



World Confederation
for Physical Therapy



Background Document on Counterfeit Medicines in Asia



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1.0 Executive Summary

Described as the crime of the 21st century, the counterfeiting of currency and consumer products are common problems that plague governments and manufacturers in Asia. However, of all the different counterfeit and falsified goods produced, none are more potentially damaging than those affecting public health and safety, such as the production, distribution, and consumption of counterfeit and falsified medicines. According to the World Health Organization (WHO), a significant fraction of the world's drug supply is counterfeit and falsified. Estimates of counterfeit drugs range from 10 to 15 % for the world drug supply, to more than 25% in developing countries (Gibson, 2004).

Drug counterfeiters not only defraud consumers, they also deny ill patients the therapies that can alleviate suffering and save lives. Increasingly well-organized counterfeiters coupled with sophisticated technologies have allowed criminals to profit from drug counterfeiting at the expense of Asian patients.

Until very recently, the focus of Asian health advocates has been on the supply of medicines at affordable prices. Despite the obvious risk that counterfeiting represents, little is known about its true prevalence, impact, existing intervention strategies and challenges, and other issues critical to developing evidence-based strategies to address it.

Combating counterfeit or falsified medicines requires collaboration at national, regional and international levels. Health professionals in particular have a crucial role to play in alerting patients to counterfeit medicines and detecting their presence. They are very closely involved in the repercussions of counterfeiting in identification, prevention and education.

This paper presents an overview of the current knowledge of the counterfeit drug trade in Asia, with the aim to generate discussion about the necessary steps to understand and respond to this problem.

2.0 Introduction

Since trade begun several millennia ago in Asia, counterfeit or falsified products have been a recurring problem. Counterfeiting is probably one of the oldest and most profitable occupations (Wertheimer, 2003). In recent years however, there has been an alarming expansion of the types of products being infringed from luxury items such as watches and jewelry to items that have impact on personal safety and health. Although an enormous worldwide problem, Asia seems to be the epicenter of the new counterfeit or falsified drug trade.

Counterfeiting is difficult to detect, investigate and quantify. Recent trends suggest a massive increase in counterfeit or falsified drug sales to over \$75 billion globally in 2010, an increase of more than 92% from 2005. This represents 15% of the size of the legitimate pharmaceutical industry (Pitt, 2003). These alarming rates of growth are in part as a result of the growing size and sophistication of drug counterfeiting rings. Poverty, weak economies and the rising cost of drugs have created a corresponding increase in incentive to produce counterfeit drugs because of profit margin. The sometimes indifferent attitude towards counterfeiting by both Asian consumers and authorities has increased a low-risk, high-reward system for organized crime.

The threat from the rising number of counterfeited or falsified medicines is aggravated by two factors. Traditionally, the most common types of counterfeit drugs were those described as “lifestyle drugs” such as those used to treat erectile dysfunction or baldness. However, recently there has been an increase in the counterfeiting of “lifesaving” drugs meant to prevent or treat asthma, malaria, cancer, HIV/AIDS, tuberculosis, blood pressure and heart conditions, diabetes, and severe diarrhea (Lyebecker, 2003).

Production does not need to occur in large infrastructures or facilities. Indeed, the majority of counterfeiters apprehended in the past carried out their activities in ordinary households, small cottage industries, or in backyards (Lyebecker, 2003). However it is difficult to ignore the fact that productions of counterfeit medicines in Asia are evolving from small basement operations to manufacturing of an industrial scale. Counterfeit or falsified medicines have been found recently to stem from large professional factories with the potential to produce thousands of pills per day. Local drug manufacturers have been found to make legitimate products during the day and counterfeits by night (Saywell, 2002)

Contrary to expectations that counterfeit or falsified medicines in Asia are bought from street contacts or unlicensed vendors, as may have been the case in the past, counterfeit medicines are beginning to be discovered in the legal supply chain, that is, through licensed wholesalers and parallel traders. In 1997, samples of chloroquine, amoxicillin, tetracycline, cotrimoxazole and ampiclox were collected from several regulated Thai pharmacies. These were then analyzed using high performance liquid chromatography (HPLC). Results showed 40% of samples had active ingredients outside the British Pharmacopoeia limits (Carpenter, 2009).

While the rapid advance of science has made possible many of the innovations responsible for new drugs, similar advances have also removed some of the obstacles for counterfeiters. Counterfeiters now have the tools to mimic authentic drugs by copying their high tech foil packaging, imprinted markings and in some cases, even logos only visible under visible light promoting fake drugs (Baker, 2002). Increasing access to the Internet coupled with new methods of advertising such as those on underground radio stations, newspapers and television have created new challenges for safeguarding medicines.

Unfortunately, there is no consensus on the definition of counterfeit or falsified medicines in Asia. Countries issuing regulations have their own definitions, making information exchange and anti-counterfeit strategies development difficult.

In recent years, most countries in the region have already stepped up their efforts to combat the widespread availability of counterfeit medicines by raising awareness, conducting additional inspections on companies suspected of producing counterfeit drugs, strengthening drug laws and imposing stiffer penalties for offenders and increasing post-marketing surveillance. However, counterfeit or falsified medicine continues to be a rising epidemic in Asia.

3.0 Extent of Counterfeit or Falsified Medicines in Asia

The magnitude of the drug counterfeiting problem in Asia is significant but it is difficult to gauge any true estimate of the extent of the problem since the crimes of producing and selling counterfeit drugs generally become known only when the perpetrators are caught. A search of medical literature yields a limited number of primary published research reports concerning counterfeit drugs in Asia. Few published studies describing the prevalence of counterfeit medicines provide sufficient methodological details to interpret results and to control potential bias.

