

## Contaminated drugs are held responsible for 120 deaths in Pakistan

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Authorities in Pakistan have temporarily closed a drug company thought to have produced contaminated drugs that killed more than 120 patients at a Lahore hospital over the past month.

The crisis has raised concern over the quality of low cost drugs and the effectiveness of the drug regulatory system in Pakistan.

A batch of the drug, Isotab (containing isosorbide mononitrate 20 mg), is thought to have caused the deaths at the state run Punjab Institute for Cardiology in Lahore, where it was given free of charge to patients with heart conditions. Tests have shown that the batch was contaminated with a heavy dose of the antimalarial pyrimethamine, which caused rapid depletion of white blood cells. Several hundred patients are still unwell after taking the drug.

Government investigators believe that more than nine million Isotab tablets were produced by a manufacturer called Efroze Chemical at its factory in Karachi. It is thought that a serious error in the manufacturing process led to the contamination.

The deaths have highlighted the weaknesses of Pakistan's drug regulatory system at a time when Pakistan's health ministry has been dismantled and reforms have devolved responsibility for health services and systems from central government to the provinces.

"This should be a wake-up call," said Sania Nishtar, president of Heartfile, a health policy think tank in Pakistan. "There are only a handful of drug testing laboratories in the country, and most of them are non-functional," she said. "While the standard operating procedures for quality testing may have been articulated, the infrastructure to implement them doesn't exist."

Dr Nishtar warned that political struggles had already delayed the creation of an independent drug regulation authority, which was approved by the cabinet in 2005, and the devolution process had caused further delays.

At the same time, corruption has allowed as many as 600 drug manufacturers to operate in Punjab province without being officially registered, the Pakistan Medical Association says.

Paul Newton of the University of Oxford's Centre for Tropical Medicine says that the Lahore deaths are an example of a global problem. The World Health Organization estimates that a third of countries worldwide have "no drug regulation or a capacity that hardly functions," he told the *BMJ*.

"Urgent international investment in human and technical capacity and finance is required to give every country a functioning regulatory authority," he said.

Investigating officials have told reporters that the contaminated batch used by the hospital was not marked with a date of manufacture or expiry. The hospital's chief executive officer and seven other senior members of staff have been suspended, pending investigation.

The drug is not thought to have been distributed outside Pakistan, but WHO has issued a precautionary alert to all regulatory authorities worldwide. The manufacturer has not commented.

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