

FOCUS ON

Parallel Imports

Public Health Risks with Parallel Imports What it may mean to Singaporeans

What Are Parallel Imports?

Parallel Imports are trademarked or patented goods that are sold by the right owner in one country for export to a second country but are purchased in the second country and exported into a third country without the consent of the patent or trademark owner.

In the case of pharmaceutical products, import by the non-right holder into a third country may violate patent rights even if the product was originally purchased from a right holder.

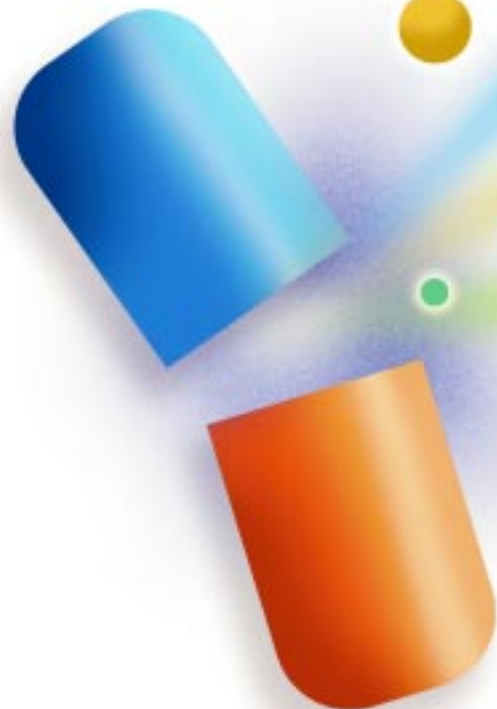
The imports are called parallel imports because traditionally the right holder was held to have the right to control importation of the product.

Public Health Concerns

Pharmaceuticals are vital for improving life expectancy and quality of life around the world, which is why the pharmaceutical industry is the most regulated global manufacturing industry. Consumers rely upon the industry to provide high-quality, safe and effective products, but parallel importation directly threatens these qualities.

Law enforcement agencies believe that parallel import regimes result in increased smuggling of tainted or counterfeit goods. While parallel importation raises general public health and safety concerns, parallel imports of pharmaceutical products create definite risks for the general public, particularly with regard to shipment and storage, given extreme climate

conditions in many markets where parallel imports take place.



There are 3 potential risks related to parallel importation, they are:

- Counterfeit &/or Substandard Medicines
- Improper Handling
- Improper Packaging

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Counterfeit &/or Substandard Medicines

Parallel trade in pharmaceuticals involves the importation and sale of medicines from sellers and, often production sites not approved by national regulatory authorities. This poses inherent risks of importing counterfeit and/or substandard medicines.

A counterfeit medicine is a compound that is not made by the authorized manufacturer, but is presented to the consumer as if it were.

Counterfeit drugs:

- may not contain an active ingredient,
- may not have enough active ingredients to be effective, or
- may contain an improper ingredient, sometimes including a toxic substance.

Even in less extreme cases, counterfeit drugs can do serious harm. A person taking a counterfeit “antibiotic” with little or no active ingredient, for example, can die of an infectious disease and/or exacerbate public health problems if the disease spreads or if drug resistance is promoted.

The magnitude of the problem varies. At a recent hearing of the US House Commerce Subcommittee on Oversight and Investigations, the Chairman noted that, according to the World Health Organization, about 5-8 percent of drug products shipped to the US are counterfeit, unapproved, or substandard.

In addition, some analysts have estimated that 50-70 percent of drugs in developing countries are counterfeit.

Improper Handling

The right holder cannot control the conditions under which the product is shipped or stored once the product is sold. Inappropriate shipment or storage conditions may adversely affect the safety and efficacy of the product.

There is no way of ensuring that a third party, who is attempting to benefit from price arbitrage between markets, will take adequate precautions to handle pharmaceutical products appropriately. It is also not entirely in his control as a number of different parties might be involved.

Improper Packaging

In many cases re-packaging is required and most parallel importers do not conform to the GMP requirements imposed by the manufacturers. Tempering

with products is not according to the manufacturers’ quality assurance policy and no liability can be claimed. Any plant that performs some sort of redressing/repackaging will have to be audited by the manufacturer to ensure compliance.

Informational materials included in the packaging of pharmaceutical products may be inadequate or inappropriate for medical consumers in a third country, and may lead to adverse health outcomes.

In the USA

Given the threat to public health and safety, the US does not permit parallel importation of pharmaceutical products.

The US declined to implement parallel importation in December 2000, citing the lack of savings to patients and the risk to public health.

In Singapore....