In 2002, Lancet reported that, according to WHO statistics, as much as 35% of the fake and substandard drugs in the world are produced by India and 20% by China (Hajani, 1998). Counterfeiting moves in all directions in Asia. Nationality and ethnicity are not relevant to counterfeiters. Many poorer countries in Asia with the geographical proximity to the counterfeit producers of China and India are deeply affected.

Counterfeit or falsified drug trade has increased steadily in complexity and organization. Counterfeit drug rings have been traced primarily to Southeast Asian countries, where the trade is developed enough that counterfeiters can copy the packaging of real drug products perfectly. Incident data from 2009 showed Asia as the top region most frequently linked to pharmaceutical crime incidents. Three out of four incidences of pharmaceutical crime involved developing countries either as source, transit or seizure point, or a country where illegal pharmaceuticals were discovered. Statistics recorded a 32% rise in pharmaceutical crime in 2005 from the previous year. (Pharmaceutical Security Institute, 2010).

It is important to note that there are huge disparities in the presence of counterfeit or falsified medical products between Asian countries. Studies indicate that a country's capacity to restrict dangerous drugs depends heavily on its wealth. In developing South-East Asian countries, counterfeit drugs are in circulation despite the development of pharmaceutical laws and regulations. The laws enacted are weakly enforced due to a number of complicating factors: poor public educational campaigns to increase awareness of the problem, general poverty throughout the country, lack of trained drug inspectors and an inadequate budget to implement regular inspections. Where governments are trying to promote world commerce, weaknesses in border control are exploited. Smuggling and illegal importation of drugs are hence rife. Counterfeit or falsified drugs are not only exported but also re-imported.

Variations can also be dramatic within countries. Limited availability of low-cost genuine medicine helps promote counterfeiting. When prices of medicines are high and price differentials exist between identical products, there is greater incentive for consumers to seek medicine outside the normal supply system. Many rural areas have few pharmacies or health clinics, and the ones that exist are often open irregularly (Gautam, 2008).

On a global basis, the types of counterfeit drugs vary by region of distribution. The World Health Organization (WHO) has indicated that hormones and steroids are common targets in developed countries. Counterfeit antibiotics, anti-malarial agents, anti-tubercular drugs, anti-retroviral agents, vitamins, painkillers, hormones, and steroids are common in developing countries where residents may be especially likely to unknowingly purchase counterfeit or falsified drug from unlicensed vendors because their government health authorities may not have suitable amounts of essential drugs in stock. The Mekong region for example consisting of countries such as Cambodia, Thailand, Laos, Vietnam and China has a high burden of infectious diseases. Counterfeiting of anti-infectives is prevalent. In 2003, the Indonesian Drug and Food Control Agency (BPOM) discovered 55 counterfeit medicines being sold in the market. Among them were amoxicillin 500mg capsules that contained only 45.84% and penicillin that contained 45.34%. In 2008, Interpol seized more than \$6.65 million of counterfeit medicines for treatment of malaria, HIV, tuberculosis and other common infections in Southeast Asia and made 27 arrests (Primo-Carpenter, 2009).

In spite of a lack of hard data, it is clear that counterfeit medicines are not confined to a handful of therapeutic classes. The top five counterfeited medicines in the Philippines provide some illustration of this point (Cockburn *et al*, 2005):

| Rank | Class | Drug |
|------|-------------------------|--|
| 1. | Anti-hypertensive drugs | Adalat Gits 30mg Tablet |
| 2. | Anti-asthma drugs | Ventolin Expectorant syrup |
| 3. | Analgesics | Ponstan 500mg |
| 4. | Anti-diarrhoeals | Diatabs Reformulated |
| 5. | Vitamins | Propan with Iron Capsule Ceelin 100mg/5mL Syrup |

Brand name drugs are especially vulnerable because of their significant market potential and profit margins. Counterfeiters also favor higher-priced drugs for conditions patients may be reluctant to reveal to their doctors such as Viagra, Cialis and Propecia. The problem also extends beyond fake pharmaceuticals to medical consumables such as non-sterile syringes and gauze and even substandard electronic medical equipment. In 2006 about 1 million counterfeit glucose test strips was found in at least 35 states of North America and in a number of countries in Europe, the Middle East and Asia. These counterfeit test strip kits, manufactured in Asia, were found to give incorrect readings (Cheng, 2009).

4.0 Health Impact

It is difficult to quantify the continental morbidity and mortality toll of counterfeit or falsified medical products. There have been no comprehensive studies to quantify its damage. Most literature derives from local investigative journalism with little scientific public health inquiry relative to the enormous scale of this criminal enterprise. Estimates put the total loss of life to counterfeit pharmaceuticals between 500 000 and 1 million people each year (Kafchinski, 2009).

Counterfeit or falsified medications can lead to varying degrees of effectiveness and danger. For some counterfeit life-style drugs, such as medications to treat erectile dysfunction, the health effects on patients can be described as „inconvenient’. But increasingly drugs counterfeited in Asia are not just „lifestyle’ drugs but widely used drugs such as those for cholesterol or high ticket items such as cancer drugs.

The impact of counterfeit or falsified medical products can be both direct and indirect. Patients who take disease prevention drugs may end up getting sick when they believed they were protected. They may not recover from illness as quickly as they would have with legitimate drugs, or may not recover at all. In 2003, the WHO calculated that out of one million people dying every year from malaria, 200,000 deaths could be avoided if anti-malarial drugs were effective, of good quality and used correctly. Recently the Fides Agency reported that, according to the WHO, about 700, 000 people die each year due to counterfeit medicines for malaria or tuberculosis (Akunyili, 2011).

Patients who take counterfeits fail to get better and lose faith in the effectiveness of modern medicine. In Asia where complementary medicine is widespread, patients may turn instead to traditional or herbal medicine. Counterfeit or falsified medicines may create the wrong impression that the medicines themselves are ineffective and, thus, lead prescribers to unnecessarily opt for others as their first line treatment. New drug development may be required in response to “ineffective medicines”, which will be more expensive and will further disadvantage patients in developing countries.

