smcs:risk

Investigation of Illegal Medicine in Cambodia

Acknowledgements

This report has been produced by experts and analysts associated with SMCS Risk, based on insights from investigations conducted in Cambodia. These investigations have culminated in raids and seizures implemented by the Cambodian National Police, Ministry of Health and Economic Police. Data from those raids and seizures has been reported in the sample.

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1 SUMMARY

1.1 SMCS Risk and this Report

The investigation of illegal medicine in Cambodia has been a key focus for SMCS Risk over the past 8 years. Through this report, SMCS Risk is seeking to further the control of illegal medicine in South East Asia, in conjunction with the pharmaceutical industry and relevant government authorities.

1.2 Key Results and Case Study Highlights

This report presents highlights from 26 of SMCS Risk's investigations conducted between late 2012 and early 2016. These investigations were conducted in 7 of 25 provinces in Cambodia. These operations are multifaceted and can be both long-term, and closely interlinked. The sample provides valuable insight into the control of illegal medicine in the region.

These investigations culminated in more than 500 raids conducted across Cambodian cities and rural communities, resulting in some of the largest seizures of illegal medicine in the region. The majority of raided targets were health providers, namely clinics and pharmacies. In total, 461 persons were apprehended as offenders, including Cambodian, Chinese, Indian, Vietnamese, Russian, Korean and Australian nationals. Most of these faced pre-judicial consequences.

Six case studies have been selected to further illustrate the issues surrounding the importation, distribution, sale and administration of illegal medicine in Cambodia. These case studies include:

Case Study	Description
Pharmacies in Kampong Cham	Raids conducted on more 117 pharmacies and clinics in the Kampong Cham Province resulted in the seizure of 178,000 dosage units across almost 600 different types of products. Detailed analysis of the sample revealed very high rates of expired product, including extended periods past expiry for critical medicine such as benzodiazepines, antimalarial medicine and antibiotics. Product had been obtained from 15 countries, particularly India, Thailand, China and the USA. Products from Thailand and Vietnam were often unregistered and unexpired.
Bulk Import of Top Selling Medicine	A raid conducted on an illegal importer in Phnom Penh resulted in the seizure of more than 1.5 million dosage units of high-quality illegally diverted medicine. These were of Turkish origin, and represented high-value, high-market share products, transported in a focused commercial shipment. Cambodia was to be used as a transit country and the product was destined for Vietnam.
Large Importation and Counterfeiting Operation	The surveillance of an illegal distributor in Phnom Penh led to the seizure of 3.5 tons of illegal medicine, including counterfeit product and packaging items. The case highlights a bulk seizure with considerable patient safety implications, as counterfeit product is packaged for sale as legitimate product.
Importation and Distribution of Counterfeit Viagra	A raid conducted on a distributor active throughout Phnom Penh yielded seizure of high quality counterfeit Viagra. This case highlights the difficulties faced by local purchasers and authorities in identifying counterfeit product.
Psychotropic Cutting Agents	The seizure of 70,000 tablets of a psychotropic drug, known as a cutting agent for narcotic drugs, shows the overlap between illegal medicine and illicit drugs.
Distribution and Administration of Injectable Medicine	Three raids conducted on illegal distributors in the Svay Rieng Province led to the discovery that unqualified people were not only distributing illegal medicine, but also administering injections in the local community.

1.3 Findings

Eight key findings have been drawn from the qualitative and quantitative information available:

1. **Illegal medicine is an understated problem**, as proven by the large seizures attained by SMCS Risk in a relatively small geographical region. These seizures are on a similar scale to Interpol's multinational operations in South East Asia, despite a much more focused area of investigation.
2. **Illegal medicine poses serious threats to patient safety**, due to large volumes of counterfeit, expired and illegally diverted medicine that has been stored and transported outside of good practice guidelines. Illegal medicine intended for use on highly vulnerable patients or in potentially life-threatening situations was detected on a frequent basis. This illegal medicine poses risks to patients such as degraded potency, substituted ingredients or contaminated product. In many instances, the illegal medicine was distributed by unqualified persons, and in some cases, administered by unqualified persons. The availability of this illegal medicine also confirms the potential for the development of drug-resistant bacteria and malaria in the region.
3. **Illegal medicine is a global issue,** highlighted in the breadth of countries of origin of illegal medicine seized in SMCS Risk's operations.
4. **Illegal medicine is linked to organized crime**, demonstrated by the discovery of well-established and multi-faceted networks capable of moving significant volumes of medicine across the borders and across Cambodia.
5. **Health providers are versatile and opportunistic**, as pharmacies, clinics and doctors in Cambodia, whether licensed or unlicensed, indiscriminately engage in importation, distribution and administration activities of illegal medicine.
6. **Importers and distributors are adapted to specific markets**, displaying different capabilities and operational methods, while all are able to secure large quantities of illegal medicine. The investigation activities and timeframe required to target each type of importer and distributor are different.
7. **International pharmaceutical supply chains are compromised**, as expired and unregistered products represent the majority of the illegal medicine in Cambodia.
8. **Investigation services are value-adding and cost-effective**, demonstrating a strong contribution to the control of illegal medicine in the region.

1.4 Recommendations

Based on these findings, it is recommended that:

1. **Greater support is required from other stakeholders**, to ensure the complex issue of illegal medicine in the region receives the necessary level of support and cooperation. Often, the gains made by the investigations in this report are diminished due to contrary, unhelpful conditions that have been allowed to exist, such as the preference for pre-judicial penalties.
2. **Other provinces in the region need to be targeted**, particularly those Cambodian provinces that border Thailand, Laos and Vietnam. Vietnamese provinces also warrant attention, particularly as pharmaceutical manufacturing is anticipated to increase.
3. **Importers and distributors need to be targeted** to a greater extent, due to their key position in the trade of illegal medicine.
4. **Local law enforcement agencies need greater support to develop capacity**, especially in the fields of packaging analysis, medicine analysis, data collection and information sharing.

2 INTRODUCTION

2.1 Illegal Medicine

For the purposes of this report, illegal medicine includes medicine that is illegally diverted, unregistered, expired, counterfeit and/or sold in deficient packaging. This definition acknowledges the public health and intellectual property violations that are inherent in this type of product (WHO 2016a; Attaran et al. 2012). The definition used here is broadly compatible with "substandard, spurious, falsely labeled, falsified and counterfeit medical products" as referred to by the WHO (WHO 2016a) and "pharmaceutical crime" as referred to by Interpol (Interpol 2016b).

Illegal medicine is a significant problem throughout the world. According to the most frequently cited estimate, attributed to the World Health Organization, 10% of the global medicine supply was counterfeit in 2010, rising to 30% in the developing world, "an alarming figure, especially given the narrow definition of 'counterfeit' used by the WHO" (UNODC 2010, 184). Specialized studies have suggested Cambodia might be even more affected by the phenomenon (Lon et al. 2006; Phanouvong et al. 2013; USP 2010).

Illegal medicine is a lucrative business for criminal networks: for example, counterfeiting a leading product (a "blockbuster") is said to generate a profit up to 500 times the initial investment (IRACM 2016a). It is also a business that kills hundreds of thousands of people every year (Harris et al. 2009; OECD 2016, 95).

Despite these figures, little is known on the methods of importation, distribution and control of illegal medicine, particularly in low and lower-middle income countries such as Cambodia.

2.2 Illegal Medicine Threatens Patient Safety and Public Health

Illegal medicine presents numerous serious threats to patient safety and public health.

Threats to Patient Safety

The primary concerns for patient safety include ineffectiveness of treatment, adverse reactions to treatment and inappropriate treatment. These occur due to several mechanisms, outlined below. Note that some mechanisms are specific to particular types of illegal medicine, discussed later.

Dangerous substitutes or additives may have been made to the ingredients during the manufacture of illegal medicine. Harmful ingredients found in counterfeit medicine have included: boric acid; leaded highway paint; floor polish; heavy metals; nickel; arsenic and brick dust (U.S. Food and Drug Administration 2016). The substitution of pyrimethamine in a counterfeit cardiac medicine was responsible for over 200 deaths in Pakistan (WHO 2013), and the substitution of diethylene glycol in counterfeit paracetemol (also known as acetaminophen) has killed many patients, including multiple incidents in Bangladesh (Hanif et al. 1995, The Guardian 2009).

Decreased drug potency is often a factor in illegal medicine. Patients consuming illegal medicine may not receive the quantity of active ingredient that is expected (Pfizer 2007). For example, a patient becomes susceptible to developing malaria if that patient is taking an expired medication for the prophylaxis of malaria which no longer has sufficient potency to provide a therapeutic effect. Chemical analysis of antimalarial medicine sampled in Cambodia reveals that 40% of expired antimalarial medicine is of poor quality (Yeung et al. 2015), and may not yield the intended benefit.

Contamination and cross-contamination is a possible outcome during the manufacture of illegal medicine. Contamination is the undesired introduction of foreign matter or impurities of a chemical or microbial nature to a medicinal product (WHO 2014b). Animal, human or synthetic fibres are often the source of contamination, but also insects, glass, paint or metals. Cross-contamination occurs where starting material, intermediate product or finished pharmaceutical product contaminates another starting material or product during production (ibid.). Contamination control during manufacture is critical to manage these risks.