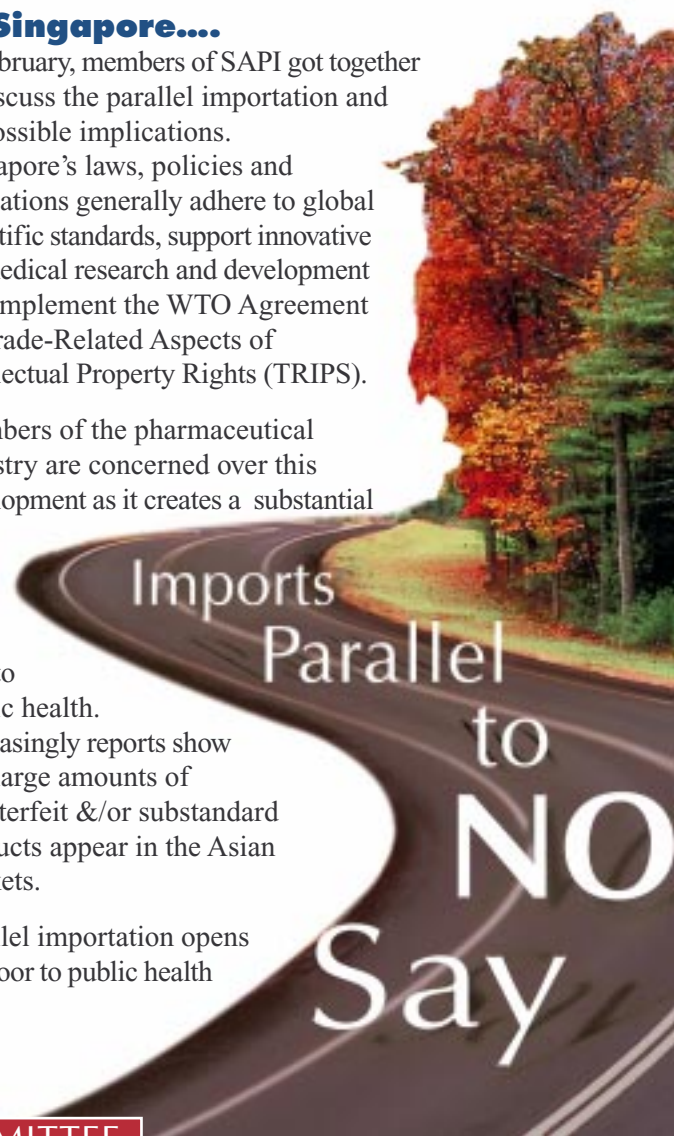
In February, members of SAPI got together to discuss the parallel importation and its possible implications.

Singapore’s laws, policies and regulations generally adhere to global scientific standards, support innovative biomedical research and development and implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Members of the pharmaceutical industry are concerned over this development as it creates a substantial

risk to public health. Increasingly reports show that large amounts of counterfeit &/or substandard products appear in the Asian markets.

Parallel importation opens the door to public health risk.



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SAPI NEWS



President's Message

A Challenging Year...

Jimmy Chan, President of SAPI, comments on the current term

The past year/term has been a very interesting year. Many things happened in the healthcare environment. Here is a quick look at the action-filled year in SAPI and the environment.

Looking at the External Environment

We started the year with our expressed concern on the rising costs of conducting clinical trials in Singapore. Compared to neighbouring countries, this may lead to Singapore becoming uncompetitive.

Parallel Imports came into the limelight again. In recent months, there have been many articles in the foreign media about the threat of counterfeit and sub-standard drugs in Asia.

Recent independent studies done by Tufts Centre for the Study of Development have shown that the pharmaceutical industry spends about US\$800 million to bring a product from the laboratory to the market. The essential and intertwined roles of profit and intellectual property protection are all the more important as incentives for continued pharmaceutical innovation.

What Have We Done in SAPI?

With the numerous changes in the healthcare environment, SAPI has had the opportunity to be involved in strategic discussions with some of the groups involved.

SAPI worked extensively with the local authorities on various issues related to the regulation of pharmaceuticals. Regulatory Affairs is critical to the successful approval and launch of any pharmaceutical product.

SAPI is working with the Centre for Pharmaceutical Administration (CPA) to regulate information provision of consumer products.

SAPI is working with CPA on Direct to Patients advertising (DTP). SAPI wishes to extend the knowledge base to create better understanding and awareness of disease states. Our goal is to ensure awareness of disease states, which will hopefully lead to patients seeking early diagnosis and treatment.

SAPI is currently working with CPA, the Clinical Trial Coordinating Centre (CTCC) and Economic Development Board (EDB) in its move towards encouraging more clinical trials to be conducted in Singapore. Via SAPI, the local Medical Directors of its members are gathering more data to further support their discussions.

Various committees of SAPI have had the opportunity to meet with stakeholders of specific projects and policies.

SAPI has set up a task force to tackle the issue of parallel importation of pharmaceutical products. The concern lies on public health with the threat of counterfeit/sub-standard drugs, improper handling and packaging of products, patients may be unknowingly affected.

SAPI has made its website more robust for members. Members can now input their sales data via the internet.

SAPI worked with the National Council of Social Services to raise funds during the Annual Dinner and Dance for the Singapore Association of the Visually Handicapped (SAVH).