It was often assumed that the active ingredients or excipients within counterfeit medicines in Asia are inert. However, forensic chemistry has demonstrated that many contain ingredients that are harmful as tragically demonstrated in Singapore where glyburide, a powerful drug used for the treatment of diabetes, was found to be a contaminant in counterfeit tadalafil and herbal preparations for treatment of erectile dysfunction. Of the 150 non-diabetic patients admitted to hospitals in Singapore, seven patients were comatose as a result of severe neuroglycopenia and four patients subsequently died (Cheng, 2009). In Taiwan, 650000 fake diet capsules and 240kg of raw materials were seized after receiving complaints from the public of palpitations and dizziness after consuming the capsules. The capsules were found to contain phenolphthalein, a cancer-causing organic acid that has been banned since 2001.

Perhaps one of the most worrying implications of the global boom in counterfeit medicines is the acceleration of new, drug-resistant strains of viruses, parasites and bacteria. Counterfeit medicines for infectious diseases containing too little or sub-therapeutic amounts of active ingredients destroy the clinical efficacy of the genuine medicine by promoting drug resistant pathogens, a phenomenon observed with malaria drug resistance in South-East Asia. In 2002, Paul Newton of Oxford University reported in the British Medical Journal that 38%-53% of vital anti-malarials obtained from pharmacies and shops were counterfeit. Samples were taken from Cambodia, Laos, Myanmar (Burma), Thailand and Vietnam (Newton et al, 2002). A more recent study discovered a much higher number: 68% of artesunate drugs collected did not contain correct amounts of active ingredient. In Burma, for example, counterfeit artesunate samples, were found to have between 3.5 and 12.1mg of artesunate per tablet, less than one fifth the amount in a standard authentic tablet (Alter Hall, 2006). *Plasmodium falciparum* artesunate resistance has been recently described on the Thailand-Cambodia border probably as a result of counterfeit artesunate (Newton, 2008).

5.0 Economic Impact

Estimates of the economic scale of counterfeiting in Asia are difficult to quantify. The economic burden of drug counterfeiting is continuously increasing. Current estimates state that 7 to 33% of the medicinal products in the world market are counterfeit medicines (Dittmer, 2008). It is estimated by WHO and the FDA that worldwide sales of counterfeit drugs represent between \$32 billion and \$35 billion annually; that is \$88 to \$96 million in sales each day (Cockburn, 2006). Although counterfeit medicines have been distributed through every economy, Asia is reported to be the largest source of economy.

Because counterfeiting is an illegal trade, counterfeiters do not pay any import duties when they bring drugs into the country and they do not pay any sales tax on the drugs that they sell so the local economy suffers. Unfortunately, the lower prices of the counterfeits encourage purchases by consumers. In a study of counterfeit medicines in Cambodia, researchers found that counterfeits were frequently preferred by patients and village health providers because of the lower price (Rozendaal, 2001).

Counterfeit or falsified drugs can damage public trust, resulting in reduced investment in the pharmaceutical industry. It also can severely affect the business of the manufacturer whose products are being copied through loss of confidence as well as revenue. Counterfeiting wastes the enormous human effort and financial outlay made in development of medicines, optimizing dosage, carrying out clinical trials, discussing policy change, and manufacturing medicines.

According to Pharmaceutical Research and Manufacturers of America (PhRMA), while it takes international companies about 10 to 15 years to develop a drug at an average cost of US\$820 million, copying the drug takes only three to five years at an approximate cost of US\$60 000 (Primo-Carpenter, 2009).

The economic impact of counterfeiting however goes beyond simply losses of sales by the legitimate rights holders. Companies face downward price pressure by competing with counterfeiters which do not incur development and advertising costs. There are macroeconomic effects as well. Labor is damaged as production shifts to lower-paying jobs creating counterfeits. The overall costs of public health and safety increase when they are threatened by dangerous counterfeit goods.

6.0 Strategies and Barriers in Fighting Counterfeits

There is clearly no simple solution to the problem of counterfeit and several strategies have been implemented in Asia.

The WHO has established guidelines against counterfeiting which requires cooperation between government organizations, health workers, industry and civil society (US FDA, 2004). However, although guidelines have been produced, most developing countries in Asia do not have the infrastructure and financial resources to implement them.

6.1 Activities of regional or international organizations

Selling counterfeit medicines and medical devices often operate outside of jurisdictional borders, creating greater obstacles to successful anti-counterfeiting enforcement. For this reason, international cooperation and coordination is essential to creating solutions for the pharmaceutical counterfeiting problem.

The problem of counterfeit medicines was brought to the foreground at a WHO conference of experts on rational drug use in Nairobi Kenya in 1985 (WHO, 2006). The meeting recommended that WHO, together with other international and non-governmental organizations should study the feasibility of collecting data and informing governments about the nature and extent of counterfeiting. In 1988, a World Health Assembly (WHA) Resolution went further and called for the WHO 'to initiate programs for the prevention and detection of export, import and smuggling of falsely labeled, spurious, counterfeited or substandard pharmaceutical preparations'. These activities culminated in the launch in 2006 of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) (WHO, 2006).

The World Health Organization (WHO) and INTERPOL have led the effort to combat counterfeit medicines in Asia. Operation Storm was a multi-country operation combating counterfeit pharmaceuticals. It brought together the Customs, Drug Regulatory Agencies and the Police of each participating country: Cambodia, China, Indonesia, Laos, Myanmar, Singapore, Thailand and Vietnam. The operation seized over \$12M in counterfeit medicines and more than 16 million pills, including antibiotics, anti-malarials, contraceptives, anti-tetanus vaccines, aspirin and drugs to treat erectile dysfunction (Interpol, 2010). In late 2009, Operation Storm II resulted in the seizure of 20 million counterfeit and illegal medicines at least 33 arrests, and the closure of some 100 pharmacies and illicit drug outlets.

