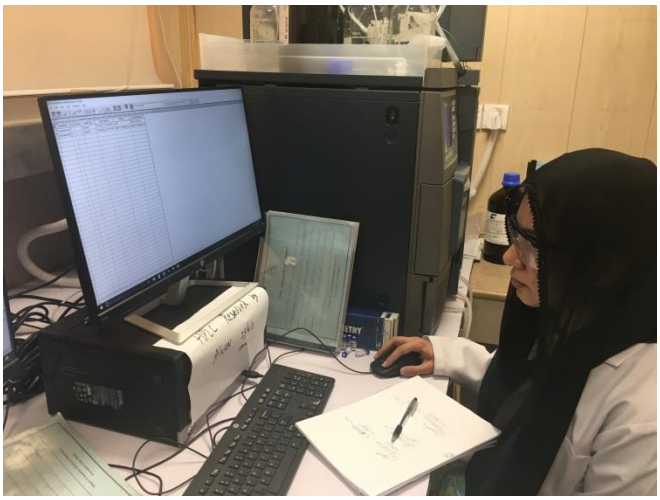
Pakistan Acts Quickly to Recall Contaminated Medicines

Tracking the source of local pharmaceutical manufacturers' raw materials is crucial to good medicines regulation



A Drug Regulatory Authority of Pakistan (DRAP) staff member reviews a pharmaceutical manufacturer's records on the sources of its active pharmaceutical ingredients. "Having full information on APIs is essential to registering a product for the national market because these ingredients have a direct effect on the safety and efficacy of medicines," advises DRAP's Director of Quality Assurance and Laboratory Control.

The U.S. Agency for International Development-funded Promoting the Quality of Medicines (PQM) program has partnered with the Government of Pakistan since 2015 to support local manufacturers of priority medicines in improving quality standards and to strengthen the Drug Regulatory Authority of Pakistan's capacity in medicines registration, post-marketing surveillance, and quality control.

With U.S. Agency for International Development (USAID) support through the Promoting Quality of Medicines (PQM) program, Pakistan joined an international recall of medicines to treat hypertension and heart disease in July 2018. The Drug Regulatory Authority of Pakistan (DRAP) was 1 of 23 medicines regulatory authorities that took swift action when a potentially carcinogenic impurity was detected in a Chinese pharmaceutical producer's stock of valsartan, an active pharmaceutical ingredient (API) that the company had been supplying to medicines manufacturers worldwide.

DRAP immediately ordered all 9 Pakistani pharmaceutical companies that had procured potentially tainted valsartan to recall their products, with the Authority's federal and provincial inspectors enforcing the removal of affected brands and batches in just a weeks' time. Yet, knowing which local manufacturers were at risk might have been nearly impossible only 1 year earlier. Until mid-2017, DRAP had not required companies that manufacture medicines for Pakistan to declare the source of the APIs they use. The decision to do so was included in regulatory reforms that DRAP made to achieve a higher maturity level (as defined by the World Health Organization) and as part of the road map to implementing the Common Technical Document, a standard format for assessing new and generic medicines based on globally accepted good review practices. These key interventions have been supported through advocacy and technical assistance from the USAID-funded PQM program.

"Having full information on APIs is essential to registering a product for the national market because these ingredients have a direct effect on the safety and efficacy of medicines. Regulating APIs helps Pakistan increase the quality and safety of medicines for consumers and harmonizing with international regulatory requirements," advises DRAP's Director of Quality Assurance and Laboratory Control.

During the highly publicized recall, DRAP took a proactive approach that ensured continued market availability of valsartan products and avoided a public health catastrophe in Pakistan, where more than one-third of the population suffers hypertension. To compensate for the recalled commodities, the Authority urged existing valsartan manufacturers to increase production and expedited the review of pending applications from new manufacturers. DRAP also anticipated possible panic that might cause patients to discontinue treatment, increasing their likelihood of increased morbidity and mortality. It accordingly worked to raise awareness among prescribing doctors and their patients about the extent of the recall, and prevailed on stakeholders to increase public communication.

"DRAP's informed response to the recall was a major turning point for our Agency," says DRAP's Chief Executive Officer. "All medicines should be efficiently regulated, and life-saving medicines like valsartan are a reminder that speed is vital to efficiency."