



INTERPOL

PHARMACEUTICAL CRIME SUB-DIRECTORATE

Pharmaceutical Crime and Organized Criminal Groups

**An analysis of the involvement of organized criminal groups in
pharmaceutical crime since 2008**



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EXECUTIVE SUMMARY

- INTERPOL member countries are reporting that criminals involved in pharmaceutical crime are operating through informal networks. Nevertheless, traditional organized crime groups across the globe are also involved in pharmaceutical crime throughout the supply chain.
- Several member countries have reported an increase in pharmaceutical crime during the past five years, especially in South and Central America.
- Both the informal networks and the organized crime groups seem to be trafficking in the same types of illicit medicines: erectile dysfunction medication; slimming pills; as well as pain and anxiety relief medication.
- A primary trend in many member countries is the increased use of illicit online pharmacies, operated by both informal networks and organized criminal groups.
- Large amounts of money are involved in these transnational criminal enterprises: one illicit online pharmacy network, which was dismantled by US authorities in 2011, managed to earn USD 55 million during two years of operations.
- Other crimes – such as money laundering, human trafficking for sexual exploitation and weapons smuggling – can also be tied to criminals involved in pharmaceutical crime.
- INTERPOL has also received increased reporting of illegal trafficking of Tramadol over the past year. The origin of shipments seems to be Asia, routed via the Middle East, with a final destination in West Africa.

LIST OF ABBREVIATIONS

B2B	Business to business
ED	Erectile dysfunction
HGH	Human growth hormone
MPCPC	INTERPOL's Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate
NCB	National Central Bureau
OCG	Organized crime group
PSI	Pharmaceutical Security Institute
UAE	United Arab Emirates
UK	United Kingdom
UNODC	United Nations Office on Drugs and Crime
US	United States of America

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1 INTRODUCTION

Pharmaceutical crime poses a grave danger to public health. Falsified medicines undermine people's faith in the health care system, while also threatening the lives of the most vulnerable members of society: the sick and frail.

Driven by financial gain, criminal elements have become involved in all facets of the chain of supply of illicit medicines, from manufacturing to distribution. In order to turn major profits, criminals are usually required to possess a high degree of sophistication and organization. Pharmaceutical crime, however, is generally not understood to be as organized as more established criminal activities, such as drug trafficking or people smuggling. In this regard, INTERPOL's Medical Product Counterfeiting and Pharmaceutical Crime (MPCPC) Sub-directorate has undertaken an analysis of available data from 2008 to present¹ to determine the extent to which organized criminal groups (OCGs) are currently active in the realm of pharmaceutical crime.

The following sections will provide an overview of the methodology employed for this analysis, and the specific definitions used to determine what constitutes an OCG and pharmaceutical crime for the purposes of this study. The remainder of the report will present the findings of the analysis – namely the scale of the problem of pharmaceutical crime and current trends, the structure and modus operandi of the OCGs involved in pharmaceutical crime, and related issues such as corruption, legislative and enforcement matters.

1.1 Methodology

For the purpose of this report, three main sources of information were used: questionnaire responses²; INTERPOL's database system (ICIS); and open source media articles³.

The questionnaire (see Appendix I) was designed to gain an understanding of the extent of pharmaceutical crime across all INTERPOL member countries since 2008. Information pertaining to the nature of OCGs – such as modus operandi, structure and scale of activities – was sought along with insights on the enforcement and legislative issues faced by organizations fighting pharmaceutical crime.

The questionnaire was distributed to all of INTERPOL's 190 member countries. In addition, networks such as the Permanent Forum on International Pharmaceutical Crime (PFIPC)⁴, the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO)⁵ and the Pharmaceutical

¹ Please note that this report contains information collected from 2008 until September 2013.

² 84 questionnaire responses were received from police (via INTERPOL NCBs), customs (via the World Customs Organization (WCO)), and drug regulatory authorities (via the Working Group of Enforcement Officers (WGEO) and the Permanent Forum on International Pharmaceutical Crime (PFIPC)).

³ Open-source monitoring was carried out through specific searches using Factiva, an online database providing access to articles produced by over 28,000 media sources. Further searches were carried out via search engines and on websites specialized in pharmaceutical crime and other medical issues.

⁴ PFIPC is an international enforcement forum aimed at protecting public health and safety through the exchange of information and ideas to foster mutual cooperation. The members of PFIPC are dedicated professionals from 15 countries worldwide whose goal is to enhance the protection of public health by combating pharmaceutical crime.

⁵ HMA WGEO was established to contribute to the protection of public health and animal health and welfare through ensuring adherence to the regulations of the manufacturing and distribution chains of medicinal products, the disruption of illegal activities and the sharing of information.

Security Institute (PSI)⁶ have also been instrumental in providing highly useful information through the questionnaires.

The questionnaire responses received were analysed to determine both global and regional results. The findings from the questionnaire responses provide the basis of the analysis below, together with data in ICIS and media articles accessed through open-source monitoring.

1.2 Definitions

1.2.1 Organized criminal group (OCG)

For the purpose of this assessment, an OCG is defined according to Article 2 of the 2000 United Nations Convention against Transnational Organized Crime:

“(...) structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences (...), in order to obtain, directly or indirectly, a financial or other material benefit.”