In 1999, the International Pharmaceutical Federation (FIP) adopted a statement on counterfeit medicines during the Council meeting at the FIP Congress in Barcelona. Because of the growing and changing aspect of this major public health care issue, FIP has updated its Policy statement on counterfeit medicines in 2003 during its Council meeting at the FIP Congress in Sydney. This statement is a strong political message of the pharmacists' profession to support the fight against counterfeit medicines to protect the safety of their patients.

In 2008, the WHPA developed a communication toolkit aiming at raising awareness on counterfeit medicines among health professionals and providing some tools and strategies for detecting counterfeit medicines and for safely informing colleagues and patients. This work has formed the foundation of the WHPA campaign on counterfeit medicines since 2008, working collaboratively with the World Medical Association, International Council of Nurses, World Dental Federation and the World Confederation of Physical Therapists in supporting national health professional associations led initiatives at country and regional levels.

Other initiatives have been made by the USP-DQI. In 2003 USAID asked USP-DQI to provide technical assistance to the Ministry of Health of five Southeast Asian regions: Cambodia, Thailand, Laos, Yunnan Province in China and Vietnam. In response USPDQI launched the Anti-malarial Medicines Quality Monitoring program in the Mekong sub-region. Data collected in 2008 showed that samples of artesunate containing no active ingredient dropped from 44% in 2004 to below 20% (Phanouvong, 2004).

In August 2008, a regional inter-country meeting was held in New Delhi India to exchange information on the problem of counterfeit medicines in countries of the Southeast Asian region and to identify country and regional priority issues for combating counterfeit medicines. It was recommended that each nation develop and establish effective mechanisms of cooperation between drug regulators, police, customs, prosecutors, including health professionals, manufacturers, wholesalers, retailers and consumers' organizations (SEARO, 2008).

Bilateral agreements exist between some Asian countries as is the case with Thailand, Laos and Cambodia and multilateral agreements with ASEA countries in developing common strategies. The Ayeyarwaddy Mekong Economic Cooperation Strategy (ACMECS) involving China, Cambodia, Laos, Myanmar, Thailand and Vietnam is developing a primary screening test to detect high risk drug groups such as anti-infectives by using near infrared spectroscopy (NIR), thin layer chromatography (TLC) and color tests (SEARO, 2008).

At the international level, there are still many barriers to curbing illegal activity. Part of the problem with developing policies towards counterfeit drugs is that counterfeits are defined differently across countries. There is a need for an internationally accepted definition. International surveillance also needs to be coordinated and information should be shared between countries.

6.2 Activities of governments and various regulatory bodies

Although a wide range of sophisticated quality assurance markers have been developed worldwide they are difficult to implement in developing Asian countries. The WHO estimates that 30% of countries have either no drug regulation or a medicine regulatory authority (MRA) that hardly functions (Newton, 2008). Most Asian countries have stepped up their efforts to combat the widespread availability of poor quality or substandard drugs. The lack of financial and human

resources however available to many MRAs makes investigation of poor-quality drugs and action impossible.

In many Asian countries, the risks of prosecution and penalties levied for counterfeiting are inadequate. In Indonesia, for example, the penalty for counterfeit manufacturing is imprisonment for six months and a fine of Rp 300000, about US\$40. Existing measures and regulations are often unevenly enforced and counterfeiters continue illegal activity because there is no fear of apprehension and prosecution. Several factors are responsible for this, including the level of corruption and the poverty rate. Inefficient cooperation among regulatory authorities, police, customs and judiciary has resulted in counterfeiters escaping detection and arrest. In Vietnam for example, 64% of all artesunate samples tested were found to be fake. Nevertheless, while prison terms of 20 years have been given in Vietnam for trading fake sildenafil, there have been no prosecutions of fake anti-malarials (Newton et al, 2002).

There are encouraging signs though. The Philippines for example assigns heavy penalties for offenders, six months to life imprisonment and a fine of US\$ 25,000 (Department of Health Philippines, 1996). In Taiwan, the manufacture or importation of illegal drugs carry a prison term for a maximum of 10 years and a fine of US\$312,000. In 2006, the Taiwan's Department of Health (DOH) gave an order that pharmacists involved in the sale of counterfeit medicines will be suspended from practicing for a maximum of three years. Where authorities have demonstrated a willingness to enforce controls more rigorously and crack down on counterfeiters the problem is diminishing. 2008 interdepartmental data of Taiwan estimates 0.8% of market value in 2008 are counterfeit (Center for Drug Evaluation Taiwan, n.d).

Strategic action on combating counterfeit drugs has been made through national programs in several Asian countries. These consist of comprehensive investigation, increased inspection and mopping up of what is in circulation. At present, there is only one published study examining the efficacy of increased inspections, in which the quality of antimicrobials was examined in districts in Laos before and 2 years after random allocation to either regular or enhanced drug inspection (Kelesidis, 2007). Although no significant differences were found between regular and enhanced drug inspection district, drug quality improved substantially over the 2 years.

