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STATE LETHARGY AMIDST COUGH SYRUP POISONING

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A few days ago, we learnt that 12 children died in Udhampur district of Jammu due to poisoned cough syrup (Coldbest-PC). More are fighting for their life in a hospital. A team of doctors at the Post Graduate Institute of Medical Education & Research, Chandigarh, attributed the deaths to the presence of diethylene glycol in the cough syrup which was consumed by all the dead children. Diethylene glycol is an anti-freezing agent that causes acute renal failure in the human body followed by paralysis, breathing difficulties and ultimately death.

This is the fourth mass glycol poisoning event in India that has been caused due to a pharmaceutical drug. In 1973, there was a similar incident at the Children's Hospital, Egmore in Chennai that caused the deaths of 14 children. In 1986, similar poisoning at Mumbai's J.J. Hospital caused the deaths of 14 patients who were otherwise on the path to recovery. In 1998, 33 children died in two hospitals located in New Delhi due to similar poisoning. In all three cases, the manufacturer of the suspect cough syrup, due to negligence or human error, failed to detect and contain the level of diethylene glycol in the syrup, thereby causing poisoning of the patients who consumed it.

There will be plenty of time later to ascertain the cause and prosecute the guilty but the immediate concern for doctors, pharmacists and the drug regulators should be to prevent any more deaths. The only way to do so is to account for each and every bottle of the poisoned syrup that has ever been sold in the Indian market and stop patients from consuming this drug any further. Any patient who has consumed even a spoon of the syrup should then immediately be referred to a hospital for treatment.

According to the information available on the website of the United States Food and Drug Administration (USFDA), in 1937, when the United States faced a similar situation with glycol poisoning, its entire field force of 239 inspectors and chemists were assigned to the task of tracking down every single bottle of the drug. Even if a patient claimed to have thrown out the bottle, the investigators scoured the street until they found the discarded bottle. This effort was accompanied by a publicity blitz over radio and television.

We do not see such public health measures being undertaken here; authorities are simply not communicating the seriousness of the issue to the general public. At most, the authorities in Himachal Pradesh (H.P.), who are responsible for oversight of the manufacturer of this syrup, have made general statements that they have ordered the withdrawal of the drug from all the other States where it was marketed. However, there is no transparency in the recall process and information about recalls and batch numbers is not being communicated through authoritative channels. There is no public announcement by the Drug Controller General of India (DCGI), which is responsible for overall regulation of the entire Indian market. The suspect product, although manufactured in H.P., has been sold across the country. The website of the DCGI, which is supposed to communicate drug alerts and product recalls, has no mention of Coldbest-PC as being dangerous as of this writing.

One of the key reasons why the DCGI and state drug authorities have been so sloppy is because unlike other countries, India has not notified any binding guidelines or rules on recalling

dangerous drugs from the market. The 59th report of the Parliamentary Standing Committee on Health as well as the World Health Organization (in its national regulatory assessment) had warned the DCGI on the lack of a national recall framework in India. A set of recall guidelines was drafted in 2012 but never notified into law. In 2016, in a report submitted by me to the Ministry of Health suggesting measures to reform the drug regulatory framework, I had pointed out to the Ministry that a national drug recall framework was in urgent need. In a pending case before the Delhi High Court, I have also sought for the notification of a national recall mechanism. The government is yet to file its response.

While a national recall of this adulterated medicine is the immediate need, the administration also needs to quickly identify which other pharmaceutical companies have received the spurious ingredient that was supplied to the manufacturer in H.P. from a trader in Chennai. It is very likely that the trader in question marketed the same ingredient to other pharmaceutical companies, who, like the manufacturer at the centre of the present scandal, may have failed to test it for its identity and purity. It is important for regulatory enforcement to raid and seize the records of the trader in Chennai and verify its sales. As of today, we have little to no information on whether any of this is happening. The lackadaisical response of drug regulators in India is not surprising. It is the result of a larger lethargy and arrogance that is emblematic of the babudom which is responsible for keeping us safe from unethical practices of pharmaceutical companies.

The writer is a public health activist and was the whistleblower in the Ranbaxy case

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