Broken down, this definition determines that an OCG fits the following criteria:

1. **Collective element:** significant group of criminals working together;
 2. **Structure:** hierarchical collective or network of criminals with specific roles;
 3. **Constant activity:** continual criminal activity over a significant period of time;
 4. **Large profit:** substantial profits gained from criminal activity.
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1.2.2 What constitutes pharmaceutical crime?

For the purpose of this assessment, pharmaceutical crime covers the following criminal offences, irrespective of which national legislation the crime falls under:

The manufacturing and distribution of counterfeit or falsified (spurious/fake/falsely labelled) pharmaceuticals or medical devices, through licit and illicit supply chains, involving:

- a. theft
- b. fraud
- c. diversion
- d. smuggling
- e. illegal trade
- f. money laundering
- g. corruption.

⁶ In 2002, the Security Directors from 14 major pharmaceutical companies established the Pharmaceutical Security Institute as a non-profit corporation based in the US. In total, eight pharmaceutical companies responded to the INTERPOL questionnaire. Out of the eight, three companies answered that they had observed an involvement of OCGs in pharmaceutical crime since 2008.

2 MAIN FINDINGS – PHARMACEUTICAL CRIME AND ORGANIZED CRIMINAL GROUPS

The primary aim of this report is to determine the extent to which OCGs are involved in pharmaceutical crime. Approximately 10 per cent⁷ of the questionnaire replies pointed to the involvement of traditionally structured hierarchical groups. Nevertheless, the majority of replies indicated that pharmaceutical crime is primarily the domain of criminals operating through informal networks.

Only two well-established OCGs, one each from Asia and North America, are known to be involved in pharmaceutical crime. Furthermore, motorcycle gangs, for example the ‘Hell’s Angels’, are known to be involved in the trafficking of medicines in both North America and Scandinavia. All three groups are primarily involved in other criminal arenas, in particular narcotics and weapons trafficking, while their pharmaceutical crime activities appear to be limited.

Apart from the aforementioned examples, it is apparent that well-established hierarchical OCGs are not heavily involved in pharmaceutical crime. The two following ‘types’ of OCGs seem to dominate this crime area:

- 1) Highly organized, yet generally informal, international affiliate networks selling medicines via illicit online pharmacies;
- 2) Small groups, not yet well established, of between 3-10 members, involved in various aspects of pharmaceutical crime.

The structure of groups and networks involved in pharmaceutical crime will be examined further in the ‘Structure and modus operandi’ section below.

2.1 Scale of activity

2.1.1 Increased level of reporting on pharmaceutical crime

A possible indicator of a general increase in pharmaceutical crime is the larger volume of media articles identified year after year since 2008 through open source monitoring conducted by the MPCPC Sub-directorate. This increase, however, may be accountable to increased media interest in such cases, or an increased crackdown by authorities which encouraged the publication of more articles. Only during 2013, MPCPC has registered several prominent cases from across the world with potential ties to OCGs involved in pharmaceutical crime, for example:

AFRICA

- In May 2013, one person was arrested for smuggling counterfeit medicines from China to Lagos, Nigeria. The illicit medicines included Coartem, Ibuprofen and Maloxine. The arrested suspect in Nigeria was unable to name any suspects in China involved in the smuggling activity. However, the scale of the smuggling operation indicates that there was involvement of an OCG.

ASIA

- In March 2013, Philippine authorities arrested five traffickers attempting to traffic slimming pills, pain relief medication and antibiotics which had been shipped to the Philippines from Singapore. Customs authorities confiscated a 40-foot container loaded with 20 pallets of fake medicines. Connections to a trading company indicates that the case is tied to an OCG.

⁷ 12 of the 84 replies to the questionnaires.

- Between 2011 and 2013, an OCG called Azuma-Gumi was running a counterfeit medicine operation selling Viagra, Cialis and Levitra in Osaka, Japan. In connection to this case, Japanese authorities reported that six people were arrested in 2013.

EUROPE

- In June 2013, during INTERPOL's Operation Pangea VI, Russian authorities reported that they had dismantled a counterfeiting operation which had been ongoing for several years in Rostov. Fake medicines such as Herceptin, Meronem, Cefobit, Mantera, Sulperason were manufactured and distributed by an OCG. In total, Russian authorities arrested seven suspects and carried out 23 raids in connection to this case.

OCEANIA

- In April 2013, open sources reported that three suspected counterfeiters were arrested with doping substances and Tadalafil in Christchurch, New Zealand. The three suspects were part of an OCG which distributed fake medicines in New Zealand. The investigation revealed that the group's leader was operating a sophisticated ring of distributors and using a pill press to make tablets, as well as an improvised lab in a garage.

SOUTH AMERICA

- In January 2013, Colombia informed that police authorities had arrested 21 suspects in an operation on the Colombian Atlantic Coast region. In total, 89,754 units of fake medicines were confiscated by law enforcement. The operation, named 'República DIPON 10', included 27 search warrants in the cities of Sincelejo, Monteria, Santa Marta and Leeds. The OCG, which was led by a ring leader and falsifying the expiration dates and batch numbers of medicines, was dismantled by the police.
- In June 2013, open sources reported that 10 people were arrested in Guatemala as part of an operation to take down an OCG. The group had a leader and operated from a legitimate pharmaceutical company, which was licensed to produce medicines. However, the OCG had taken advantage of this cover to produce illegal medication in order to increase the company's revenue⁸.