What's Next?

SAPI will continue working with the Ministry of Health, Economic Development Board, and other key stakeholders in achieving a common objective.

SAPI pledges to protect the interest of patients and its members to create a healthy Singapore.

Casemix or Mixed Case

Snippets of a talk given by Dr. Lee Chien Earn, Head, Casemix Project Office, MOH, to SAPI members in March 2002

By Daniel Tan, Chairman, Training Committee, SAPI

If you have a \$1m and are running a supermarket chain, and you buy a variety of fruits from several suppliers, would you...

- Pay and leave it to the suppliers to decide which fruits to deliver?
- Pay according to how many boxes they deliver in?
- Pay according to how many of each type of fruit?

It is natural that we would want to pay based on what we actually receive (ie outputs) rather than on what the supplier decides (ie inputs).

In the healthcare context, this begs the question, what do hospitals produce? How do we describe the hospitals' output? We need a common unit of measure before we can measure output, track resource utilisation and perform benchmarking across institutions. Casemix systems were developed in the mid 1970s to fill this need.

What is Casemix?

Casemix is a generic term that describes the mix of patients in a hospital or health care system. Casemix categorizes patients such that those who belong to the same group have similar clinical conditions, and thus treatment cost should be similar.

There are many types of Casemix classifications being used in the world today. The most widely used is the Diagnosis Related Groups (DRGs). The DRGs system broadly groups all disease conditions into Major Diagnostic Categories (MDCs).

Each MDC refers to a disease type or body system and contains between 4 and 53 sub-groups or DRGs. Each DRG therefore describes a cluster of patients with related diagnoses incurring similar treatment costs.

The Ministry of Health (MOH) has adopted the

Australian National Diagnosis Related Groups (AN-DRGs) version 3.1 as the current Casemix classification system for Singapore. The AN DRG v3.1 groups disease conditions, based on International Classification of Diseases 9–Clinical Modification (ICD-9-CM) codes, into 667 DRGs. Although we adopted an Australian classification system, the actual parameters used are derived from data that reflects local practice.

How is Casemix used in Singapore?

Casemix has been used since October 1999 as a tool to determine the amount of subsidies to be given to the public hospitals for acute inpatient care and day surgery. Previously, public sector hospitals are funded for inpatient services on a per day basis. This system of funding does not adequately take into account the differences in treatment and costs of different medical conditions.

With Casemix, funding will be based on each DRG. It will be proportional to complexity of the case and thus the resources that are needed to treat the patient.

Casemix translates to a fairer system of government funding for the public hospitals. Hospitals will have to ensure that they search for most efficient and cost-effective treatments



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while maintaining the quality of clinical outcomes.

Teaching and research activities will continue to be funded separately. SOC and A&E cases which cannot be classified under AN-DRG v3.1 will also be funded separately.

What Casemix is not?

Casemix is **NOT**:

- A method of cutting the government health budget or subsidy to the public hospitals. Casemix can help ensure that available funds are distributed fairly and rationally. There was also no change to the subsidy rates for patients when Casemix was implemented
- A way of discharging patients from hospitals prematurely. Public hospitals will continue to provide the appropriate level of care for patients and discharge them only if they are medically fit. Audit and quality control measures will be conducted to ensure that patients are not denied access to medical care or are discharged prematurely. Additional funding is provided for “outliers” ie patients who need to stay longer than expected for medical treatment.
- A tool to control doctors. It does not dictate how doctors should practise medicine. Casemix helps doctors do their work better by providing useful information on variations of the care provided and find ways to improve the standard of care.

How will Casemix help make healthcare affordable?

Information collected will help to better understand the cost of providing hospital care within each hospital. By better understanding how care is provided, delivery can be made more efficient, ensuring value for money.

How will Casemix help to improve quality of care?

Casemix information on patient care (for example average length of stay) will help to identify variations in care and issues in quality so that they can be addressed and resolved quickly. Hospitals will have

the incentive to standardise care processes through implementing clinical guidelines and pathways based on best practices to ensure that patients receive cost-effective treatment and enjoy good clinical outcomes.

What does the future hold?

The Ministry is working on Casemix as a means to revise the Medisave Withdrawal limits. When implemented this will involve patients in both public and private sector hospitals.

How will Casemix impact Medisave withdrawal limits?

Casemix enables the Ministry to set Medisave withdrawal limits according to the complexity of treatment. This change will allow patients with more severe diseases to withdraw more from their Medisave accounts to pay for their medical bills.

Similarly, the MediShield claim limits would be reviewed to vary according to the complexity of the medical condition.

Conclusion

Casemix is a measurement system. It is also a communication system as we cannot communicate without a common language.

The key asset of Casemix systems is information. In Singapore Casemix has been implemented to support the government’s commitment in ensuring good and affordable healthcare to all Singaporeans



SEMIX OR
MIXED CASE?