Lack of adequate control during distribution can affect the quality and the integrity of medicinal products (European Commission 2013), contributing to the risk of contamination and decreased drug potency. Key considerations for the storage and transportation of medicine include:

1. Temperature monitoring and control: products sensitive to high temperature can deteriorate at temperatures outside their specified limits thus decreasing active ingredient content (Snow 2003). Products sensitive to low temperature can also be damaged if the product has been frozen as this can cause an irreversible change to the structure of the active ingredient. A product stored at an inappropriate temperature may lose its efficacy which presents major safety concerns as discussed earlier (Ammann 2013). This is of particular importance for medicine that requires an unbroken cold chain, as the product must be maintained within a very narrow temperature range throughout the distribution chain (HPRA 2011).
2. Humidity: inappropriate humidity levels also have the potential to degrade medicine, altering its efficacy (Shafaat et al. 2013). Particularly in a country where humidity levels are high, humidity should be monitored in medicinal product storage sites.
3. Contamination: pest control, cleaning and anti-bacterial measures are important to minimize the risks of contamination during transport and storage. Exposure to risks such as pest or insects is a mishandling of medicinal products, and may result in a serious health hazard following patient ingestion of contaminated drugs (Mugoyela and Mwambete 2010; Johnston and Holt 2014).
4. Storage in private residences: the quality of products which were manufactured legitimately can no longer be guaranteed when illegal distributors store these products in their private residences. The quality of substandard and counterfeit products has the potential to further deteriorate in these circumstances. This is especially true of expired medicine, which accumulates a history of poor storage conditions over the product's lifespan.

Adequate controls are unlikely to have been applied when medicine is transported through illegal supply chains. For example, humidity is rarely controlled in an illegal supply chain (Porter 2013). Consider the implications to medication for the treatment of malaria: artemisinin derivatives are inherently unstable and are very sensitive to heat and humidity, and must be stored appropriately to maximize their effectiveness (Yeung et al. 2015).

The presence of unqualified persons in the diagnosis and administration of treatment increases the risk that a treatment will not be appropriate and/or it will not be correctly administered. Illegal medicine is often distributed by unqualified persons, as reported across various countries, particularly in Asia and Africa. The most common error made by unqualified doctors is the over-prescription of antibiotics, and in some cases, fake doctors in India have been associated with illegal organ trading (The Economist 2008). Illegal medicine also encourages **the entry of unregistered and unqualified manufacturers**, increasing the risk of substitution, contamination and cross-contamination.

Deficient packaging increases the risks that medicine will be used inappropriately, as patients may not receive the intended information with the medicinal product. For example, the patient information leaflet is a crucial document that allows patients to check for themselves important details of medicine such as posology, adverse effects, therapeutic indications, contraindications and other important warnings. In the absence of good medical advice this document can be crucial in supplying necessary information to the patient. Additionally, identifying the origins and establishing the authenticity of such products can be difficult (if not impossible) if the packaging is deficient.

Threats to Public Health

In addition to the threats to patient safety from ineffective treatments and adverse effects, illegal medicine also poses several profound long-term threats to public health. For example:

1. **Antibiotic resistance** is already a significant issue in South East Asia. However, this problem is greatly exacerbated by counterfeit and expired medicine which can contain sub-therapeutic doses (Johnston and Holt 2014). Such misuse of antibiotics accelerates the emergence of drug-resistant strains of bacteria. Antimicrobial resistance threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria (WHO 2014a). This poses a large risk to public health in terms of treating resistant bacterial strains in the future.
2. **Malarial resistance** is also a significant issue in South East Asia, particularly in Thai-Cambodian border regions and possibly across the Greater Mekong region (WHO 2011). The availability and consumption of poor quality antimalarial medicine has played a significant part in the emergence of antimalarial drug resistance (Yeung et al. 2015). Trade in illegal medicine is a key driver of poor quality, and threatens the effectiveness of existing treatment options in the future.

Threats to Patient Safety Differ Between Types of Illegal Medicine

The specific threat to patients and public health varies according to the type of illegal medicine.

Counterfeit medicine can be highly dangerous to patients. The WHO defines a counterfeit pharmaceutical product as a product that is deliberately and fraudulently mislabelled with respect to identity and/or source (WHO 2016a). This includes products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging. These products pose a significant threat to patient safety.

Counterfeit medicine is particularly susceptible to substitution of and additives to the active ingredients, resulting in sub-therapeutic dosages for prophalaxis and treatment of malaria. Interpol has estimated that one million people die each year from counterfeit medicine, and according to another study, 700,000 deaths from malaria and tuberculosis alone would be attributable to “fake drugs” (OECD 2016, 95; Harris et al. 2009).

Expired medicine can also be highly detrimental to patient safety. The supply of expired medicine is a criminal offence in many countries. The UK National Health Service advise that the following risks are present with expired medications:

- Decreased drug potency and thus effectiveness (Bilal 2014);
- An increased risk of product contamination;
- Potentially unstable active ingredient/s;
- Potentially dangerous degradation products (resulting from chemical changes to the medicine); and
- An increased risk of adverse events (WHO 1999).

Finally, **unregistered products** or **illegally diverted medicine** also pose implications to patient safety. Unregistered medicine are products that are not granted market authorization in a country, and although they “may be of good quality, some research indicates they are often not” (Buckley and Gostin 2013). This type of medicine is often distributed in illegal supply chains, where it is subject to poor standards of transport and storage, and distributed by those without medical qualifications.

2.3 The Role of SMCS Risk

Picture 1: 2012 Seizure of 5.5 Tons of Illegal Medicine

SMCS Risk has been investigating illegal medicine in Cambodia for 8 years. SMCS Risk's involvement rose to attention after the seizure of 5.5 tons of illegal medicine by National Police, Customs and Health Ministries of Cambodia in 2012. This was the result of a 14-month investigation by a team of investigators and field officers.

SMCS Risk represents leading companies to identify instances of illegal diversion, counterfeiting and other issues associated with a company's products. SMCS Risk investigates and documents these instances, and communicates the instance to local authorities where relevant. SMCS Risk acts as the liaison between these companies and local authorities.

Importantly, SMCS Risk has no jurisdictional power of arrest or search. SMCS Risk relies on the assistance of the courts, Police and Ministry of Health to conduct enforcement actions.

SMCS Risk has established the capabilities and the networks to be effective in Cambodia. SMCS Risk is now seeking to develop a proactive agenda to advance this cause in the region, in conjunction with leading pharmaceutical manufacturers and relevant government authorities.

2.4 Introduction to this Report

This report provides an overview of selected investigations conducted by SMCS Risk in Cambodia since the seizure in late 2012, through to early 2016. This report concludes with findings and recommendations to mitigate the issues surrounding illegal medicine in Cambodia.

This report has been prepared for pharmaceutical companies and relevant government authorities. This report is intended to generate further discussion on the next steps to address the trade in illegal medicine in South East Asia, particularly Cambodia. This report will also assist government authorities to understand illegal medicine supply chains and related issues.

Picture 2: Illegal Medicine

3 OVERVIEW OF OPERATIONS

3.1 The Sample

The descriptive analysis presented in this chapter is based on 26 selected investigations conducted from December 2012 to February 2016, a period of 39 months. This is a convenience sample that illustrates the patterns of importation, distribution, sale and control of illegal medicine in Cambodia. This sample is by no means exhaustive of SMCS Risk's investigations in the region.

3.2 SMCS Risk's Investigations

An investigation by SMCS Risk typically involves several types of activity:

- **Target profiling and collection of evidence:** self-initiated or upon request from a pharmaceutical company**,** to set the foundation for action by relevant local authorities. Activities include:
  - *Checks and Verification*: identity checks, location checks and interviews with neighbours, amongst other miscellaneous tasks.
  - *Surveillance activities:* undercover monitoring of suspects, including the recording of pictures and video.
  - *Sample purchases:* acting as customers and acquiring samples of illegal medicine.
- **Facilitation of Enforcement:** assistance provided upon request to the Cambodian authorities once a search warrant is granted from the courts. Activities include:
  - *Raids:* assist the police forces (national police, economic police or medicine task force) and Ministry of Health officials in conducting raids to seize illegal medicine.
  - *Task Force Operations:* multiple raids conducted to assist the police forces (national police, economic police or medicine task force) and Ministry of Health officials in conducting raids to seize illegal medicine.
- **Provision of Post-Enforcement Assistance and Analysis:** assistance provided as follow-up to enforcement activities, to ensure full utilization of information that SMCS Risk has provided, collection of potentially useful new data, and full implementation of any relevant procedures within the remit of authorities. Activities include:
  - *Interviews:* identification of the modus operandi, the source of supply and the clients of the offenders, to supplement formal police interviews.
  - *Seizure processing:* sharing of expertise with the authorities in identifying and classifying the different types of illegal medicine seized.

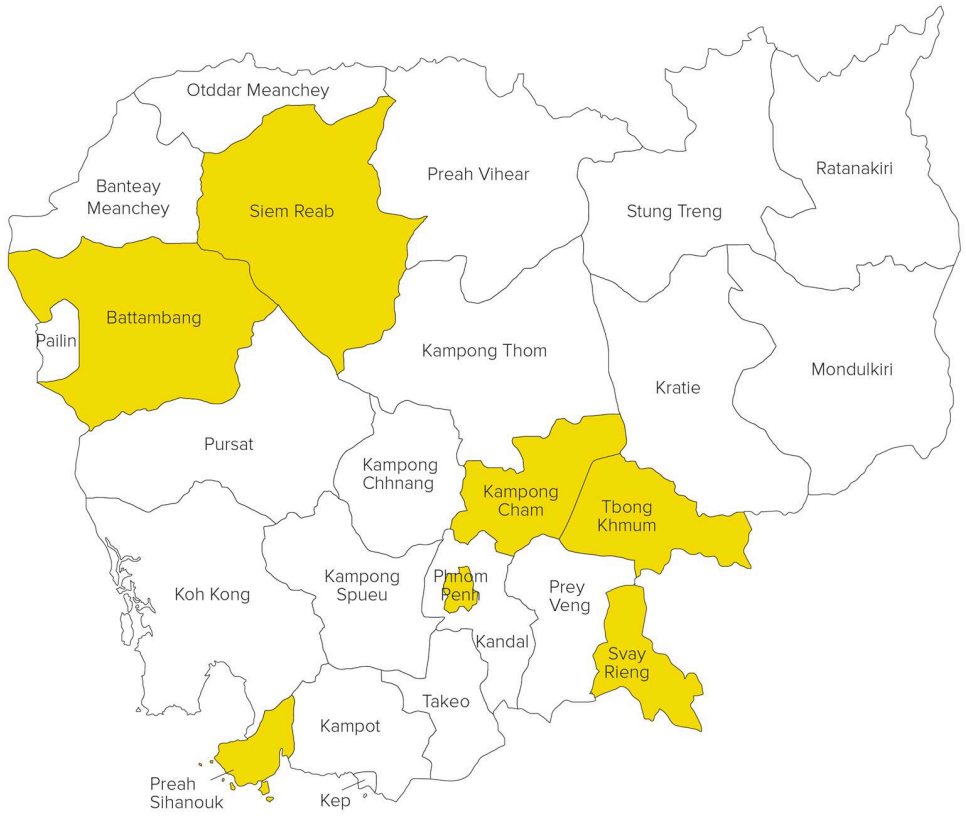
The sample of investigations covered in this report address 551 targets and 539 raids. This sample represents a substantial body of information in a field that has very limited data. However, there are some issues of data compatibility and some restrictions on the analysis that is possible to present.