2.1.2 Results from INTERPOL questionnaire

Opinions among member countries⁹ are divided almost evenly as to whether or not there has been a rise in the level of pharmaceutical crime activities during the past five years. However, the situation is clearer for some regions, such as Latin America. All responders from South and Central America indicated an increase in the number of active groups, cases, seizures and arrests since 2008. In both regions, clear signs of counterfeit production were stipulated, with finished illicit medicines or raw materials for illicit production exported to other countries in the region. For example, yearly illicit profits in one South American country were found to total almost one-third of profits made in the licit pharmaceutical market between 2008 and 2012; the sale of licit pharmaceuticals was estimated to be USD 100 million and the sale of illicit pharmaceuticals to total approximately USD 30 million. Counterfeit and illicit medicines are also exported to other parts of the world via the Internet, with customs authorities from one South American country reporting almost 1,000 sales of medicines to countries in Asia from 2011 to the present. In 2012-13, an OCG in Guatemala established an

⁸ "Desarticulan en Guatemala banda que falsificada medicamentos", Agence France Presse, 8 June 2013.

⁹ 84 questionnaire responses received from police (41), customs (34) and DRAs (9). It should be noted that questionnaire replies from police and customs in two countries were identical, and thus results from these questionnaires have only been counted once.

underground supply chain in Latin America of local over-the-counter medicines. Guatemalan authorities carried out raids and arrested several suspects.¹⁰

In Europe and North America, several investigations in Canada, Sweden and the US have linked the Hell's Angels with the manufacture and distribution of counterfeit medicines, such as ED medication and steroids¹¹. In Europe, OCGs have been involved in robbing trucks transporting various prescription medicines since 2010. There have been reports from some European Union member countries that the stolen products have been found in the legal supply chain¹².

In Eastern Europe, it appears that OCGs are becoming increasingly involved in the manufacture and supply of doping substances, aimed primarily at amateur athletes and persons involved in body building. One country even indicated that amateur athletes are involved with criminal groups, a finding further substantiated by open-source cases that discussed the involvement of former athletes, coaches and owners of sports clubs in criminal rings.¹³ Counterfeits can be purchased from suppliers who advertise on business-to-business (B2B) e-commerce websites and then imported into countries where customs controls may be more lax. In Slovakia, suspects recruited local alcoholics and drug addicts to receive shipments containing counterfeit pharmaceuticals.¹⁴ This is suspected to be a growing issue, with one questionnaire reply indicating an increase in the production of counterfeits in the region, whereas previously, finished products were almost exclusively imported. However, efforts are being made to counter this trend: for example, during Operation Pangea VI in 2013, Russian authorities investigated 145 illicit online pharmacies, arrested two suspects and seized 9,535 units of illicit medicines.

In Asia there is a continuous demand for slimming pills, with an estimated 5 million slimming pills being consumed in Thailand alone each year¹⁵. Asia represents a large market with increased Internet connectivity and several strong developing economies, which are all lucrative factors for illicit online pharmacies and counterfeiters to take advantage of¹⁶. In recent years, a few noteworthy cases involving pharmaceutical crime and OCGs have occurred in the region:

- In 2009, an OCG with possible Triad connections was distributing counterfeit ED medication through local nightclubs and brothels in Malaysia. The primary suspect was identified as a Triad head, working for a Chinese syndicate in Kuala Lumpur. In Cambodia, a network with ties to the Japanese Yakuza was targeted for distributing fake medicines such as Viagra to patients in both Cambodia (via unlicensed pharmacies) and Japan (via websites).¹⁷
- In 2011-12, an OCG delivered counterfeit and diverted human growth hormone (HGH) products to various local subcontractors in China. Chinese authorities carried out raids and arrested several suspects.¹⁸
- In 2013, another pharmaceutical company identified a director of operations based in China who buys illicit medicines from Chinese manufacturers. The illicit medicine is then shipped via cargo container to Jordan, where it is distributed around the Middle East.¹⁹

¹⁰ Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

¹¹ Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

¹² Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

¹³ CTK Daily News, 26 July 2011, Czech police break up gang of fake anabolic producers; The Daily Telegraph, 18 May 2011, Britons arrested in Spanish drugs raid - Seven from UK among 26 held on dope charges Distribution ring linked to Glasgow and Manchester.

¹⁴ Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

¹⁵ <http://www.asiantribune.com/news/2003/01/28/govt-act-public-consumes-5m-slimming-tablets-year>

¹⁶ http://www.whpa.org/background_document_counterfeit_medicines_in_asia.pdf

¹⁷ Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

¹⁸ Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

However, for most regions, and in a more general global sense, it is difficult to determine an increase or decline in the level of pharmaceutical crime since 2008. Although challenging to conclusively define an escalation in pharmaceutical crime universally, it is clear that several global trends have developed in recent years.

2.2 Recent trends

Increased use of the Internet

The primary trend, as indicated in the majority of questionnaire replies, is the increasing use of the Internet to sell medicines. Only one European country indicated that the number of illicit websites registered in their country has decreased, due to enforcement action. Indeed, criminal elements are increasingly turning to the Internet to sell illicit products as it offers a high degree of security and anonymity for their actions. The profits earned from illicit online pharmacies are substantial, with one network in the US, active for five years, earning USD 55 million during two years of operation alone. Profits were laundered through the purchase of companies, often operating within the pharmaceutical industry, or through offshore banks in countries such as St Kitts and Nevis, and Panama. The increasing role of the Internet partly explains the augmenting involvement of informal networks, rather than traditional hierarchical groups, in pharmaceutical crime.

