WHO Global Surveillance and Monitoring System

for Substandard and Falsified Medical Products

World Health Organization

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ABBREVIATIONS

Gavi	The Vaccine Alliance
GMP	Good manufacturing practices
GSMS	Global Surveillance and Monitoring System for substandard and falsified medical products
ICG	International Coordinating Group
NGO	Nongovernmental organization
NMRA	National or regional medicines regulatory authority
UNICEF	United Nations Children's Fund
US FDA	United States Food and Drug Administration
WHO	World Health Organization

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A CASE IN POINT

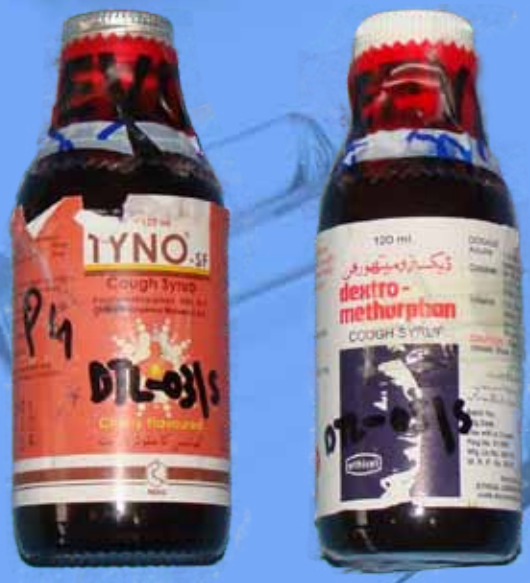
In September 2013, a hospital in Paraguay admitted 44 children in quick succession. All of them had difficulty breathing – six were so badly affected that they were taken to intensive care. Hospital staff could not immediately identify the cause of the outbreak; they feared some unrecognized disease. National authorities began to investigate straight away. They found that the condition always started with symptoms of the common cold, which parents had treated with locally-made cough medicines.

The national medicine regulator alerted the World Health Organization (WHO), and the information was passed on to the WHO Substandard and Falsified Medical Products Group in Geneva. The story was worryingly familiar to that team who had seen a similar case in a completely different part of the world: Pakistan.

In that earlier case, 60 adults in two cities in Pakistan had died after consuming large quantities of cough syrup as part of their drug addiction. The Government of Pakistan had acted quickly to suspend production of the medicine by two local manufacturers (Fig. 1). Both manufacturers had recently changed their source of active pharmaceutical ingredient to a cheaper one. The authorities in Pakistan recalled the remaining stock and the active ingredient, dextromethorphan, which had been imported from India. Indian authorities were notified and they suspended production until the cause of the problem was established. But initial laboratory test results were confusing. The medicines appeared to contain the correct amount of dextromethorphan; there was no clear indication of why patients taking it had died.

Authorities in Pakistan requested WHO to help to investigate further. Tests in laboratories overseas

FIG. 1: BOTTLES OF COUGH SYRUP CONTAINING LEVOMETHORPHAN THAT CAUSED DEATHS IN PAKISTAN 2012-13



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Paraguayan investigators went to the factory where they found import records for the dextromethorphan in the cough medicines the sick children had taken. A quick check against the WHO substandard and falsified medical products database showed that it came from the same Indian manufacturer that had supplied the factory in Pakistan; indeed, it had the same batch number. Within days of reporting their concerns, doctors in Paraguay were able to treat their patients with an antidote to levomethorphan and, because of this quick action, the patients survived.

WHO provided support to investigate the incident more thoroughly, and issued a second alert listing the batch numbers of all the dextromethorphan that might have been contaminated. It had been exported to several countries in Europe, north Africa, the Middle