The number of activities within these investigations undertaken by SMCS Risk has steadily risen over the past years. 2013, 2014 and 2015 showed exponential growth, with a new focus on raids and seizures in partnership with the authorities as momentum was established by SMCS Risk for the enforcement of laws controlling the flow of illegal medicine in Cambodia.

These investigations are often highly interlinked. One investigation will often lead to the commencement of other investigations as suspects and distribution locations are identified. In this sample, 7 investigations out of 26 (26.9%) were initiated on the evidence collected in a previous investigation, and 3 were initiated on the evidence collected during a second investigation (11.5%). In total, over a third of investigations were commenced from evidence collected in a previous investigation.

3.3 Location of Raids

SMCS Risk has established a network of operational partners and informants across Cambodia. Investigations have been implemented in a whole range of environments including urban cities and remote rural areas. Target provinces are shown on the map below.



Map 1: Location of Raids

In total, 539 raids have been conducted in 7 of 25 provinces in Cambodia. The distribution of raids by province is shown in the chart overleaf. Please note that some raids may involve multiple targets located in one location, as explored further in Chapter 3.4.

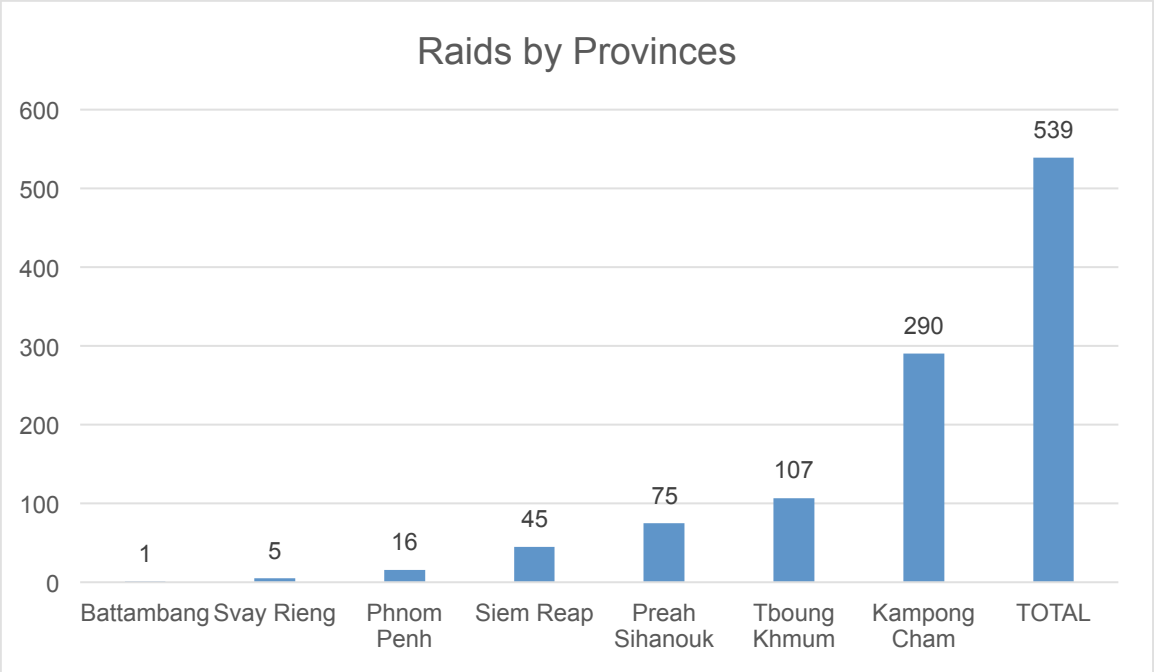


Chart 1: Number of Raids by Provinces

These raids include targets in main cities and province communities. The largest number of raids has been conducted in Kampong Cham, Tboung Khmum and Preah Sihanouk.

3.4 Type of Targets

From a total number of 551 targets investigated, 545 targets were raided. Chart 2 below shows the breakdown per business category.

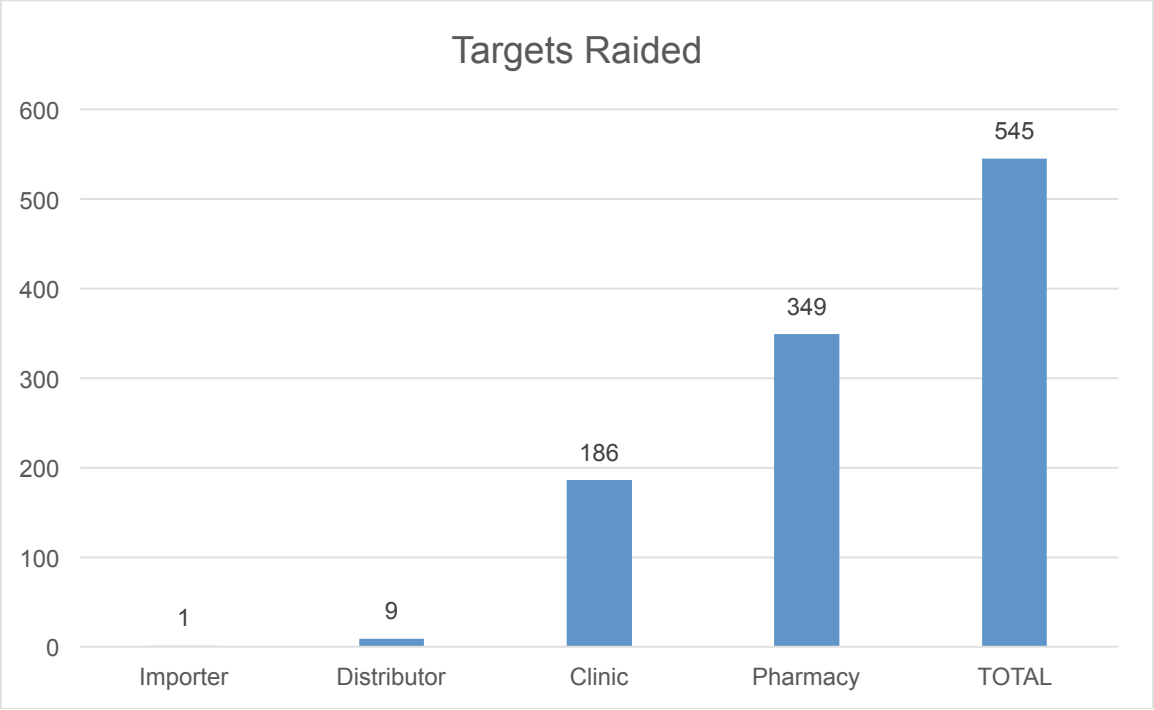


Chart 2: Number of Targets by Business Categories

The majority of these targets are health providers (clinics and pharmacies), as they are in direct contact with the population and are more numerous than distributors and importers.

It should be noted that the biggest seizures of illegal medicine were attained from an importer and a distribution company. Targeting these business categories can have a significant multiplier effect on the whole supply chain of illegal medicine, right down to the level of health providers. However, investigations targeting importers and distributors are generally much lengthier and more complex.

3.5 Offenders

Picture 3: Processing an Offender

There were 556 individual suspects involved in the 26 investigations. Of these, 461 were processed as offenders. Most of these offenders were involved in small businesses (individually owned).

Amongst the offenders was a notable range of nationalities: Cambodian, Chinese, Indian, Vietnamese, Russian, Korean and Australian.

The outcomes for these offenders were varied, as shown in chart 3 below. Typically, offenders received a 'pre-judicial' outcome (93.7% of cases), in the form of warning and final warning notices and/or having to attend a workshop and sign a statement.

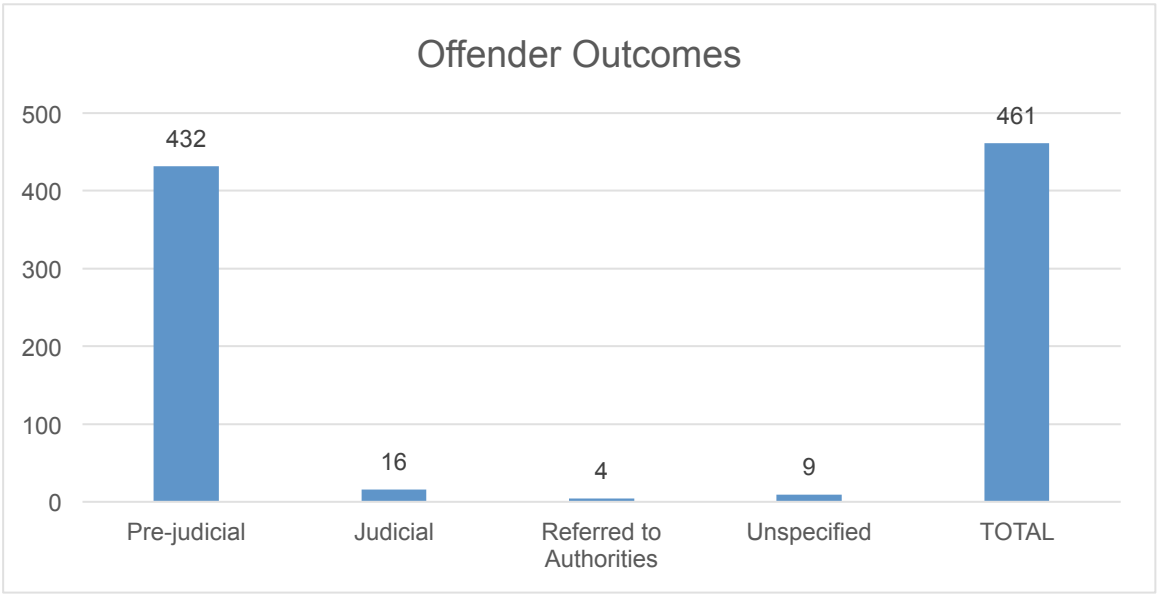


Chart 3: Offender Outcomes

While 16 offenders received a judicial outcome through the court system, and a further 4 were referred to authorities, the high prevalence of pre-judicial outcomes is due to the contribution of offenders from pharmacies and clinics. This group has typically been granted pre-judicial treatments in Cambodia.

