

# Pakistani drug regulator 'destined to be a failure'

Experts question whether newly formed agency can bring order to pharmaceutical industry.

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Pakistan's government has created an agency to regulate the country's pharmaceutical industry. The Pakistani Supreme Court ordered the move following the deaths in January of nearly 150 patients taking an adulterated heart drug.

But experts question whether the agency will have the staff, funding or clout to be effective. "With a weak implementation mechanism and a dearth of experts, the newly announced drug-regulation agency is destined to be a failure," says cardiologist Ashur Khan of the Heart International Hospital in Rawalpindi.

Pakistan's pharmaceutical industry has operated in a legal vacuum since 2010, when a constitutional amendment dissolved the ministry of health and shifted responsibility for drug regulation to the country's provincial governments.

The provinces, however, lacked the funds, facilities and personnel to run such a system. "Registration of 6,000 drugs in the last two years indicates weak internal control of registration of medicines and there is the possibility that many drugs might have been registered in return for bribery," says Tipu Sultan, president of the Pakistan Medical Association.

Antibiotics, sleeping tablets and injectables such as steroids are sold without prescriptions, and many traditional medicines are unregulated. One health official estimates that Pakistan has more than 400 drug companies, and that 70,000 different drugs are available in the country.



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Deaths caused by adulterated drugs have triggered protests in Pakistan.

## Early stages

The Drug Regulatory Agency of Pakistan, established in a February ordinance from President Asif Ali Zardari, is to be based in Islamabad. The government has not yet announced any funding and might not do so until the national budget for 2012-13 is finalized in June.

"At the moment, nothing has gone beyond paperwork. No budget has been allocated and no staff or experts have been hired to make a start. There is a possibility that we might face another tragedy," says Sania Nishtar, the founder and president of Heartfile, a non-profit health-care policy think tank based in Islamabad.

Presidential ordinances expire after some months. Pakistan's parliamentary health committee has called for a vote in parliament to establish the regulator on a more permanent basis.

Only one position on the regulatory body is earmarked for a person with medical or pharmaceutical expertise. The other 12 will go to bureaucrats.

The parliamentary committee wants more technical experts at the regulator. It has also urged the Pakistani government to increase the number of drug inspectors, allocate more resources to train technical staff, and set up specialized laboratories in all provinces to monitor drug quality.

Mehmood Jamal, executive director of the Pakistan Institute of Medical Sciences in Islamabad, rejects predictions that the regulator will be ineffective. "It is too early to suspect its success," he says, adding that the body will have sufficient technical staff.

## The cost of regulation

The drug thought to be responsible for January's deaths is called Isotab-20 and was made by Efroze Chemical Industries in Karachi,

Pakistan. It was distributed to patients at the Punjab Institute of Cardiology in Lahore.

Tests carried out in a UK lab showed that the batch of Isotab-20 thought to have caused the deaths consists of an angina drug, isosorbide-5 mononitrate, mixed with 14 times the standard dose of the anti-malarial compound pyrimethamine. Pyrimethamine suppresses the body's production of blood cells. An overdose can be fatal.

The World Health Organization has issued a global warning to stop use of the drug. Thirteen arrests have so far been made in relation to the case.

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