Prevalence of illicit ED medication

Another primary trend established from questionnaire replies was the increasing trade in ED medication, which has become a target to focus on for many customs agencies. These medicines constitute the vast majority of medicines sold online, with destinations all across the globe.²⁰ A large portion of cases extracted from open-source analysis further indicate the predominant rank of ED medication. Other lifestyle medicines²¹ and expensive medicines, such as those for the treatment of AIDS and cancer, are also reported to be sold in large numbers.

Prevalence of doping substances

The counterfeiting of doping substances also appears to be a growing and profitable field for criminals, especially in Eastern Europe. From questionnaire replies, three small international groups from this region were found to be involved in the production of counterfeit doping substances intended to be sold online or directly to athletes at sports clubs and gyms. One questionnaire reply exemplifies the clear involvement of small OCGs in trafficking steroids and doping substances across Eastern Europe. It was reported that, in cooperation with groups in at least two other countries in the region, raw ingredients²² were purchased from Asia and used in the production of counterfeit doping substances, which were subsequently sold in Europe and further abroad. Israel has reported that OCGs are smuggling steroids from Lebanon. Approximately two or three OCGs operate within Israel but control labs in the US. There is also a prominent courier network using foreign workers and 'tourists' from Moldova who smuggle in illegal substances, and in late 2012 there was a large seizure of anabolic steroids that were smuggled in from Moldova.

¹⁹ Response from PSI members regarding INTERPOL Questionnaire on Pharmaceutical Crime and OCGs.

²⁰ This finding is based on questionnaire replies and results from Operation Pangea. Operation Pangea is a yearly global operation, coordinated by INTERPOL, which brings together law enforcement, customs, drug regulatory authorities and the private sector to target the illegal online supply of medicines to the public.

²¹ For example, dietary supplements and hair-loss products.

²² The questionnaire reply also indicates that the groups travel to an Asian country to import finished medicines. However, the majority of their dealings in Asia concern the purchase of raw ingredients, as mentioned above.

Illicit medicines and narcotics

Two further questionnaire replies highlighted the importation of opioid-based analgesic medicines for illicit use in the production of narcotics and/or substance abuse. Open-source analysis indicates that large markets exist for the abuse of opioids themselves.²³ In the US, medicines such as oxycodone and hydrocodone are known to be diverted or stolen from pharmacies and sold without prescriptions. There are indications that large OCGs are trafficking in such medicines, with one well-established US-based OCG found in 2011 to be involved in the trafficking of counterfeit Vicodin, Oxycontin, Codeine, Xanax, and Percocet.²⁴ More recently, a small Seattle-based group was dismantled for trafficking and distributing large amounts of oxycodone.²⁵

Tenuous ties to terrorism

Multinational OCGs are similar in structure to multinational companies. The OCG in country A can be responsible for the production of counterfeit medicines, while another OCG in country B can be in charge of the distribution process of the illegal pharmaceuticals. Various groups cooperate when there is a mutual gain. For example, in East Africa the counterfeit industry is sourced mainly from India and China. A report to the United Nations Security Council has also established links between OCGs operating in East Africa and the terrorist organization Al-Shabaab: “An opportunistic and mutually beneficial kind of ‘pax commerciale’ has been established between those criminal networks and al-Shabaab”²⁶. However, there is no conclusive evidence of an established connection between OCGs operating within the pharmaceutical crime area and terrorism.

Increased trafficking of Tramadol

During the past year, INTERPOL has become aware of a sudden rise in the importation of Tramadol into Western Africa²⁷. Tramadol is a weak opioid receptor known to be used as a recreational drug which is suspected to be increasingly used as a substitute for heroin, with seizures similar to those witnessed in West Africa replicated in other regions, such as the Middle East. Several cases²⁸ from May 2012 alone indicate the extent of the issue in the United Arab Emirates, with 91 million tablets seized at Jebel Ali Port at the beginning of May, followed by three further seizures which led to the arrest of 10 individuals involving in distributing Tramadol. However, so far no links to organized crime have been established in relation to these cases.

In short, several trends have been identified through concrete cases but the identity of those responsible for carrying out these activities is still to be determined.

²³ US Department of Justice, 17 February 2012, Two New York men charged with selling fraudulent oxycodone prescriptions, <http://www.justice.gov/usao/nj/Press/files/Polo,%20Jack%20et%20al%20Arrests%20News%20Release.html> and David Giambusso, 31 August 2011, Twin sisters are charged with operating N.J. oxycodone distribution network, http://www.nj.com/news/index.ssf/2011/08/twins_sisters_are_charged_with.html

²⁴ Targeted News Service, 18 August 2011, ‘DEA San Diego/El Cajon PD Arrest 60 in Nine Month Operation’

²⁵ Seattle Time, 18 August 2012, Seattle-Area Raids Target Oxycodone Ring, <http://blogs.seattletimes.com/today/2012/08/federal-agents-searching-multiple-seattle-locations>

²⁶ United Nations, *Report of the Monitoring Group on Somalia and Eritrea*, UN Doc. S/2011/433, New York, 18 July 2011, para 76, p. 31.