When assessed across the total number of investigations, the outcomes were more balanced. From the 26 investigations, 12 had pre-judicial consequences, 9 had judicial consequences and 3 involved a referral to the authorities to take action.

3.6 Seizures

The seizure of illegal medicine is not the primary focus of SMCS Risk's operations. Without the jurisdictional power to search or arrest, SMCS Risk relies on partnerships with relevant authorities to achieve seizures. Nonetheless, seizures were reported in 21 of the 26 operations in our sample.

Picture 4: Various Seizures Achieved during Recent SMCS Risk Investigations

The recording of data for a particular seizure was conducted by a relevant authority. There are several measures by which a seizure may be reported, including weight, dosage units and/or tablet numbers. Often there are practical issues that govern which measure is used.

Unfortunately, this leads to issues of data comparability: it is not possible to present a comprehensive analysis of the origins and types of products seized due to these challenges. For this reason, SMCS Risk presents more detailed analyses of individual seizures in Chapter 4.

Within the sample, there were several instances where more than 50,000 dosage units were seized (or an amount of similar significance in weight or tablet numbers, if the dosage units were not reported by the relevant authorities). These seizures are outlined in the table below.

Table 1: Seizure Volumes from Recent SMCS Risk Investigations

Seizure Volume	Number of Items Reported	Date of Conclusion
3.5 tons	n/a	September 2014
1.6 tons	518	March 2015
1.65 million tablets	6	April 2015
266,000 dosage units	872	April 2015
256,000 dosage units	685	November 2015
178,000 dosage units	577	November 2015
142,000 dosage units	102	October 2015
70,000 tablets	1	June 2014
51,000 dosage units	187	February 2015

Please note that the date on which the SMCS Risk investigation concluded may be slightly different to the official reported date of the seizure. Seizure volumes have been rounded to the nearest thousand dosage units (or tablets, as appropriate).

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4 CASE STUDIES

4.1 Overview of the Case Studies

Six investigations have been selected to provide a greater level of insight into the problem of illegal medicine in Cambodia. The case studies vary considerably, in terms of:

3. The length and complexity of the investigation conducted by SMCS Risk;
4. The type and source of the illegal medicine;
5. The nature of the medicine (expired, unregistered and/or counterfeit);
6. The focus of the offenders (importation, counterfeiting, distribution and/or administration);
7. The sophistication of the offenders; and
8. The specific patient safety risks posed by each case.

The case studies are as follows:

1. Pharmacies in Kampong Cham;
2. Bulk Import of Top Selling Medicine;
3. Large Importation and Counterfeiting Operation;
4. Importation and Distribution of Counterfeit Viagra;
5. Psychotropic Cutting Agents; and
6. Distribution and Administration of Injectable Medicine by Unqualified Persons.

These case studies are a useful cross-section of the violations of health, medical, customs and intellectual property law in Cambodia.

4.2 Pharmacies in Kampong Cham

In late 2015, an SMCS Risk operation focused on 117 pharmacies and clinics in Kampong Cham province. 177,682 dosage units of illegal medicine were seized during this operation. This seizure followed an SMCS Risk investigation in the same province 6 months earlier involving some of the same offenders: 265,765 dosage units were seized from 173 targets in the operation on this earlier occasion.

Both operations were conducted in partnership with the Ministry of Health and the Medicine Task Force. The review of the more recent operation provides a useful picture of the practices of small health businesses outside Phnom Penh. With nearly 600 different types of medicine seized, representing more than 90 drug classes, this was a rich and complex sample of what is available locally at the point of purchase.

Picture 5: Pharmacy Raided during Investigation

Picture 6: Seized Illegal Medicine from a Pharmacy

73% of the illegal medicine was expired, and some of the drug classes that were seized were considerably past their expiry date (chart 4 below). The health risks of expired medicine are considerable, as potency can diminish, compounds may become unstable, cross-contamination risks rise and degradation by-products can accumulate.

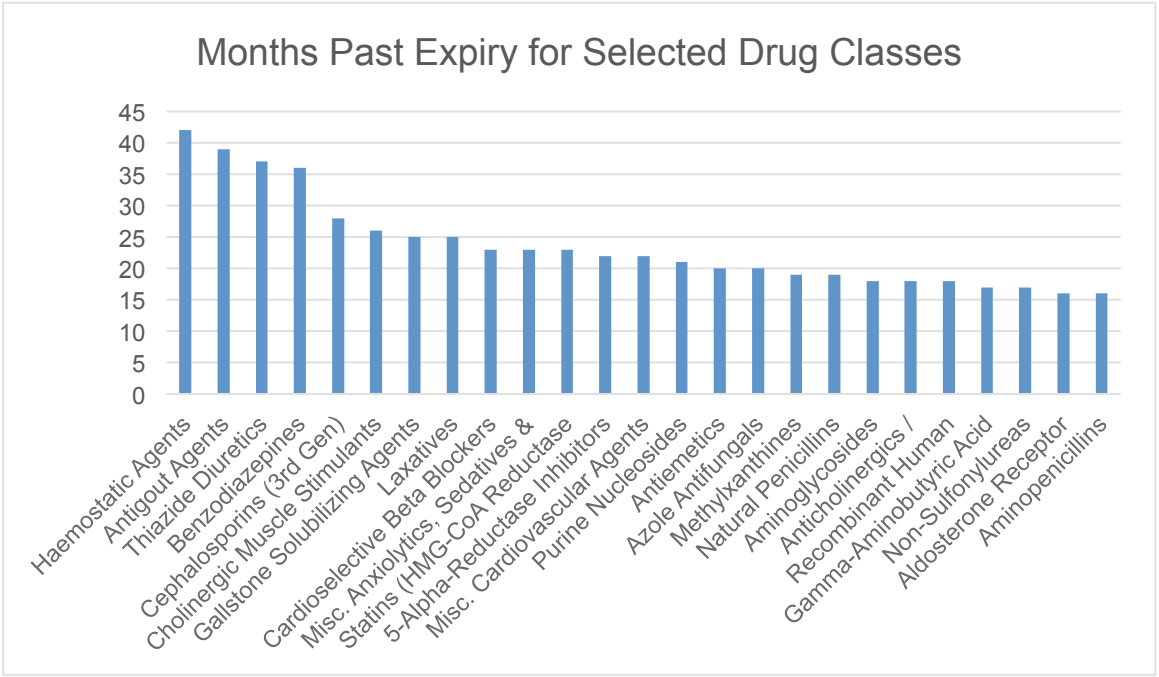


Chart 4: Average Number of Months Post-Expiry for Selected Drug Classes

As one example, benzodiazepines were on average 36 months past expiry. This medicine is used to treat illnesses such as anxiety, epilepsy and alcohol withdrawal syndrome among others. Some of these drugs, such as diazepam, can be used 'recreationally' or in association with illicit drugs (see Case Study 4.5).

Storage conditions that are consistently high temperature and high humidity pose further risks for these expired products. The overwhelming majority of raided pharmacies exhibited conditions that would fail to meet requirements for the effective monitoring and control of temperature, humidity and contamination risks. These conditions can accelerate the degradation of medicine.

This seizure included many types of critical medicine, including injectable preparations and medicines used in extremely vulnerable patient groups, including neonates. Medicine was seized that may have been used in high risk conditions, such as in the treatment of epilepsy, status asthmaticus, myocardial infarction, diabetes, cardiac dysrhythmias, cardiac failure and many more.

Picture 7: Seizure from a Pharmacy

For example, one of the medications found in the sample was Aminophylline. This is used in emergency situations, such as status asthmaticus. Aminophylline has a narrow therapeutic index, therefore cautious dosage determination is essential to patient well-being. Gabapentin was also found in the sample. This drug is used in the treatment of epilepsy: a sub-therapeutic dose could have serious implications for an epileptic patient.

Picture 8: Seizure from a Pharmacy

Many antibiotics were found in the sample, including gentamicin, ceftazidime, lincomycin, cephalexin, ciprofloxacin, cefuroxime, cephalexin, moxifloxacin and amoxicillin. There is an immediate risk that a patient in a potentially life-threatening situation may not receive a therapeutic dose from an expired antibiotic. Furthermore, the development of antibiotic resistance may be accelerated by the use of degraded antibiotics, particularly advanced antibiotics such as gentamacin, lincomycin and moxifloxacin.

Antimalarials such as doxycycline and artenimol/piperaquine were found in this seizure. Doxycline is used in the prohylaxis and treatment of malaria, and artenimol/piperaquine is used in the treatment of malaria. The presence of expired antimalarial medicine poses risks to patients by diminishing their access to effective prevention and treatment of malaria.

It is also of note that medical devices such as condoms were found. Expired condoms have an increased risk of breakage (as well as local irritation). The use of these products poses a risk of contracting HIV and other dangerous sexually transmitted diseases such as hepatitis B, chlamydia, gonorrhea and syphilis.

Medicine that was not expired was generally unregistered for use in Cambodia.

