The drug debacle – Part I

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In 1937, more than a hundred people died in the United States as a result of using a drug formulated with a toxic solvent in what came to be known as the Elixir Sulfanilamide Tragedy. The incident was a wakeup call for the then US administration and led President Roosevelt to sign the Food, Drug and Cosmetic Drug Act into Law in 1938. The new law significantly increased federal regulatory authority over drugs and mandated the creation of the US Food and Drug Regulatory Authority (FDA).

The FDA was created as a federal entity in the United States' federal system, even though health was a state subject. Since then, the FDA has become a global reference institution and has prevented the occurrence of similar events. For example, in the late 1950s and early 1960s, when the Thalidomide horror struck in the rest of the world with more than 10,000 children in 46 countries born with limb deformities, as a result of their mothers using the drug Thalidomide, for morning sickness, the US was largely insulated as it had already refused to authorise Thalidomide for market use because of concerns about the drug's safety.

Although the United States and Pakistan are not comparable from a capacity or a resource standpoint there are important lessons to be learnt. Eight decades on, a similar situation has occurred in Pakistan. A hundred and fifty individuals are reported to have died as a result of drug-induced fatal bone marrow suppression. Pyrimethamine-contaminated Isosorbide 5-Mononitrate (a medicine used for the treatment of heart disease) dispensed from a public sector hospital pharmacy in Punjab was identified as the culprit drug. The hospital itself has a large catchment area, so the actual number of people who may have suffered could be higher than the known deaths.

Amidst the media frenzy around the issue, speculative opinions, and reckless punitive action, clarity is needed in three respects: where does the onus of responsibility lie? What is the potential fallout? And what needs to happen next?

In terms of responsibility, it must be appreciated that this is clearly both a failure of manufacturing and control systems at the level of the manufacturer as well as regulation. This notwithstanding, its determinants are complex. Collusion was systemically pervasive all along in granting manufacturing licenses, drug registrations and monitoring of quality with inspectors complicit in fostering deliberate inattention to oversight at the manufacturing level.

It appears that the situation deteriorated further after the 18th Constitutional Amendment. When the latter abolished the Concurrent Legislative List, devolution of “drugs and medicines” was a mistake. Provinces started calling for provincial drug regulation, in complete deviation from international best practice.

There was a clear way forward to mandate the federal government and build further on the 2005 framework for the establishment of an independent Drug Regulatory Authority (DRA), but things got complicated as the “drug regulation turf” became an additional ground for the political fight between the federal government and the government of Punjab.

As a result, seven months passed since the Ministry of Health’s (MoH) abolition, and the process of creating the DRA did not come to fruition. Meanwhile, however, the provinces used a constitutional instrument to grant the federal government a temporary regulatory mandate, which is where the Drug Cell was placed after MoH’s abolition-a fact relevant to tracking the onus of responsibility. It was only in compliance with the Superior Court’s ruling earlier this month that the DRA has been established, for the time being, in theory.

The three-fold fall out of the debacle should be fully appreciated. The tragic mortality has adversely impacted both domestic as well as international confidence. Consumers and doctors are losing faith in the safety of locally produced medicines. Although it is early to assess the quantum of impact vis-à-vis exports, signs are worrying. If left unaddressed, this could render an irreparable blow to Pakistan's local pharmaceutical industry. Many may be producing good medicines but at the moment we have no way of demonstrating that they are GMP (Good Manufacturing Practice) compliant and produce quality tested medicines.

So what needs to happen next? Four steps are being outlined here. First, there has to be a high level international independent inquiry, including experts from FDA, the European Medicines Agency (EMA), the Australian Therapeutic Good Administration (TGA) but also countries like Malaysia, Singapore and Indonesia, as well as the World Health Organization (WHO). It is critical to ascertain what really happened and place findings in the public domain.

Secondly, from now on there must be transparency in all GMP inspection reports. The WHO Prequalification site publishes all inspection reports. For example, the report from Kenya is illustrative (http://apps.who.int/prequal/WHOPIR/WHOPIR_Universal13-16June2011.pdf). There are many others at http://apps.who.int/prequal/ in the section labeled inspections.

All locally produced products that are widely used in Pakistan should be tested and the results posted on a publicly accessible website, such as the one the Global Fund for AIDS, TB and Malaria maintains at the page Global Fund – Pharmaceutical Quality (http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/) in the section labeled "pre shipment testing". Each cell in the spreadsheet links to a Certificate of Analysis. Experts will confirm that testing does not ensure quality, but

when combined with GMP inspections and regular checks, it does go a long way. Capacity has to be built in order to implement such stipulations.

(To be concluded…)

The writer is the founding president of the NGO think tank Heartfile. Email: sania@heartfile.org