Efforts have also been intensified to crack down on smuggled raw ingredients for manufacturing drugs. Random testing of imported drugs is being reinforced. The Philippines have formulated a special law on counterfeit drugs which requires random sampling and monitoring of drug quality in pharmacies and hospitals (Forzley, 2005). The capacity of the national drug quality control laboratory to conduct quality testing of drugs continues to be a limitation in poorer Southeast Asian countries due to lack of qualified personnel and testing equipment, as in the case of Cambodia and Myanmar. A WHO study noted that only 32 samples were tested in 1994 (Morris et al, 2006)

There is a concerted effort by governments and companies in combating counterfeiting through increasing professional education and public awareness. In Taiwan for example, the department of

health launched a joint campaign to crackdown illegal drugs by implementing training programs and supervising local health authorities to inspect illegal drugs on the market. Furthermore TMPACT (Taiwan Medical Product Anti-counterfeiting Taskforce) was established in 2007 to provide education programs to pharmaceutical professionals (Center for Drug Evaluation Taiwan, n.d). Cambodia adopted a social marketing program to improve the availability of quality-assured anti-malarial drugs coupled with an information campaign about fake drugs. Such strategies significantly reduced the prevalence of counterfeit anti-malarials in the country (Seyhar, 2002).

7.0 Country Situation

Indonesia

| Statistics |
|--|
| Total population: 229,965,000 |
| Gross national income per capita (PPP international \$): 3,600 |
| Life expectancy at birth m/f (years): 3,600 |
| Probability of dying under five (per 1000 live births): 39 |
| Total expenditure on health per capita (Intl \$, 2009): 99 |
| Total expenditure on health as a % of GDP (2009): 2.4 |



Extent of Counterfeit Medical Product Problem

- The International Pharmaceutical Manufacturer Group (IPMG) estimates a loss of US\$500 million from the purchases of counterfeit medicines (Rulistia, 2008)

Cause of Problem

- Indonesia is located between two continents and two oceans which is easily accessible by land, sea or air. Problems arise from borderline areas which are susceptible to smuggled counterfeit medicines.
- The continuous deterioration of Indonesia's economic conditions makes pharmaceutical products, especially new molecules unaffordable to consumers. This lack of access makes low-priced counterfeit products quite attractive.
- There is a lack of compliance to regulations that prohibit the selling of drugs outside of pharmacies and authorized outlets and regulations that require prescription products to be sold with a prescription.
- Counterfeit medical products have not been identified as a specific crime. This takes police and health authorities more time to seize counterfeit products and to proceed against counterfeiters.
- Penalties for counterfeiting are mild and inadequate. The maximum fine is Rp 300 000, or approximately US\$40 and six months of imprisonment.
- Modern technology and the increasing access to medicines through the Internet have further facilitated this problem. (Akib, 2007)

Strategies implemented to combat counterfeit medical products

- Border Posts have been established in some areas to control imported goods and minimize illegal and counterfeit drugs entering the country.
- Strategies have been made to break the supply counterfeit medical products. In August 16th 2003, the National Agency of Drug and Food Control (NADFC) and the National Police signed a Memorandum of Understanding to strengthen the cooperation between law enforcement agencies. This has resulted in the comprehensive investigation and mopping up of what is already in circulation through the use of analytical methods for active ingredients and sampling training for investigators. Since 2001, an annual meeting has been held between the National Police, General Attorney and Custom Service.

- Infrastructures have been strengthened through Good Manufacturing Process seminars for inspectors and auditors. Legal industries and distributors have been requested to improve their in-house security and to carry out more market surveillance on their products. Manufacturers/importers have been encouraged to develop measures such as the introduction of security systems including security tags.
- Public awareness has been increased by the issue of a public warning not to purchase products from illegal sources.
- Health professional association networking have been strengthened in an effort to actively search for information on counterfeit drugs, including identification and reporting on any suspected counterfeit drugs to the legal authority. (Akib, 2007)

Malaysia

| Statistics |
|---|
| Total population: 27,468,000 |
| Gross national income per capita (PPP international \$): 13,740 |
| Life expectancy at birth m/f (years): 71/76 |
| Total expenditure on health per capita (Intl \$, 2009): 677 |
| Total expenditure on health as % of GDP (2009): 4.8 |



Figures are for 2009 Source: Global Health Observatory

Extent of Counterfeit Medical Product Problem

- A small proportion of drugs on the Malaysian market are counterfeit.
- A study in 1997 by the Ministry of Health found that 5.3% of sampled drugs fell in this category. According to the Pharmaceutical Services Division, around 5.28% of all OTCs on sale in Malaysia were counterfeit in 2008, with slimming products accounting for around 10% of all illegal medicines seized in 2007.
- Due to the conservative nature of Malaysian society, erectile dysfunction (ED) therapeutics are the most frequently copied medicines on the market, estimated to account for 30 to 40% of all counterfeits.
- The total number of items seized rose from 6233 in 2005 to 20235 in 2006. The value of fake medicine confiscated was MYR\$18.4 million (US\$5.3 million) in the same year.
- In 2007, the value of seizures of counterfeit medicine was MYR\$35.8 million (US\$10.6 million), which was nearly a 40% increase on the 2004 figure.
- In March 2007, the Health Ministry seized 1.4million capsules of counterfeit erectile dysfunction medicines worth MYR\$14 million (US\$4 million) from a container in Penang.
- The biggest seizure to date was made by the ministry's pharmaceutical enforcement division, where enforcement officers detained a container from Singapore loaded with 142 boxes of counterfeit medicines. (Malaysia Pharmaceuticals and Health Care Report, 2010)

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- Driven by an expanding economy and ageing population the BMIs Pharmaceutical Expenditure Forecast Model expects market to expand by 7.96% between 2009 and 2014. This has produced a very profitable market for counterfeiters.
- Lax enforcement
- Enforcement work has become very challenging as the criminals that supply these products use advanced technologies to avoid detection and cunningly exploit Malaysia's land and sea borders with Thailand and Indonesia. (Malaysia Pharmaceuticals and Health Care Report, 2010)

Strategies implemented to combat counterfeit medical products

- In October 2005, the Ministry of Health issued the requirement that all registered pharmaceutical products be labeled with a Meditag, a hologram security patch. This was to combat the prevalence of unregistered copy drugs, counterfeits and other healthcare products in the domestic pharmaceutical market.
- The Meditag scheme involves the participation of enforcement officers who conduct visual

scans of the symbols and markings on the Meditag device, as well as verify the manufacturer's serial number. The authenticity of the hologram can be confirmed by examining it with a special decoder and a microscope.