This seizure also highlights the significant penetration of Cambodian borders and the limited supply capacity of the national pharmaceutical industry to meet demand. Indeed, the vast majority of the illegal medicine originated from outside Cambodia (87%), as shown in Chart 5 below.

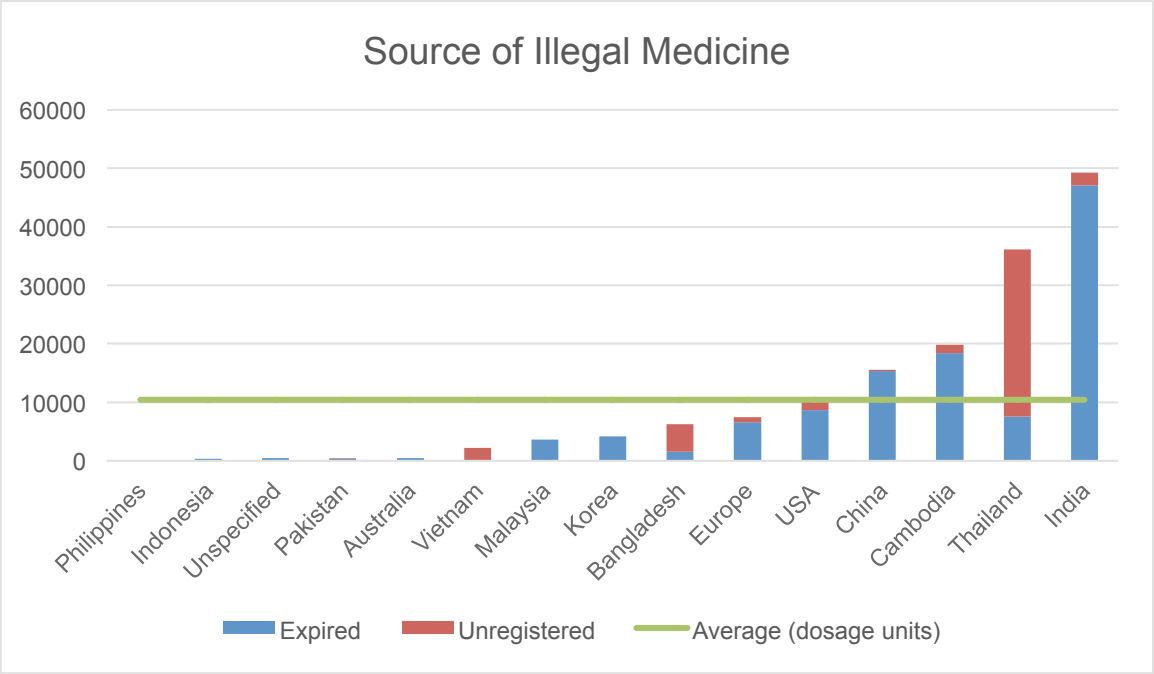


Chart 5: Origin of Manufacture of Dosage Units Seized in Case Study

In terms of dosage units, the illegal medicine seized in this investigation was predominantly from India, Thailand, Cambodia, China and USA. There is strong evidence of a "westward" connection, with significant supplies received from Thailand, Bangladesh and India. Eastern sources also feature heavily, with supplies from China, Vietnam and Korea.

The majority of the illegal medicine from Thailand, Bangladesh and Vietnam was unregistered. This could show opportunistic behaviour by manufacturers and distributors in nearby countries, given the porosity of Cambodia's land borders. That would align with the interviews with owners of the pharmacies and clinics, which revealed the owner travelled to Thailand and Vietnam to buy their supplies, or family members brought the medicine with them from another country.

Another way to get supplies was to be approached by Cambodian medicine salespeople who proposed them cheap products, or by companies in Cambodia that sell medicine.

Whether expired or unregistered, all of the illegal medicine in this particular investigation was destined for the Cambodian domestic market. There seems to be an economic incentive for local health providers: Cambodia is seen as a viable market for products that cannot be sold elsewhere (expired products) and that are easy to smuggle in (unregistered products). This is especially clear after some pharmacies and clinics kept selling illegal medicine after the initial raid.

4.3 Bulk Import of Top Selling Medicine

After several months investigating a suspected storage location, SMCS Risk received intelligence that a large shipment of illegal medicine was coming into Cambodia via Phnom Penh International Airport in early 2015.

Picture 9: Delivery Truck

Picture 10: Delivery Premises

Picture 11: Seizure from the Truck

In cooperation with Cambodian Economic Police, the delivery truck was stopped and searched, resulting in the arrest of one male and the seizure of 1,646,380 tablets of illegally diverted medicine. At the time, this was the largest recorded seizure of illegally diverted medicine of one of the companies involved.

The shipment was very specific, containing only five different products: Plavix, Nexium, Augmentin, Crestor and Diamicron MR. Four of these products generate significant sales worldwide, especially in emerging markets for pharmaceuticals.

Picture 12: Seized Illegal Medicines including Crestor (left), Nexium (centre) and Plavix (right)

According to a relevant study (IMS Health 2013, 12), Plavix ranked number 1 in sales in these markets and had an average growth year on year of 9%, "despite widespread generic competition". Nexium ranked number 4 in sales and had an average growth year on year of 17%. Augmentin ranked number 8 and had a growth of 13%, when it is absent of the Top 20 drugs in "mature" markets due to its age. Crestor was number 10 and grew by 6%, and is number 3 in the Top 20 drugs in mature markets. While Diamicron MR is not mentioned as a major seller, it belongs to the World Health Organisation's List of Essential Medicine.

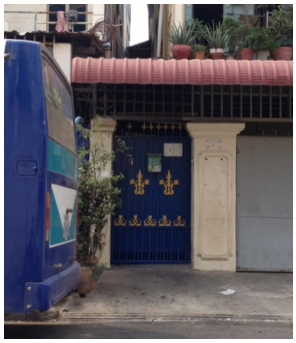
The medicine was reportedly destined for the Vietnamese market: these products would have been carefully chosen for this market. This is evidence of commercial behaviour by an organized criminal network.

The interview of the arrested male revealed the medicine was sourced from a Turkish factory and flown to Phnom Penh airport via Singapore airport. There it was meant to be stored at the facility before being trucked into Vietnam at the Takeo Province border crossing and delivered to the Vietnamese importer/distributor behind this operation.

Likewise, the route would have been carefully chosen to avoid Vietnam's strict licensing rules and high taxes and duties on imported medicine: Singapore as a transit point to lower Cambodian customs suspicions, and Cambodia as a re-exportation country to use its porous land borders with Vietnam.

This case also highlights the issues with international supply chains and the risk of factories illegally shipping medicine. This risk was recently highlighted as a major vulnerability in conducting business operations across borders by the International Chamber of Commerce (BASCAP 2015). There is clear evidence in this case study that legitimate, licensed operators were acting illegally.

4.4 Large Importation and Counterfeiting Operation



Over a period of five months, SMCS Risk conducted surveillance on a Phnom Penh family that was using its private house near Olympic Market as a storage place and delivering illegal medicine to nearby pharmacies and clinics by foot, bicycle and motorbike.

In mid 2014 the Cambodian National Police executed a search warrant on the suspected venue, with SMCS Risk assistance, and seized 3.5 tons of unnamed/unlabeled medicine, counterfeit medicine and illegally diverted medicine from several Asian countries.

Picture 13: Private House

Large boxes containing empty plain medicine bottles, bags of individual tablets and flat packs of labels and boxes were also found, indicating that part of the offenders' business consisted in packaging illegal product to be sold in a form that the public would recognize as legitimate. This poses clear risks to public health.

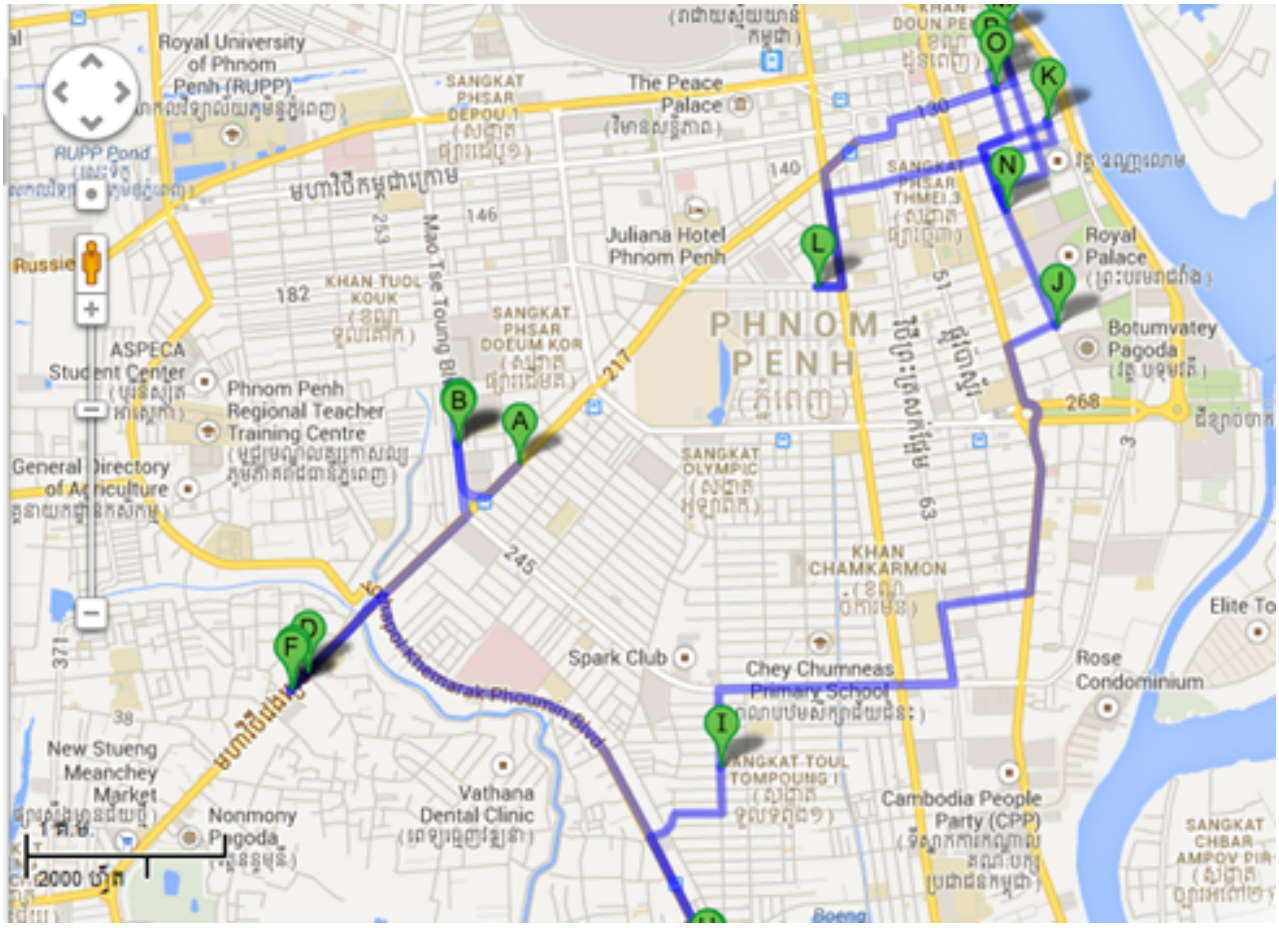
Picture 14: Medicine Seized at Storage Place, including Counterfeit Medicine (right)

