Tushar Mehta, the solicitor general, resisted the petition. He claimed that after reading newspaper articles, Tiwari rushes to the Court. Additionally, he stated that the affected states would take action to resolve the problems.

"Madhya Pradesh, Tamil Nadu, and others will take action. The States cannot be trusted. "They will definitely take action," SG Mehta stated.

"**There was no proper lab test or clinical trial done,**" Tiwari asserted.

"**Whenever something happens even though all Institution in place, he (Tiwari) reads newspapers and come here**," Mehta continued.

The petition was subsequently dismissed by the court.

Tiwari's appeal demanded that India's drug safety and recall systems be completely redesigned.

The petition was filed in response to reports that at least 14 children, all under five, died in Madhya Pradesh lately after ingesting **Coldrif Cough Syrup, which is produced by Sresan** Pharma Pvt. Ltd., a company based in Tamil Nadu.

The State Forensic Science Laboratory in Bhopal provided laboratory tests that verified the existence of Diethylene Glycol (DEG), a hazardous industrial chemical that is prohibited for use in pharmaceuticals and utilized in antifreeze.

The suit claims that after eating the syrup, several youngsters in the Chhindwara district experienced severe renal failure, which brought the tragedy to light. The number of fatalities increased quickly, and suspected instances also surfaced in Rajasthan and Maharashtra.

The request claimed that neither the Central Drugs Standard Control Organization (CDSCO) nor the Union Ministry of Health and Family Welfare had issued an immediate statewide recall despite confirmed contamination.

Drawing comparisons to the 2022 events in the Gambia and Uzbekistan, when Indian-made syrups were connected to the deaths of more than 90 children overseas, the petition claimed that such delay constituted a catastrophic regulatory failure.

At the time, the World Health Organization (WHO) had advocated for systemic change and sent out global notifications alerting India to the dangers of DEG and EG pollution.

The petitioner argued that because India still does not have a national drug recall policy or any standardized pre-release testing, these warnings were ignored.

Although local sales of the tainted cough syrup were finally stopped in a number of states, including Tamil Nadu, Kerala, and Maharashtra, the petition pointed out that the absence of a centralized recall procedure allowed tainted batches of the medication to continue to be sold for weeks.

The petition also brought attention to the fact that hundreds of small-scale pharmaceutical producers do not have proper testing facilities or raw material traceability.

> The petitioner argued that the majority of these producers purchase unreliable chemical excipients, which are the base constituents of the syrup and may contain industrial-grade glycols.

The appeal further stated that the State is required to preserve the right to life and public health under Articles 21 and 47 of the Constitution, which are violated by such systemic neglect.

Therefore, the petitioner asked the Supreme Court to issue a number of orders, one of which

was to establish a judicially overseen National Expert Committee led by a retired Supreme Court judge to investigate the production, control, testing, and distribution of tainted cough syrups and suggest changes to drug safety.

Additionally, it called for the immediate recall and seizure of all batches of **Coldrif** Cough Syrup, the suspension of **Sresan** Pharma's production license, and a Central Bureau of Investigation (CBI) investigation into all linked deaths in all states under judicial supervision.

> The petition also called for the creation of a Central Digital Drug Recall and Pharmacovigilance Portal to track contaminated or subpar medications in real time, as well as a statewide testing requirement for DEG and EG contamination for all syrup-based formulations.