- All products registered with the Malaysia Drug Control Authority (DCA), including traditional medicines and health supplements are required to bear the Meditag device. Anyone who fails to abide by this law will be subject to a fine, imprisonment or both. First-time offenders will be fined up to MYR\$25000 (US\$6632) and/or jailed for up to three years. Any corporate entity failing to abide by this law will also be charged a fine of MYR\$50000 (US\$13264) for first time offenders or MYR\$100000 (US\$26529) for subsequent offenders (Malaysia Pharmaceuticals and Health Care Report, 2010).
- In 2006, the program expanded by supplying pharmacies with a decoder unit designed to be placed on store counters or shelves with instructions on their use. Pharmacists and consumers are encouraged to check the authenticity of a given medicine's Meditag by sliding the medicine pack under the decoder unit (Bate et al, 2008).

Singapore

Statistics

Total population: 4,737,000

Gross national income per capita (PPP international \$): 47,970

Life expectancy at birth m/f (years): 79/84

Probability of dying under five (per 1000 live births): 3

Total expenditure on health per capita (Intl \$, 2009): 2,086

Total expenditure on health as % of GDP (2009): 3.9

Figures are for 2009: Global Health Observatory



Extent of Counterfeit Medical Product Problem

- Cases of counterfeit medical products are largely confined to fringe or black markets in Singapore.
- No penetration into main-stream healthcare systems and formal sources such as hospitals.
- The type of medicines involved are mostly „lifestyle’ drugs particularly those for erectile dysfunction (e.g. Viagra, Cialis).
- Essential drugs such as antibiotics are not affected.
- The number of confirmed cases of counterfeit medical products in 2005, 2006 and 2007 were 7, 4 and 5 respectively. All cases were detected at border checkpoints and all were prosecuted.
- All cases were detected at border checkpoints and all were prosecuted.
- In the advent of budget travel, Singaporeans travel regularly to neighboring countries. (Singapore Situation Report, 2007)

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- Prior to 2007, legislative infrastructure did not have specific provisions against dealing with counterfeit medicines and did not have specific definition of counterfeit medicines. Offenders were dealt with on the basis of unlicensed or unauthorized dealing.
- Low criminal penalties were assigned prior to 2007. The penalty for an offence under the Poisons Act was a fine of up to \$10 000 and or imprisonment for up to two years or both.
- Differing priority between agencies (i.e. cases involving medicines not necessarily considered to be high priority)
- Lack of knowledge and technical expertise of officers in other agencies (e.g. differentiating between authentic and counterfeit medicines). (Singapore Situation Report, 2007)

Strategies implemented to combat counterfeit medical products

- In 2007, the Health Products Act was enacted which gave specific definition for “counterfeit health product”. A health product is counterfeit in Singapore if it is presented in such a manner as to resemble or pass off as a registered health product when in fact it is not, or, it is presented with any false information as to its manufacturer or origin. (Hung, 2007)
- The improvements in the new Health Products Act include specific prohibitions against dealing

in counterfeit health products in manufacture, import and supply. Heavier penalties have been assigned for offences relating to counterfeit health products (i.e. fines of up to \$100 000 and imprisonment for up to three years).

- Collaborative efforts with regulatory and law enforcement agencies involving the Immigration and Checkpoints Authority (ICA), Singapore Customs, Singapore Police Force (SPF), Central Narcotics Bureau, Agri-Food and Veterinary Authority (AVA) and the Housing Development Board (HDB) have been made. The benefits of operational collaboration include larger pool of trained officers, more extensive enforcement powers and more skills and experience in enforcement.
- On the 19th August 2005, the Singaporean Association of Pharmaceutical Industries (SAPI) and Singapore Medical Association (SMA) released a joint statement stating, “procuring drugs from unauthorized sources, whether these are purchased online or during overseas trips, exposes patients to risk of counterfeit drugs that may be ineffective or even harmful”. (Singapore Situation Report, 2007)

Japan

Statistics

Total population: 127,156,000

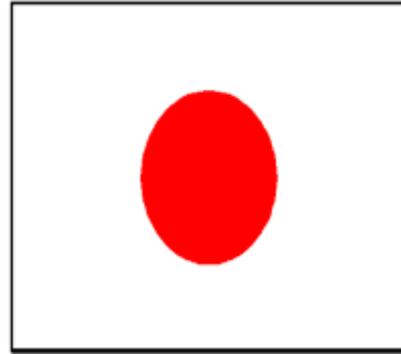
Gross national income per capita (PPP international \$): 35,190

Life expectancy at birth m/f (years): 80/86

Probability of dying under five (per 1 000 live births):3

Total expenditure on health per capita (Intl \$, 2009): 2,713

Total expenditure on health as % of GDP (2009): 8.3



Figures are for 2009 Source: Global Health Observatory

Extent of Counterfeit Medical Product Problem

- The current national definition of counterfeit medical products in Japan refers to goods that infringe patent rights, utility model rights, design rights and trademark rights.
- Counterfeit medicines have not been detected in legitimate channels but counterfeit erectile dysfunction (ED) treatment medicines are increasingly being smuggled (Japan Pharmaceutical Manufacturers Association, 2007).

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- In 2006, 107000 tablets of Viagra were confirmed to be illegally imported.