²⁷ Various seizure reports received via the United Nations Office on Drugs and Crime (UNODC) Regional Office for West and Central Africa.

²⁸ Dubai foils Dhs1b drug smuggling bid, Gulf Today, 2 May 2012, <http://gulftoday.ae/portal/13d162bd-bad7-461b-82d7-96c2e1fb058e.aspx>; Seven suspected drug dealers arrested, Gulf News, 22 May 2012, <http://gulfnews.com/news/gulf/uae/crime/seven-suspected-drug-dealers-arrested-1.1026066>; Trio tries to sell tramadol pills to undercover police officer, 3 May 2012, Khaleej Times, http://www.khaleejtimes.com/nation/inside.asp?xfile=/data/courtroundup/2012/May/courtroundup_May4.xml§ion=courtroundup

2.3 Structure and modus operandi

2.3.1 Traditional hierarchical structure

A small number of questionnaire responses indicated that traditionally structured OCGs involved in pharmaceutical crime are small, with between three and 10 members. The groups have one primary leader, sometimes supported by deputies. The other members of the group have specific roles, such as those responsible for stealing medicines, counterfeiting medicines, and/or repacking and relabeling packages.

Such groups often sell counterfeit and illicit medicines at marketplaces, to dealers or street hawkers, and/or directly to pharmacies and medical centers. For more specialized medicines, such as doping substances, groups target specific locations to sell the medicines, such as gyms and sports clubs.

Groups involved in counterfeiting medicines vary as to their level of proficiency, from producing poor imitation pills and packaging²⁹ (misspelling, number of different languages, etc.) to high-quality counterfeits which are difficult to distinguish from genuine versions. The more sophisticated the product, apparently the more sophisticated the criminals responsible. For example, an international OCG based in the UK and dismantled in late 2011 produced counterfeit ED tablets physically identical to the genuine product and containing the required active pharmaceutical ingredient (API).

A recently published Europol threat assessment on counterfeiting concluded that there are a wide variety of actors operating within the pharmaceutical crime arena, encompassing both OCGs and individual criminals, both of which are involved at any point in the supply chain³⁰.

There are significant intelligence gaps when it comes to the extent of OCGs involvement in pharmaceutical crime, as well as intelligence on what other crime areas these OCGs might be involved in. Yet, the market is already large and expanding, providing opportunities for both OCGs and individual criminals to become engaged in pharmaceutical crime along the supply chain of counterfeit medicines. For OCGs involved in pharmaceutical crime there is often no need to resort to external violence – unlike OCGs which deal exclusively with illegal drugs such as heroin and cocaine – which allows these OCGs to keep a low profile and avoid law enforcement authorities. The comparatively low level of violence might also lower the threshold for individuals to join the pharmaceutical crime arena and become part of the supply chain³¹.

According to Europol and UNODC, there is also evidence to suggest that OCGs which are involved in the production of synthetic drugs have access to materials and expertise to also produce counterfeit medicines. Although there are significant intelligence gaps within this area, there are a few examples in both Europe and Southeast Asia where ‘criminal manufacturers of amphetamine-type substances have been involved in the production and distribution of counterfeit medicines’³². In addition, OCGs can also buy decommissioned machines from pharmaceutical factories, such as tableting machines, at auctions³³.

²⁹ The Moscow Times, 10 February 2012, ‘Ex-Cop Runs Bogus Drug Plant at Home,’

<http://www.themoscowtimes.com/business/article/ex-cop-runs-bogus-drug-plant-at-home/452818.html>

³⁰ Europol, 2013. *Threat Assessment 2013 – Counterfeit goods violating health, safety and food regulations and sub-standard goods*; p. 9.

³¹ Europol, 2013. *Threat Assessment 2013 – Counterfeit goods violating health, safety and food regulations and sub-standard goods*; p. 13.

³² UNODC, 2013. “Fraudulent essential medicines from East Asia to Southeast Asia and Africa” in *Transnational Organized Crime Threat Assessment – East Asia and the Pacific*; p. 136.

³³ Europol, 2013. *Threat Assessment 2013 – Counterfeit goods violating health, safety and food regulations and sub-standard goods*; p. 9.

Medicines also illegally enter the pharmaceutical market through theft or diversion, with small criminal groups specializing in the robbery of medicines which are then resold to secondary distributors and wholesalers, or, as is often the case, directly to pharmacists. From here, the medicines make their way back into the licit market. For example, Brazil's Internal Affairs Division seized 61 boxes of stolen medicines at legitimate clinics in Sao Paulo in late 2011.³⁴ One example of diversion is antimalarial medicine diversion, which has been seen across numerous African markets. This type of diversion can lead to serious stock shortages in the public sector, which can be dangerous to countries with high numbers of infected patients.

Nevertheless, only a small number of respondents indicated the involvement of classic hierarchical organized criminal elements in pharmaceutical crime. Instead, most replies highlighted that groups are far less conventionally structured, especially those selling medicines online, a growing trend in recent years.

2.3.2 Informal network structure

The networks are often globally dispersed, with one person or a small group directing the overall actions of the network engaging a group of associates to sell medicines for them via affiliate websites.

These networks are composed of thousands of affiliate websites run by associates who are paid on commission for sales made through their sites.³⁵ As a result, the activities of the core network members are incredibly difficult to track, allowing many network operators to evade detection for long periods of time. For example, several groups identified to INTERPOL were found to have been active for up to 10 years before being dismantled.

