Tilleke & Gibbins

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Vietnam Pharma Update

# Pharmaceutical Parallel Imports: A Solution or a Problem?

As a developing country with a large population, Vietnam has long viewed parallel imports as an effective antidote to the high price of innovator drugs. The parallel importation of medicines for the prevention and treatment of human diseases is permitted, and even encouraged, under Vietnamese law. Many pharmaceutical manufacturers, however, are understandably concerned that parallel importation could lead to diminished profits, thereby reducing research and development efforts, and leading to a slowdown in the innovation of new drugs. Even worse, in certain situations, parallel imports could put the public health at risk.

A recent case brought these issues to the forefront. A major European pharmaceutical innovator learned that a Vietnamese company was importing diabetes drugs into Vietnam that the company had manufactured for the Turkish market. While these drugs were "genuine" products of the manufacturer, and drugs under the same brand name had been authorized for circulation in Vietnam, the markets were not truly "parallel." Turkey requires different standards for storage than Vietnam, and the quality of the drugs could deteriorate more rapidly in Vietnam's tropical climate. Understanding that this could negatively impact consumer health as well as the manufacturer's reputation, the European company called on Tilleke & Gibbins to map out a creative strategy to crack down on the parallel importation.

At the outset, we conducted a mark survey to determine the prevalence of the products in the market, and located the major distributors. We also examined the products to identify any violations of other prevailing laws, such as those in the regulatory area. Based on the fact finding, we called on the competent authorities to tackle the situation.

In December 2014, the Hanoi Market Control Department in cooperation with the Inspectorate of the Department of Health conducted a sweep action against two major distributors of the products. After the raid, the authorities seized hundreds of parallel import products. We raised the authorities' attention to the quality of the goods and pointed out some violations of labeling regulations that could mislead consumers. Within a month, with a view to protecting the public health, the authorities decided to sanction the distribution of the parallel imports by relying on regulatory aspects, especially labeling regulations, including imposing a monetary fine and seizing the products.

The authorities then sent a letter to the Drug Administration of Vietnam (DAV), bringing the DAV's attention to the violations in particular and the parallel import situation in general. This may lead the DAV to take further precautions in granting licenses for parallel importation. In its recent practice, when weighing the decision to grant a parallel import license, the DAV has focused on the price and the name of the drugs, but not the quality or any special characteristics of the original market.

The affordability of drugs that comes with parallel importation is an undeniable benefit. However, the health authorities must also take into account the risks and complications posed by grey-market drugs, especially in relation to public health. In the future, it is expected that Vietnam will lay down further regulations on parallel importation to guarantee the quality of the imported drugs as well as the post-sales responsibility.


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