Strategies implemented to combat counterfeit medical products

- The Pharmaceutical Affairs Law of Japan prohibits sale of counterfeit medicines. The violator is sentenced to imprisonment of less than 3 years and/or subject to penalties less than 3 million Yen.
- In 1989, Japan Manufacturers Association (JPMA), created a study course on pharmaceutical quality control and supply of reference substances.
- The Japanese International Corporation of Welfare Services (JICWELS) completed a project between 1993 and 1996 on counterfeit medicines. This was called the “Rapid Examination Methods against Counterfeit and Substandard Drugs” (REMCSO).
- In 2006, JPMA and the Cambodian Ministry of Health worked together in a joint project in combating counterfeit medicines. JPMA donated high performance liquid chromatography (HPLC) and Atomic Absorption spectrophotometric (AAS) assay to Cambodia and Laos. In 2007, a Framework for the Anti-Counterfeiting Trade Agreement (ACTA) was made.
- It has been proposed that Japan should control personal import especially through the Internet involving the Ministry of Health, Labors and Welfare.
- Public awareness should be raised against the risk of personal import. (Japan Pharmaceutical Manufacturers Association, 2007).

Philippines

| Statistics |
|--|
| Total population: 91,983,000 |
| Gross national income per capita (PPP international \$): 3,900 |
| Life expectancy at birth m/f (years): 67/73 |
| Probability of dying under five (per 1 000 live births):33 |
| Total expenditure on health per capita (Intl \$, 2009): 136 |
| Total expenditure on health as % of GDP (2009): 3.8 |



Figures are for 2009 Source: Global Health Observatory

Extent of Counterfeit Medical Product Problem

- The Philippines Department of Health has placed the amount of fake or counterfeit drugs in the country at around 10%.
- In 1995, the Philippines Counterfeit Action Program (Philcap) found that 17% of counterfeit medicines in the country were imported illegally (Primo-Carpernter, 2009).

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- Philippines define a counterfeit drug as containing less than 80% of the labeled amount of active ingredient. Thus, a drug product with an unspecified reduced amount of active ingredient may be classified as counterfeit in some countries but not in the (Philippines Department of Health Philippines, 1996)

Strategies implemented to combat counterfeit medical products

- The current law considers any medicine not registered with the Philippine FDA has counterfeit.
- The Republic Act No 82303 or the Special Law on Counterfeit Drugs punishes sellers of counterfeit medicines with imprisonment of 6 years and a fine of at least 100000 pesos.
- Establishment of the single point of coordination (SPOC) program from different agencies and private sectors
- The government has designated a FDA station in all possible ports of entry where drugs and medicines may be received with corresponding coordination mechanisms (Herriman, 2010).

South Korea

Statistics

Total population: 48,333,000

Gross national income per capita (PPP international \$): 27,840

Life expectancy at birth m/f (years): 77/83

Probability of dying under five (per 1 000 live births):5

Total expenditure on health per capita (Intl \$, 2009): 1,829

Total expenditure on health as % of GDP (2009): 6.5



Figures are for 2009 Source: Global Health Observatory

Extent of Counterfeit Medical Product Problem

- The general consensus is that counterfeit pharmaceuticals in Korea is growing rapidly. No deaths however have been linked to fake drugs in Korea.
- In 2004, the Seoul police seized more than 150 million Won in imitations of Cialis and Viagra after raids on 123 pharmacies.
- Between January and July of 2010, 18 cases of smuggled impotence medicine worth 90.6 billion Won (\$77 million) were found
- The amount of counterfeit medicines have jumped 23 fold from 2005 to 2010.
- 99% of counterfeit medicines are impotence cures either containing an illegal over dose of active ingredients or toxic substances such as mercury or lead.
- The majority of fake medicines in Korea are manufactured in China (Garikipati, 2004).
- In March 2011, more than a dozen pharmacists were indicted for the first time for distributing fake Viagra pills that were manufactured in China (Bae, 2011).

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- The pharmaceutical market is estimated to be the 10th largest in the world worth over \$1 billion. Since the mid-1990s, many US and European pharmaceutical companies have set up ventures to control close to 60% of the market. The size of the market for pharmaceutical products has attracted distributors of fake medicines.
- The criminal sanction for violation of trademarks and pharmaceutical affairs leads to a maximum imprisonment of up to 7 years and a penalty of up to 100 million Won.
- Administrative sanction for violation of the law includes canceling the pharmacy business license for 6 to 15 months or cancellation depending on repeated crimes or value of the products.
- Advertisements for fake drugs are frequently found in newspapers and on the Internet (Korean Medical Association, 2011).

Strategies implemented to combat counterfeit medical products

- In 2001, the Korean Medical Association (KMA) requested cooperation to prevent sale of illegal or defective drugs via the Internet and their advertisement. KMA members conducted public notice and promotion activities to prevent the purchase of such drugs.
- In 2010, the Korean Society of Sexual Medicine and Andrology launched a campaign to eliminate fake drugs for erectile dysfunction. This involved the operation of a website which not only explained the risks of using fake erectile dysfunction drugs but also set up a line for reporting traffickers. The Society also collaborated with the Citizens' Coalition for Restroom Culture to produce and attach stickers explaining the risk of fake erectile dysfunction medication in public (Korean Medical Association, 2011)

Taiwan

Statistics

Total population: 23.2 million

Gross national income per capita (PPP international \$): 18000

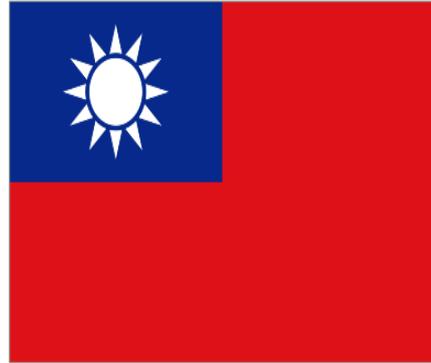
Life expectancy at birth m/f (years): 75.5/81.36

Probability of dying under five (per 1 000 live births):7.26

Total expenditure on health per capita : 9.5

Total expenditure on health as % of GDP: 7.9

Sources: DOH, Health and Vital Statistics 1996
CEPD, Taiwan Statistical Data Book 1997