Networks also often informally involve botnet³⁶ operators that are paid on commission for each customer directed to an affiliate network website from a spam advertisement. For example, in 2008, a Russian network was found to be recruiting botnet spamming partners to advertise its illicit online pharmacy network. The network also used a covert system for processing orders online, indicating the high skill level of those running the network.³⁷

Those operating online pharmacy networks are predominantly not involved in the production of counterfeit or illicit medicines themselves.³⁸ Instead, medicines are bought from the original manufacturing countries, resold over the Internet through both their own and affiliate websites, and distributed through regular mail or courier services. Those working within this network structure often do not know each other. For example, in one European case a suspect importing counterfeits from Africa only knew an intermediary from another European country, and in fact did not know where the counterfeits were produced, or from whom they were purchased. This

³⁴ BMI Industry Insights - Pharma & Healthcare, Americas, 17 August 2011, Industry Trend Analysis - Medicine Thefts Plague Country's Public Hospitals.

³⁵ Affiliate websites are linked to the core website(s) of the network. In most cases, prospective clients are redirected from the affiliate website to the principal network website(s) at some point before purchasing the medicines.

³⁶ A large number of private computers which have been infected with malicious software and are controlled collectively by a third party without the knowledge or consent of the owners. The computers are set up to forward transmissions, for example spam advertising medicines sold on illicit online pharmacies, to other computers on the Internet.

³⁷ Middle East Company News, 'IronPort research reveals link between malware botnets and illegal online pharmaceutical supply chain,' 28 August 2008.

³⁸ Agence France Presse, Six arrested in fake medicine bust: Europol, 19 March 2012 and Philippines: CIDG neutralizes counterfeit drug ring, 3 April 2012, Thai News Service.

compartmentalization is a contributing factor to the difficult task of establishing the full extent of the workings of such networks.

Networks also have a high level of sophistication and are often structured to resemble the organizational makeup of a genuine enterprise. For example, two European countries indicated that suspects have very specific roles, such as dealing with website customers, updating websites, acting as an administrator, acting as an accountant, and handling order forms. Another European respondent highlighted that a member of a network which distributed unlicensed and counterfeits via the Internet documented every step of the illicit transactions in a database. The group had an elaborate global structure, with logistical chains established in various countries. These findings are further corroborated by a recent academic study in which researchers gained access to client lists and highly detailed accountancy documents from several major affiliate networks.³⁹ The level of sophistication and coordination of these online networks clearly stems from the fact that they are attempting to present the illusion that they are a genuine company.

Similarly, Israel has reported that the illicit online pharmaceutical companies often mimic the structures of international marketing or financial companies, with Israel as the hub and other countries acting as the producers and distributors. This way there are no customs violations since not a single drug is imported or exported from Israel. Financially, it is difficult for authorities to trace the money that is being laundered via other countries and through legitimate companies in Israel. One indicator is that many of these companies have very compartmentalized marketing and finance departments and a large computer maintenance department.

As a result, such informal networks are difficult to target. Despite the best efforts of law enforcement through initiatives such as Operation Pangea,⁴⁰ the activities of illicit online pharmacy networks continue to flourish. Additionally, environmental factors – such as corruption, enforcement and legislative shortfalls – have a significant effect on the ability of law enforcement agencies to tackle both affiliate networks and more traditionally structured OCGs.

2.4 Corruption, enforcement and legislative elements

Several roadblocks lie in the way of disrupting this criminal activity. The three main challenges relate to:

- corruption
- enforcement
- legislation

Legislative and enforcement insufficiencies at both the national and international levels are major hindrances preventing countries from taking action. Furthermore, the corruption of those within the licit pharmaceutical industry by high-profit criminal enterprises is also a factor.

2.4.1 Corruption

Corruption was found to exist in several countries which responded to the questionnaire, with replies indicating varying degrees of corruption, from low levels at hospitals to higher levels at wholesalers,

³⁹Damon McCoy, Andreas Pitsillidis, Grant Jordan, Nicholas Weaver, Christian Kreibich, Brian Krebs, Geoffrey M. Voelker, Stefan Savage, and Kirill Levchenko, Proceedings of the USENIX Security Symposium, Bellevue, WA, PharmaLeaks: Understanding the Business of Online Pharmaceutical Affiliate Programs, August 2012.

⁴⁰Since its inception in 2008, Operation Pangea has shut down more than 46,337 illicit online pharmacy websites.

registered pharmacies and local markets. In particular, highly profitable online networks possess the financial pull necessary to corrupt those within the licit pharmaceutical industry. Cases in the INTERPOL database system indicate that such networks have paid pharmacists to fill fraudulent prescriptions and physicians to review medical questionnaires filled by prospective patients. Further examples are found in open sources, including a recent case in India which pointed to the suspected involvement of 12 doctors at two hospitals with a criminal group supplying counterfeit medicines. The doctors are suspected to have knowingly prescribed prescription medicines in order to gain large commissions.⁴¹

Likewise, criminals have been found to also be qualified pharmacists or doctors, holding positions within genuine pharmacies and diverting medicines or buying known counterfeit medicines in order to make private gains. Criminals are also known to operate the pharmacies themselves, as well as wholesalers,⁴² distribution companies and other facilities, leading to the development of criminal rings in which counterfeit and illicit medicines are moved through the legal supply chain. One example from 2012 highlights this issue, with two New York pharmacists found to be involved in purchasing almost USD 274 million worth of illegally obtained HIV and AIDS medication since 2008 through a distribution network run by another suspect.⁴³