This case shows how an apparently unsophisticated distribution operation can be linked to large scale organized crime: bicycle riders carrying small black plastic bags were part of a network of suppliers able to source several tons of extremely diverse products from international locations. They were then able to transform these products into a more valuable form through counterfeiting and fraud, and to then supply dozens of local buyers.

Picture 15: Storage Conditions

4.5 Importation and Distribution of Counterfeit Viagra

In early 2013, SMCS Risk investigated a distribution operation servicing multiple pharmacies and clinics in Phnom Penh. This operation involved ongoing surveillance activities across multiple persons and properties over a nine month period. A map of one delivery is provided below, as an example of the behaviour of a local distributor.



Map 2: Map Showing One Delivery of Counterfeit Viagra in Phnom Penh

During the surveillance period, it was established that the operation comprised an owner and multiple delivery persons, and was the source of deliveries of large amounts of illegal medicine.

The operation culminated in a raid and seizure of 158 boxes of counterfeit Viagra, amongst other items. Unfortunately, the volume of medicine seized did not match expectations, but it is likely that the raid was conducted at a lull in the supply cycle. Significant volumes of medicine were being distributed by the operation each day. Since there was no delivery observed to the premises under surveillance nor manufacturing equipment seized on site, it is likely that the owner's holdings were much larger during the period preceding the execution of the raid.

Picture 16: Counterfeit Viagra

The counterfeit nature of the product had been established by the purchase of samples during the investigation. The counterfeiting had been completed to a very high standard. As demonstrated in the pictures below, the seized product was close to the legitimate Viagra, in a visual sense.

Picture 17: Counterfeit Viagra (Details)

From a visual inspection, it is unlikely that the Cambodian law enforcement agencies and pharmacy or clinic operators would have been able to detect that the product was counterfeit. Pfizer itself, the maker of Viagra, acknowledges it is impossible for non-specialists to see the difference between the original product and a fake (Pfizer 2015). Only extensive training of authorities on how to determine if medicine is counterfeit and access to specialist testing equipment will assist in reducing this trade.

According to the International Institute of Research Against Counterfeit Medicine, Viagra is one of the most counterfeited drugs in the world (IRACM 2016b). Viagra is a medicine that should only be taken with a doctor's prescription, and unqualified advice can lead to serious adverse effects, especially for people with heart conditions. Counterfeit Viagra, on the other hand, may have too much active ingredient, or the active ingredient may have been replaced by amphetamines or antibiotics (such as Metronidazole), and it may contain additives such as blue printer ink or binding agents such as drywall (The Counterfeit Report 2016).

Uninformed tourists are particularly at risk from this type of counterfeited product due to the over-the-counter availability and the extent of prostitution in Cambodia and South East Asia. In the absence of systematic autopsies and toxicology analysis on the deceased persons, the link between these deaths and the consumption of counterfeit Viagra can only be assumed, albeit strongly (Goldberg 2012).

The suspect would not disclose the source of the Viagra, but it was established that her products were imported. Given the scale and quality of the Viagra, this could only be achieved by organized crime. Stronger enforcement action is required to address this issue in Cambodia.

As this case shows, the trade in counterfeit Viagra is an established industry in Cambodia with ramifications across neighbouring countries. It should also be noted that Pfizer's patent expiration by 2020 is likely to induce changes in the control of this product (Transparency Market Research 2015).

4.6 Psychotropic Cutting Agents

In 2014, SMCS Risk conducted surveillance on a premise in Phnom Penh for a period of 6 months, observing numerous individuals attending the location on a daily basis and delivering bags and boxes of various medicine to pharmacies around the city.

Picture 18: Suspects

The premise was subsequently raided by Cambodian National Police and SMCS Risk. Medicines including esomeprazole, bromhexine, chymotrypsin were seized, but also phenobarbital and diazepam, both listed as psychotropic substances under international control by the International Narcotics Control Board (INCB 2015). All were illegally imported into Cambodia.

Picture 19: Storage conditions

Picture 20: Seized Diazepam

The 69,600 tablets of diazepam that were seized are of particular concern. Diazepam is controversial as a prescribed medicine, because of the dependence it can create on a patient and some of its adverse effects (Rogers 2013). Prescription by a doctor is important to minimize these risks.

More importantly, it is also increasingly popular as a heroin substitute and cutting agent, partly because of its affordability (BBC News 2008; UNODC 2011).

This case is concerning as it shows a link between smugglers of illegal medicine and the production and distribution of illicit drugs. Cambodia is said to have a "significant and growing problem with drug consumption, trafficking and production" (US Dep. of State 2014).

4.7 Distribution and Administration of Injectable Medicine by Unqualified Persons

After several months of investigation in late 2015, SMCS Risk conducted a raid with the Cambodian Economic Police and Ministry of Health officials on three storage locations in Svay Rieng Province. Although these locations were supplying illegal medicine locally and to pharmacies in Phnom Penh, this case highlights the issues of unqualified administration of medicine in Cambodia.

Picture 21: Raided Premises, including Livestock Storage (right)

In total, 5,208 dosage units of illegal medicine were seized in this investigation, including a large proportion of liquid formulation of medicine, syringes, needles, and hundreds of used syringes. Medicine manufactured in Asia comprised some 92% of the whole seizure and the products were mostly illegally diverted.

The liquid medicine formulations mentioned above comprised drugs such as:

- Metronidazole (picture 22, right), an antibiotic used to treat septicaemia, bacteraemia and pneumonia;
- Oxytocin, which is used to induce labor or strengthen labor contractions during childbirth, and to control bleeding after childbirth;
- Ceftriaxone, which is used to treat many kinds of bacterial infections, including severe or life-threatening forms such as meningitis and septicaemia; and
- Gabapentin, an anti-epileptic medicine mentioned in Case Study 4.2.

Picture 22: An Antibiotic Injected by the Offenders

The owners of the houses, who weren't qualified in medicine, were administering injections to patients. The offenders weren't trained to use potentially dangerous medicine or to prevent contamination of injection equipment and medication. The offenders were also reusing syringes. This incident comes only a few months after the mass HIV outbreak in the Battambang village of Roka, which was most likely caused by contaminated syringes (ABC Australia 2015).

Picture 23: Discarded Syringes

The storage conditions at these locations were remarkable, including the housing of domestic pigs at two of the three premises. Medicines were stored in insecure locations, in extreme heat, in highly contaminated environments.

This case highlights people's vulnerability to unqualified medical practitioners in rural communities.

Picture 24: Discarded Syringes

5 FINDINGS

5.1 Illegal Medicine is an Understated Problem

The problem of illegal medicine is wide-ranging and, in our informed position, appears substantially understated. Consider two perspectives, outlined below.

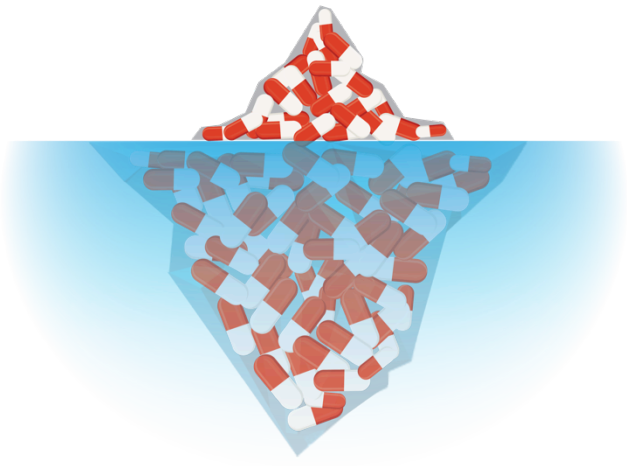
Firstly, the data reported here by SMCS Risk has arisen from operations in a relatively small geographical location within South East Asia. Whilst large seizures are reported in this sample, this sample has arisen from operations in 7 of 25 provinces in Cambodia, including only three border provinces (Battambang, Svay Rieng and Tboung Khmum).

Secondly, the outcomes obtained by SMCS Risk from local-level operations in these 7 of 25 provinces in Cambodia are comparable to Interpol's flagship operation in South East Asia, Operation Storm (Interpol 2016a). In the last two years, for example:

1. Interpol's Operation Storm V seized 3.5 tons of illegal medicine, with 11 participating countries in July and August 2014. In June 2014, SMCS Risk seized 3.5 tons in Phnom Penh; and
2. Interpol's Operation Storm VI seized more than 2 tons of illegal medicine, with 13 participating countries in September 2015. In March 2015, SMCS Risk's investigation in Preah Sihanouk Province seized 1.6 tons of illegal medicine.