Extent of Counterfeit Medical Product Problem

- Taiwan was ranked third in serious counterfeiting in the Asian region before 2003. This was due to the low awareness from the government and public and light punishment against counterfeit medicines. There was poor political will for enforcement and punishment against counterfeit.
- Inter-departmental data of Taiwan in 2008 estimates that counterfeit medicines represent 0.8% of market value in 2008.
- Common seen counterfeit medicines include lifestyle drugs (e.g. Viagra, Cialis, Propecia), weight losing drugs (e.g. Xenical, Reductil), gastrointestinal drugs (e.g. Serogan, Dulcolax, Zantac, Losec), blood pressure drugs (e.g. Norvasc) and hypnotics (e.g. Stilnox).
- The majority of sources of reported cases for illegal products come from health authorities (Center for Drug Evaluation Taiwan, n.d).

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- Issues to be improved include the lack of coordination among government agencies, and no incentives for investigators. (Center for Drug Evaluation Taiwan, n.d)

Strategies implemented to combat counterfeit medical products

- The Pharmaceutical Affairs Act was amended in April 21st, 2004 to increase penalties. The penalty for manufacturing or importing counterfeit drugs is up to 10 years of imprisonment and up to NT\$10million (US\$312.5 thousand).
- The penalty for sale, supply, dispensing, transportation, storage or transfer of counterfeit drugs could lead to 7 years of imprisonment and up to NT\$5million fine (US\$16000).
- Pharmacists involved in counterfeiting crime are subject to additional penalties including invalidation of board exam and practice license.
- From October 2003, cross departmental taskforce consisting of the Department of Health, Ministry of Justice, National Police Agency, District Court, Bureau of Investigation, Customs Office, Ministry of Finance, Intellectual property offices and International Research-Based Pharmaceutical Manufacturers Association (IRPMA), Taiwan Pharmaceutical Marketing and Management Association (TPMMA) and Pharmacists association have held annual meetings. The meeting functions to integrate all the resources from all organizations to combat illegal drugs. Roles and duties have been allocated to government agencies (see table below).
- The distribution system has also been strengthened through the establishment of a Good Supply System (GSP). Parallel imports of medicines and Internet pharmacies are prohibited. The management of purchasing is included in all hospital accreditations and evaluations. A reporting system has been established as well.
- Near Infra-Red spectrograph detection technology has been the main project of Taiwan in 2008 to 2009. The project has seen the development of NIR spectrums for 131 common seen counterfeit medicines. (Center for Drug Evaluation Taiwan, n.d)

Thailand

Statistics

Total population: 67,764,000

Gross national income per capita (PPP international \$): 7,770

Life expectancy at birth m/f (years): 66/74

Probability of dying under five (per 1 000 live births): 14

Total expenditure on health per capita (Intl \$, 2009): 345

Total expenditure on health as % of GDP (2009): 4.3



Figures are for 2009. Source: Global Health Observatory

Extent of Counterfeit Medical Product Problem

- According to Thailand's FDA, almost \$30 million worth of counterfeit drugs are sold each year.
- The most common fake drugs are those indicated for treating AIDS, bird flu, malaria, tuberculosis, anti-obesity and erectile dysfunction.
- Counterfeits now present in Thailand are manufactured in other countries such as China, India, Pakistan and Vietnam.
- In January 2006, the Thai FDA arrested counterfeits of Reductil 10 and 15 mg at the drug stores in front of Siriraj Hospital.
- In October 2005, the Thai FDA arrested drug store in Thonburi district sold counterfeit Primobolan Depot 25 and smuggling counterfeits of Sildenafil (Viagra group) from India.
- In June 2005, a Chinese passenger who came from Hong Kong at the Bangkok International airport, Don Mueang airport, was arrested with the counterfeits of Viagra (11,700 tablets) and Cialis (1,300 tablets).
- In 2009 the government seized more than 145000 tablets of counterfeit medicines worth Bt 58 Million (Tankeo, n.d).

Cause of the Problem/ Difficulties in Combating Counterfeit Medical Products

- Thailand has seen a dramatic growth of Internet Pharmacies many with undisclosed locations, uncertain prescriptions, dispensing and quality precautions. The volume of express mail medical shipment is too large for customs officials to begin to check and control.

Strategies implemented to combat counterfeit medical products

- In 2010, nine government agencies signed a Memorandum of Understanding to join the fight against the trade of counterfeit medicines.
- Thai health authorities recently entered into a partnership with the United States Pharmacopeial Convention to train professionals across Thailand to test for counterfeit medicines. (Tankeo, n.d).

8.0 Conclusion

There are certain truths about medicines that cannot be denied. For many people they are too expensive forcing people to search for cheaper alternatives. For some they are inconvenient prompting some to search for „doctor free’ alternatives. Counterfeiting impacts nations of every size and income levels and drugs of every description. No drug is invulnerable and no country is immune.

While data are limited, there is little doubt that counterfeit drugs are an increasing problem globally, with hundreds of thousands of people dying annually as a result.

Asia represents a lucrative market for counterfeiters of medicines and medical devices. Weak economies, increasing prices, a large market, increased internet connectivity, inconsistent regulatory oversight and a complex supply chain all conspire to encourage those engaged in the manufacture and supply of counterfeit medicines and devices to target this area. The increasing availability of the Internet has facilitated a global communication channel for counterfeiting that has no political or geographic boundaries.

Even with reforms, Asia faces significant logistical and social challenges in cracking down on counterfeit production. The existing situation has been facilitated by the lack of coordinated anti-counterfeiting initiatives by various national and multinational regulatory agencies and professional organizations. Health professionals must take an active role in evaluating and implementing both revised and new responsibilities that further protect patient safety.