There are also indications that government and law enforcement officials have been corrupted in certain countries. From a few open source cases, government officials are known to have had direct involvement in criminal activities, helping to embezzle government medication as was the case in the Sialkot region of Pakistan in 2010.⁴⁴ In a prominent case from a country in South America in 2009, illegally imported, expired and counterfeit medicines were knowingly supplied to a pharmacy and union-run healthcare centre whose deputy director was later arrested for his involvement.⁴⁵ Thus, although not prominent or well documented at this time, corruption does occur within the licit pharmaceutical industry⁴⁶. With the increase in the use of illicit online pharmacies, one can expect a future rise in the level of corruption of pharmacists and medical professionals at clinics and practices, notably through fictitious prescriptions and other medical documentation.

2.4.2 Enforcement

The degree of resources allocated to fighting pharmaceutical crime varies greatly from country to country. A little more than half of respondents⁴⁷ indicated that sufficient resources are dedicated to targeting the issue. Even among those who responded positively, marked differences were evident in the number of enforcement officers targeting pharmaceutical crime. For example, several countries have large and well-established units dedicated to fighting pharmaceutical crime, while others proactively target criminal elements utilizing non-dedicated officers from various other units.

On the other hand, a little more than 40 per cent of replies found that levels of enforcement were not sufficient in their country. The inadequacy of enforcement is found to be chiefly caused by a lack of officers dedicated to working on pharmaceutical crime, or too few dedicated officers to cover the entire country. This is especially true with regards to the lack of dedicated IT crime units in many national police administrations.

⁴¹ The Times of India, Dept. seeks report on doctors guilty of prescribing fake drug, 22 October 2012.

⁴² Associated Press, Puerto Rico indicts suspects in \$650M prescription drug scheme affecting US pharmacies, 14 December 2012.

⁴³ Newsday, 5 April 2012. 'Drugs sold to HIV, AIDS patients may have expired'.

⁴⁴ The Daily Post, 7 October 2010. '5 accused in government medicine scam jailed.'

⁴⁵ Fake Medicaments Scandal Could Implicate Argentine President, Irenia Renuncio Mateos, 10 September 2009, HIS Global Daily Insight Analysis.

⁴⁶ <http://www.who.int/mediacentre/factsheets/fs335/en/>

⁴⁷ Excluding those who answered the questionnaire but did not specifically answer the question on the sufficiency of law enforcement.

2.4.3 Legislation

There was a general positive consensus among questionnaire replies concerning current legislation. More than two-thirds of respondents found current national legislation to be sufficient in tackling the issue of pharmaceutical crime. Most replies indicated that pharmaceutical crimes can be adequately prosecuted under more general criminal codes.⁴⁸

However, most countries do not possess legislation directly addressing pharmaceutical crime. Rather than examining pharmaceutical crime as a specific type of crime requiring specialized legislation, many countries continue to place it under the category of intellectual property crime or use existing criminal law on narcotics or fraud.⁴⁹ As a result, almost one-third of replies stated that countries do not possess the necessary legal apparatus to effectively target the issue, while others argued that penalties were far too low for the offences committed.

Certain countries have specific laws related to medical products and pharmaceuticals, with strict penalties currently in place for criminal activities such as counterfeiting and trafficking of illicit medicines. Several countries also indicated that, although their national legislation is not currently sufficient, new specific legislation is being developed or will soon be adopted. Additionally, several European countries have made positive comments in relation to upcoming European Union legislation⁵⁰, which is found to be more specific and effective than current national legislation and will impose more stringent and proportionate penalties for pharmaceutical crimes.

⁴⁸ Examples – illegal use of a trademark, fraud, anti-doping legislation.

⁴⁹ The Jakarta Globe. 12 April 2012. 'Editorial: Fake Drugs a Problem Both Penal, Systemic.'

⁵⁰ They are referring to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) - <http://conventions.coe.int/Treaty/EN/Treaties/Html/211.htm>

3 CONCLUSION

Pharmaceutical crime is a multifaceted criminal area. We see varying forms of criminal organizations involved in pharmaceutical crime, ranging from small clusters of three to 10 members, to larger well-established hierarchical groups, to sophisticated international networks with elusive structures. With the move to the Internet to sell counterfeit and illicit medicines, law enforcement agencies are increasingly dealing with the latter form of criminal enterprises. Such networks are difficult to target due to the ease with which they can move and establish new websites, the high level of anonymity offered in the virtual world, and the difficulty in piecing together the different criminals involved in wide-ranging affiliate networks.

Authorities are also faced with auxiliary challenges, such as corruption within the licit pharmaceutical community and a lack of dedicated national enforcement units to tackle the issue. This second point is especially alarming given that criminals are increasingly using the Internet to carry out their activities and are, in turn, developing sophisticated techniques to avoid detection. As a result, there is a need to enhance the number of specialized enforcement officers dedicated to targeting the ever evolving online activities of criminal networks.