Furthermore, SMCS Risk's results are significantly higher than the majority of the operations reported by the International Institute of Research Against Counterfeit Medicine (IRACM 2016c). This includes operations by national police and customs in nearby countries, including Thailand, Vietnam, Indonesia, Malaysia and the Philippines.

SMCS Risk's achievements are likely to show only 'the tip of the iceberg' in relation to the problem of undetected illegal medicine in South East Asia. The potential issues posed by increasing manufacture of pharmaceuticals in the region and the continued growth of online pharmaceutical sales are significant. Based on trends like these, the problem is likely to intensify in the coming years (UNODC 2014).



Picture 25: The Problem of Undetected Illegal Medicine in South East Asia

5.2 Illegal Medicine poses Serious Threats to Patient Safety

The issues facing illegal medicines (as outlined in Chapter 2.2 of this report) are broadly applicable to the sample reported here by SMCS Risk. Recent investigations have resulted in the seizure of large volumes of illegal medicine, including counterfeit, expired and unregistered medicine. This report confirms the operation of importation and distribution networks that are of a significant scale. This report also confirms the presence of counterfeiting and re-packaging operations in Cambodia, resulting in the deception of and potentially harm to consumers.

In addition, SMCS Risk's investigations confirm the presence of unqualified persons throughout the system for the distribution, sale and administration of illegal medicine. As seen regularly in the case studies, the administration of illegal medicine occurs in close correlation with unqualified medical practitioners, both doctors and pharmacists. This is especially prominent outside Phnom Penh. These unlicensed and unqualified practitioners undoubtedly contribute to misdiagnosis, mistreatment and potentially fatal outcomes for patients in Cambodia.

Unsanitary conditions for the transport and storage of medicine have also been a common feature of all investigations reported here by SMCS Risk, contributing to the risk of contamination and compromise of drug potency.

The potential risks to patients are magnified when the nature of the illegal medicine that has been seized is considered. Many types of critical medicine are reported here, including: antimalarials, antibiotics, anti-hypertensives, anti-psychotics, anxiolytics, anti-epileptics, antivirals, oral hypoglycaemic agents and hemostatics. These are intended for use on highly vulnerable patients or in potentially life-threatening situations, and many of these have a narrow therapeutic index. Precise dosing is important to achieve the required therapeutic effect, and this is unlikely to occur given the absence of qualifications held by offenders, the poor storage conditions and the substantial periods that have elapsed since the expiry dates of some medicine.

Picture 26: Unidentified Caps Seized During Investigation

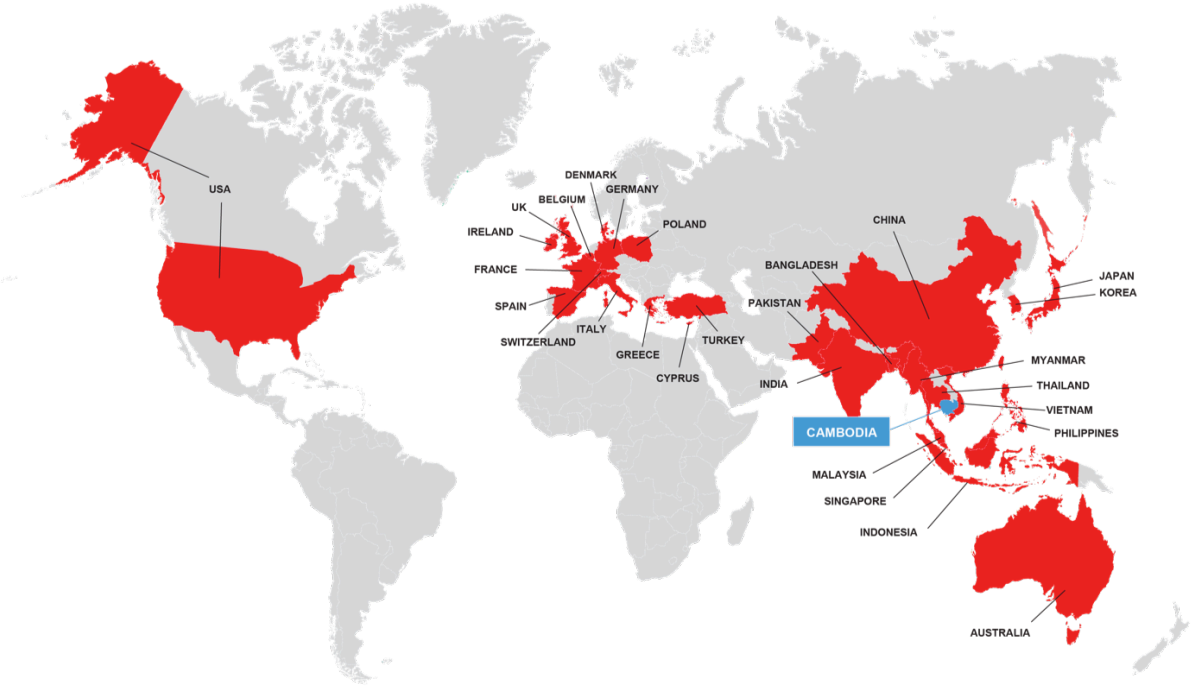
It should be noted that the Cambodian public are particularly vulnerable to the threats posed by illegal medicine due to a range of cultural factors:

- Cambodian patients have a strong preference for injections and IV drips (BBC 2015). These treatments are seen as highly desirable, yet carry high risks of infection, contamination and product degradation.
- There are very low levels of trust in the public health system and patients prefer to seek medical care in the largely unregulated private health sector (Van Damme et al. 2004), represented by the pharmacies and clinics investigated by SMCS Risk.
- Cambodians also face some of the highest out-of-pocket expenditures in the world on health treatments compared to their revenues and poor people often take large debts and/or have to sell some of their meager assets to face even benign diseases (ibid.).

Due to these constraints, Cambodian consumers are looking for cheap products and services, and yet lack the awareness of the significant issues that exist in relation to the private health sector or illegal medicine.

5.3 Illegal Medicine is a Global Issue

The literature on illegal medicine places significant emphasis on China as an origin of illegal medicine. However, illegal medicine seized during investigations conducted by SMCS Risk was manufactured in 29 countries in total, highlighting the breadth of the issue.



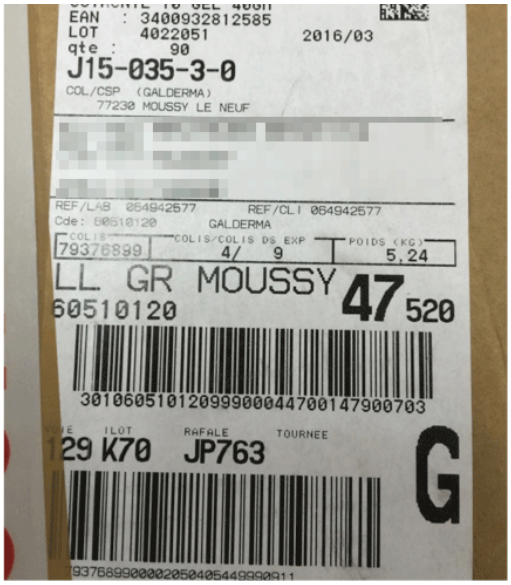
Map 3: Countries of Origin for Illegal Medicine Seized in Cambodia

With a majority of imports and large quantities of either illegally diverted and/or unregistered foreign medicine in the sample, there is ample evidence to suggest that Cambodian smugglers have connections in many countries in Asia and the rest of the world.

There are issues that prevent further detailed analysis to determine the relative importance of various countries as an origin of illegal medicine. However, SMCS Risk places emphasis on the importance of product originating from Vietnam, Thailand and Turkey.

In addition to the country of origin, further data from the investigations demonstrates the international links. For example:

- Foreign offenders such as health providers import medicine from their country of origin, such as China, as seen in one of our case studies;
- Importers receive a shipment from Turkey via Singapore, to be re-exported to Vietnam, as reported in the earlier case study (4.3); and
- Distributors have been observed driving from Phnom Penh to the Vietnamese border to get some supplies.



Picture 27: Illegally Diverted Medicine

5.4 Trade in Illegal Medicine is Linked to Organized Crime

The economic incentives to be involved with illegal medicine are currently significant enough to encourage wide-spread participation. Pharmacies, clinics, distributors and importers are being detected on a routine basis. The existence of a well-established and multi-faceted network that is capable of moving significant volumes of medicine could only be achieved by organized crime.

Organized crime is known to have an interest in the importation of distribution of illegal medicine, and there is evidence that criminal networks use similar routes and modus operandi to move counterfeit goods as they do to smuggle drugs, firearms and people (UNODC 2014). Proceeds from other crimes also feed the production and distribution of counterfeit goods (ibid.).

5.5 Health Providers are Versatile and Opportunistic

Health providers are at the interface between the supply and the demand for drugs and health services. They are critical for patients' safety both in terms of the quality of the care they provide (skills and ethics) and of the quality of the drugs they prescribe and administer. There are two types of health providers: the pharmacies and the clinics.

- Pharmacies have been observed getting supplies of illegal medicine from illegal distributors throughout the country and prescribing illegal medicine to their patients. Their status (licensed or unlicensed) doesn't seem to impact on their engagement in these activities, but there is an over representation of illegal businesses.
- Clinics and doctors have been observed getting supplies of illegal medicine from illegal distributors throughout the country and administering illegal medicine to their patients. Their status (licensed or unlicensed) doesn't seem to impact on their engagement in these activities, but there is an over representation of illegal businesses.

Picture 28: Unqualified Foreigner Injecting Locals

In Cambodia, both types can be highly opportunistic:

1. Pharmacies can operate clinics to administer medicine to patients, and clinics can sell medicine to patients. This illustrates a blurring of the boundaries between the two types.
2. Clinics and pharmacies have been observed importing and distributing drugs to other clinics and to pharmacies. In this latter case, foreigners were always involved, probably due to their position in the organization (owner, operator, practitioner) and their ability to travel between Cambodia and their home country.

