Lessons Learned from a Global Sentinel Event: Priorix Vaccine Returns to Vietnam

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Nine months after its embargo following a deadly infectious disease scare among children at Ho Chi Minh City Health Center in Vietnam, GlaxoSmithKline’s Priorix measles-mumps–rubella (MMR) vaccine has been allowed to return to the market here. The nation’s Ministry of Health’s initial response to the reports of illness in six children within days of receiving Priorix provoked questions about product contamination and cold storage mismanagement. However, because methicillin-resistant *Staphylococcus aureus* (MRSA) was the pathogen that caused the infections, the product seemed less culpable than the provider who administered it. Follow-up testing at World Health Organization (WHO) investigational laboratories in Germany and Japan have since confirmed that Priorix was not at fault and that the MRSA strain that infected the children genetically matched that of a member of the vaccination team at the Ho Chi Minh City satellite vaccination facility.

The answer to this public health mystery is now clear. For companies that market vaccines in developing nations and depend on brand reputation throughout the world, questions remain about the pace of proving the vaccine safe and allowing its return to the market.

In this case, archived vaccines were readily available from the manufacturer, but samples from the batch that were used at the vaccination facility had to be tracked, secured, and then shipped to approved reference laboratories. The recovery and international transport process itself allowed some of the vaccines to become damaged and resulted in variances from recommendations for cold storage. The changes in the products and their packaging needed to be identified and separated from any alterations that occurred prior to their use in patients.

Because no specific instructions were universally accepted as to how to prove that the vaccines were safe, WHO’s reference laboratories were methodical and comprehensive in their evaluations, providing a degree of pharmacological assurance that was time-consuming.

In the meantime, GlaxoSmithKline had hoped for the return of Priorix for use in Vietnam before the previously distributed product reached its expiration date. While the product sat in refrigerators in hospitals and in doctors’ offices, vaccines from the same batch that were involved in the MRSA scare were quarantined at pre-distribution sites.

The time spent in verifying the safety of these vaccines represented GlaxoSmithKline’s potential direct losses; costs resulting from the forfeiture of market participation exacerbated the losses. A manufacturer’s greatest fear—a tarnished brand in the global market—did not occur with the Priorix scare in Vietnam, as there was no drop-off in use of this vaccine outside Vietnam. This was probably a result of the swift and transparent responses from the manufacturer, WHO, and Vietnam’s Ministry of Health—a global collaboration that increased public confidence in the type of public health partnerships that are necessary for safe vaccine production and use.

Supporting Priorix’s return to Vietnam, GlaxoSmithKline and the Ministry of Health’s Pasteur Institute have jointly sponsored a series of classes in safe immunization practices for vaccination teams. It is hoped that this “ounce of prevention” will protect children from vaccine-related infections and manufacturers from lengthy interruptions of market participation.

**REFERENCE**