Some INTERPOL member countries also face legislative challenges to thwarting those responsible for pharmaceutical crime, as few countries appear to possess specific legislation to target this type of crime. Furthermore, many countries cited poor penalties as a contributing factor for the proliferation of criminal networks, who are encouraged to continue to take risks as the rewards outweigh the potential punishments.

Yet from many questionnaire replies, there is an apparent confidence that enforcement and legislative structures currently in place are strong enough to tackle the issue of pharmaceutical crime. The law enforcement community is gradually gaining a fuller picture of the scope of such criminal activity and the structures behind it. For example, there is already a recognition of the problem of the sale of medicines online, illustrated by the growing global interest in participation in Operation Pangea, which reached 100 participating countries in 2012.

This study has also highlighted the need for law enforcement and the public health sector to work together in order to prevent illicit medicines from entering the market and to prosecute those responsible once it does. Some countries have employed a well-functioning multi-agency approach, with close communication between law enforcement officials and public health employees in order for both sectors to gain a better understanding of the challenges within each specific field.

Such coordination and concerted efforts are a step in the right direction to effectively combat pharmaceutical crime. In the long term, this will serve as a prime antidote against a crime area in which traditional structures are being replaced with more dynamic and constantly evolving network-orientated criminal enterprises.

4 APPENDIX I – INTERPOL QUESTIONNAIRE

Questionnaire

Pharmaceutical Crime and Organized Criminal Groups (OCGs) 2008 - present

Before answering the questionnaire, please refer to the definition of an OCG below. If such groups are not active in your country, please provide information on other types of criminal activities related to pharmaceutical crime in your country by attaching documents.

Definition of an organized criminal group (OCG)

For the purpose of this assessment, an OCG is defined, according to Article 2 of the 2000 United Nations Convention against Transnational Organized Crime, as a:

“(...) structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences (...), in order to obtain, directly or indirectly, a financial or other material benefit.”

When broken down, this definition determines that an OCG fits the following criteria:

5. **Collective element:** significant group of criminals working together;
6. **Structure:** hierarchical collective or network of criminals with specific roles;
7. **Constant activity:** continual criminal activity over a significant period of time;
8. **Large profit:** substantial profits gained from criminal activity.

1. Has there been a noticeable increase in OCGs involvement in pharmaceutical crime in your country since 2008?

If yes, how have you identified the increase?

Click here to Enter Details of how you identified this increase.

2. Please provide details on common Modus Operandi of OCGs involved in pharmaceutical crime in your country.

Click here to Enter Information on common Modus Operandi

3. Please provide details on the common structure (hierarchy, network, etc.) and size of OCGs involved in pharmaceutical crime in your country.

Click here to Enter Information on common Structure and Size of OCGs

4. Have you witnessed any trends specific to the activities of OCGs in pharmaceutical crime since 2008 (e.g. increased use of Internet to sell medicines, increase in seizure of specific types of medicines, etc.)?

If yes, please provide details on each trend:

Click Here to Enter Details on Trends

5. Since 2008, to which scale have OCGs from your country been active in pharmaceutical crime (none, low, medium, high)?
 - a. *Groups operating on a regional level:* -----
 - b. *Groups operating on a national level:* -----
 - c. *International groups (2 or more countries)* -----

6. OCGs are involved in the counterfeiting of which types of medicines and medical products in your country? Please provide details (seizure figures, percentages, etc.).

Click here to enter details of types of medicines seized.

7. Since 2008, how many OCGs active in pharmaceutical crime have been:
 - a. *Investigated?* *Click Here to Enter Number*
 - b. *Dismantled?* *Click Here to Enter Number*

8. Since 2008, how many suspects have been prosecuted for pharmaceutical crime?
 - a. *Suspects Arrested?* *Click Here to Enter Number*

9. Are OCGs involved in pharmaceutical crime also linked to other crime areas (drug trafficking, human trafficking, etc.)?

If yes, please provide details for each crime area.

Click here to enter details on links to other crime areas.

10. Have OCGs corrupted employees in the following facilities, and to what extent? (none, low, medium, high.)
 - a. *Registered Pharmacies* -----
 - b. *Hospitals/Clinics* -----

- c. *Wholesalers* -----
- d. *Manufacturers* -----
- e. *Markets/Street Vendors* -----
- f. *Government Officials* -----
- g. *Customs Officials* -----
- h. *Enforcement Officials* -----
- i. *Other* -----

11. a) How many law enforcement officers are currently working on pharmaceutical crime in your country? [Click Here to Enter Number](#)

b) Is this sufficient to tackle pharmaceutical crime?

If Yes, please provide details:

[Click here to enter details.](#)

12. Is there sufficient legislation in place in your country to effectively target pharmaceutical crime?

If Yes, please provide details:

[Click here to enter details](#)

13. a) If information is available on specific OCGs, please attach documents providing an overview of each group (MO, number and roles of members, scope of activities, etc).

[Click here to enter details on criminal groups OR alternatively attach documents](#)

b) Please also use the space below to provide any additional comments on pharmaceutical crime in your country, and any other information you may deem important.

[Click here to enter additional comments.](#)

► **ABOUT INTERPOL**

INTERPOL is the world's largest international police organization. Our role is to assist law enforcement agencies in our 190 member countries to combat all forms of transnational crime. We work to help police across the world meet the growing challenges of crime in the 21st century by providing a high-tech infrastructure of technical and operational support. Our services include targeted training, expert investigative support, specialized databases and secure police communications channels.

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