This opportunistic behaviour is not surprising. Historically, enforcement in this area has not been sufficient to dissuade entry into the business of health, and established businesses do not seem to fear interference from the authorities or their patients. Likewise, the context of poverty in Cambodia makes it tempting to start a pharmacy or a clinic with limited or non-existent qualifications and limited capital.

Furthermore, warning letters, workshops and statements seem to have limited effect on all these diverse trades: SMCS Risk has detected repeat offenders in some pharmacy and clinic operations.

5.6 Different Importers & Distributors serve Different Markets

Distributors are clearly adapted to a whole range of different markets: local, national, international. In the Cambodian context, they use vastly different amounts of financial capital, connections with criminal networks and corrupting opportunities among the authorities. The smuggling methods they display and the illegal medicine they trade can be highly varied as well.

Distributors can be considered in three broad types, presented below as low, medium and high level.

Picture 29: Activities of a Low-Level Distributor

Low-level distributors are usually a family business. These are always illegal, where a female figure generally holds the main position. These distributors work as a small unit: either alone or with a partner (husband, brother/sister, maid, friend, employee) or two.

The territory of a low-level distributor is located around the storage place, that is the private house or apartment, within a radius of a several kilometers. The distributor delivers plastic bags or cardboard boxes of medicine to local pharmacies by foot, bicycle, motorbike, motodop, tuk tuk, and more rarely, by car. The quality of their products is highly variable, ranging from top-tier illegally-diverted medicine to unregistered, counterfeit, and expired medicine.

Note also that some illegal distributors have been observed administering illegal drugs to patients in rural communities, therefore acting as a clinic. This poses clear dangers to public health.

Medium-level importers and distributors seem to be similar in their structure: they are illegal family businesses. However, the quantities involved and the distances covered are more significant. A car or even a minivan is used for distribution, and men seem to be more active in these businesses. The Vietnamese border appears as a frequent destination for their supplies. The quality of the illegal medicine is arguably better, due to a higher proportion of illegally-diverted drugs.

Picture 30: Activities of a Licensed Distributor

In this regard, they can supply low-level distributors. Some of these distributors can also operate as illegal doctors, perhaps due to the easy access to medicine, the economic benefits, and low chance of being caught and punished.

High-level importers and distributors can be legal businesses or illegal businesses. They have the capability to source their products straight from the manufacturers overseas. They deliver very large volumes of medicine throughout the country using minivans and can re-export shipments to third countries. Evidence from the field has shown connections between industrial distributors and international criminal networks.

5.7 International Supply Chains are Vulnerable

There are critical weaknesses in the pharmaceutical supply chain that undermine efforts to achieve the legitimate sale of necessary product in a safe manner. Illegal medicine has become prevalent in Cambodia. As identified in one of our case studies, it is now possible for a local importer to arrange the procurement of illegal medicine from a licensed factory on another continent, and the shipping and storage of that product to a third and fourth country en route to its destination.

Several weak points in the supply chain are apparent. Firstly, authorized manufacturers have been detected selling medicine illegally. Governments have contributed to this situation by providing incentives. Immediate steps are required to resolve this situation.

Secondly, pharmaceutical products across the world are failing to be managed appropriately upon expiry. Large quantities of product that should have been disposed of appropriately are being found in Cambodia.

Thirdly, several notable pharmaceutical companies are not investing sufficiently to assist customs and border control in countries facing a problem with illegal medicine. Government departments are extremely constrained in the resources they have available to monitor and control the flow of illegal medicine, and it is incumbent on all pharmaceutical manufacturers to support the work of customs and border control with surveillance and education activities in these relevant countries.

Finally, multi-lateral organisations have not acted sufficiently to stop the trade in illegal medicine. Given the profound public health issues and the significant economic losses being incurred, greater assistance needs to be provided from organisations such as WTO or WHO, or in the event of non-compliance with relevant laws and expectations, the possibility of imposing sanctions or penalties should be considered.

5.8 Investigation Services are Cost-Effective and Value-Adding

The use of an investigation service has many benefits in low or lower-middle income countries where police and other enforcement agencies have restricted resources or capabilities, such as Cambodia. Acting on behalf of companies and brands, investigation services can bring additional specialist resources, capabilities and networks into reach of enforcement agencies.

SMCS Risk is an example of a highly effective investigation service. The collection of information conducted by this private company has lead to multiple successful raids and seizures, carried out by local enforcement agencies. These seizures are comparable to much larger organisations with significantly greater levels of resources, such as Interpol.

SMCS Risk has established a strong set of capabilities to support the investigation of issues relating to pharmaceutical products. These capabilities are much deeper than simple market surveillance, as demonstrated by the arrest of multiple importers and distributors. Legal firms and market research firms may offer baseline studies of illegal medicine in a particular market, but these firms rarely have the capability to effect a raid and seizure, nor address criminal activity further up the illegal medicine value chain.

Unfortunately, despite the seizure of their products in South East Asian countries such as Cambodia, several pharmaceutical companies are still not prepared to invest appropriately in investigation services to maintain patient and public safety.

6 RECOMMENDATIONS

Various factors make a country attractive to counterfeiters, importers and/or distributors of illegal medicine: poor enforcement, weak judiciary, lack of education, and corruption amongst others. The large amounts of illegal medicine detected and seized in investigations conducted by SMCS Risk suggest that Cambodia needs to address some, if not all, of these factors to achieve a reduction in the trade of illegal medicine.

Four recommendations are proposed to advance the control of illegal medicine in the region.

1. Greater support in the region is required from other stakeholders in the region;
2. Other provinces in the region need to be targeted;
3. Importers and distributors need to be targeted; and
4. Local law enforcement agencies require support to develop capability.

6.1 Greater Support is Required from Other Stakeholders in the Region

SMCS Risk has demonstrated a strong track record investigating illegal medicine in Cambodia alongside the National Police of Cambodia, Ministry of Health and Economic Police. However, the outcomes achieved during these investigations would deliver longer-lasting benefits to Cambodia if:

1. Pharmacies and clinics were required to meet minimum storage conditions, and breaches of these standards were identified and penalized;
2. The judiciary and health officials stopped or limited the practice of giving warning notices to those that sell illegal medicine;
3. Illegal pharmacies and clinics were shut down and offenders processed in court;
4. Any person who has a pharmacist qualification and either permits another person or another venue to use their license, or employs unqualified people to work in their venue and administer medicine, was prosecuted; and
5. All pharmaceutical companies contribute appropriately to market surveillance and control activities.

In regard to support by pharmaceutical companies, it should be noted that while 29 leading pharmaceutical companies have contributed to the Pharmaceutical Industry Initiative to Combat Crime administered by Interpol (Interpol 2016c), this commitment of €4.5m over three years amounts to slightly over €50,000 per annum per company. When spread across many countries, this amount is inadequate to contribute meaningfully to positive on-the-ground results that will impact the supply of illegal medicine in South East Asia.

Furthermore, only one pharmaceutical company can arguably lay claim to having sufficiently invested in market surveillance to achieve meaningful, regular seizures of illegal medicine in Cambodia in recent times. Greater support is required from the broader pharmaceutical industry given the scale of the public health issue that is now apparent in South East Asia.

6.2 Other Provinces in the Region need to be Targeted

SMCS Risk's investigations show that significant results can be delivered at the local level, on the basis of an established capability set and strong relationships with provincial authorities. There are an additional 18 provinces that need to be targeted in Cambodia alone, particularly the 14 provinces that border Thailand, Laos and Vietnam. Investigations in these areas are expected to yield further significant seizures and further improvements to the control of illegal medicine in Cambodia.

Provinces in Vietnam also warrant close attention. Vietnam was identified as a leading origin of unregistered product and a leading source of product named by offenders caught in possession of illegal medicine. Land borders between Vietnam and Cambodia are porous, and ethnic links on both sides are likely to have a significant impact on illegal cross-border trade (Khmer Vietnamese and Vietnamese Cambodians). Furthermore, Vietnam faces several looming challenges. Vietnam permits parallel imports and also permits manufacture by companies without Global Manufacturing Practice certification, a situation that complicates the control of illegal medicine and the attainment of acceptable standards in the market. It is also anticipated that the Vietnamese pharmaceutical industry will grow considerably in the coming period: greater regulation and enforcement is required on both sides of the Vietnamese-Cambodian border to ensure that the trade of illegal medicine doesn't also grow.

6.3 Importers and Distributors need to be Targeted

Greater attention and resourcing is required to curtail the illegal importers and distributors operating in Cambodia. They are a key point of potential influence to the system of supplying illegal medicine in Cambodia: targeting of importers and distributors has significant potential to deliver seizures and disrupt the supply chain to a far greater extent than operations on pharmacies and clinics. Importers and large distributors are key to the volumes of illegal medicine that enter the country, as well as presenting a key risk to corruption among authorities.

6.4 Local Law Enforcement Agencies Require Support to Develop Capability

Cambodians law enforcement agencies are developing skills and capabilities relevant to the issues surrounding illegal medicine. There are considerable challenges to this due to limited resources. Other stakeholders need to make more resources available to Cambodian authorities to improve the capabilities to detect, analyse and control illegal medicine.

We note that the agencies like UNODC, WHO and WTO are active or have been active in Cambodia, However, there is relatively little support for the development of local law enforcement relevant to pharmaceutical crime in Cambodia or Vietnam, particularly in recent times. Local law enforcement agencies would potentially benefit further from:

1. Capabilities to conduct packaging analysis for the identification of counterfeit products, as it may be a more cost-effective route than laboratory analysis.
2. Capabilities to collect and share data regarding seizures, to better allow comparisons and yield further information; and
3. Resources to allow local testing of suspected counterfeit product.

High returns on investment from programs run by leading pharmaceutical manufacturers and large multi-lateral institutions can be achieved where efficient collaborations with local law enforcement authorities have been established and maintained.

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