Asia Pacific Economic Cooperation
Toolkit to Combat Illegal
Internet Medical Product Sales

(12-07-2015)

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I.   Introduction

This toolkit, developed by the Internet Sales Working Group of the Asia Pacific Economic Cooperation (APEC) *Roadmap on Medical Product Quality and Supply Chain Integrity* project under the Regulatory Harmonization Steering Committee (RHSC), is a collective resource and recommendations guide.[1] The draft Internet Sales Toolkit was reviewed during the August 2015 APEC Internet Sales training program in Cebu, Philippines.This revised Toolkit reflects the comments and discussion during this workshop.

The purpose of this toolkit is to educate governments, healthcare professionals, consumer safety groups, and consumers directly about the growing problem of illegitimate medical products being sold via the Internet. The toolkit recommendations and resources underscore the need for stakeholders to take action to make the Internet safer for consumers.

In this toolkit, the Internet Sales Working Group has provided an overview of best practices to combat illegal Internet medical product sales, as well as recommendations and tools to combat the issue. The toolkit is designed as a resource guide, and provides examples of voluntary initiatives that may be replicated across APEC economies. For reference, a list of definitions can be found in *Appendix C*.

Based upon the feedback during the August 2015 Cebu training program, the Internet Sales Working Group will revise the toolkit and will distribute the revised toolkit to participants for further review. Following a reasonable comment period, the toolkit will be finalized and submitted to RHSC for review, endorsement, and housed by the RHSC secretariat for future access by APEC economies.

II.   Background on APEC Engagement on the Issue

In 2012, the APEC Life Sciences Innovation Forum (LSIF) approved a five-year project to develop the *Global Road Map for Medical Product Quality and Supply Chain Integrity* (Road Map). Specific areas being explored are:

- sale of medical products via the Internet (the subject of this toolkit),

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[1] This draft toolkit is based upon the results of an Internet Sales Working Group survey analyzed by the University of Tennessee Health Science Center, a "Best Practices Document - Safe Online Pharmacies" developed as a work product following the May 2013 APEC Medical Product Safety Workshop in Seoul, Korea, materials from the Alliance for Safe Online Pharmacies, and the Center for Safe Internet Pharmacies' (CSIP) Principles of Participation.

- good distribution practices,
- good manufacturing practices and quality management systems,
- import and export practices,
- detection technologies, and
- establishment of a single point-of-contact (SPOC).

The online purchase of unsafe medicines by consumers is a significant and growing problem across APEC economies and around the world. Working to prevent illegal Internet sales and to support legitimate Internet sales (in markets where they are permitted by law) is a work stream being addressed by the Internet Sales Working Group. There have been several previous APEC workshops focused on safe medicines.[2]

III.   Scope of the Problem

Illegal online medical product sellers, sometimes called rogue online or Internet "pharmacies," threaten the health, lives, privacy, and security of Internet consumers globally. According to multiple sources,[3] at any one time, there are approximately 40,000-50,000 active online medical product sellers worldwide, and 93-96 percent of them are operating illegally. Operating illegally, these sellers operate not in compliance with laws of the jurisdiction in which they are located, or to which they are selling products. These criminals target consumers globally and can generate between $1 million USD and $2.5 million USD in sales each month.[4]

APEC economies are adversely impacted by the manufacture and distribution of substandard, spurious, falsified, falsely labeled, and counterfeit (SSFFC) medical products. Today the Internet is the largest marketplace for SSFFC medicines, with 1 in every 2 medicines sold online reported to be counterfeit.[5] While a significant percentage of online medical product sellers are illegal, some online pharmacies provide legitimate services supplying legitimate health products to consumers. The rise of online medical product sales can be attributed to increased Internet usage, technology access, and Internet commerce — all of which are on the rise and expected to increase in the future.

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[2] http://www.nifds.go.kr/apec/content/view.do?contentKey=152&menuKey=64
[3] LegitScript, LLC; generally consistent with the findings of World Health Organization (WHO) and National Association of Boards of Pharmacy (NABP).
[4] MIT's Technology Review; University of California San Diego, 2011.
[5] http://www.who.int/mediacentre/factsheets/fs275/en/

The confluence of numerous global trends — increasing use of the Internet, limited access to or inconvenience of seeing a healthcare professional, rising consumer confidence in online shopping, ongoing demand for medication, and high prescription medical product costs — foreshadow an even bigger global market for illegal online medical product sellers, exacerbating the already significant consumer safety threat. Moreover, APEC economies, like all countries, are impacted by globalization whereby the supply chain of medical products complicates traditional mechanisms of oversight. It is within this context that stakeholders — including national regulatory authorities (NRAs), law enforcement, customs officials, non-governmental organizations (NGOs), manufacturers, distribution companies and Internet commerce companies — must act to protect consumers who may be shopping online for medical products.

As criminals become more sophisticated in how they promote and transact illegal online medical product sales, stakeholders listed above must work more effectively together to protect consumers.

IV. Recommendations to Combat Illegal Internet Medical Product Sales

In 2014, the Internet Sales Working Group conducted a survey of how APEC economies address Internet sales of medical products through a qualitative and quantitative survey (*see Appendix B.1*). The purpose of the survey was to explore how each economy addressed the following:

- *Capacity*: Legal, regulatory, enforcement, and laboratory;
- *Standards/regulatory convergence*: Identifying areas where standards development and regulatory convergence are needed;
- *Information sharing*: Including technological means and needs; and
- *Collaboration and cooperation*: Identifying global and regional venues for collaboration, cooperation, and oversight of implementation of the roadmap, bringing together regulators, industry, law enforcement, border protection agencies, and other stakeholders.

The survey was specifically directed at each economy's NRA, with ten APEC Economies (of a possible twenty-one) responding to the survey. The following recommendations were developed based on an examination of policy gaps and best practices informed by the Internet Sales survey. Specific examples are provided in the appendices as referenced.

Recommendation 1

Develop and deliver public awareness activities, including targeted education campaigns, to educate consumers and healthcare professionals about the threat of illegal online medical product sellers and how to purchase medicines safely. Publicly available educational materials and statistics from credible resources are available for use which can be translated and disseminated in each APEC economy. (*See Appendix A.1*)

Recommendation 2

Strengthen laws and policies to protect consumers from medical products purchased online. (*See Appendix A.2*)

Recommendation 3

Distinguish the safe, legally-operating online pharmacies that sell to consumers from the illegal online medical product sellers doing the same. (*See Appendix A.3*)

Recommendation 4

Establish Model Voluntary Protocols for Internet commerce companies. (*See Appendix B.2*)

Recommendation 5

Participate fully in INTERPOL's Operation Pangea and other cooperative international activities, including the World Health Organization Member State Mechanism on SSFFC.

Recommendation 6

Establish effective NRA, customs, and law enforcement coordination to remove rogue Internet sites using the Single Point of Contact (SPOC) system as appropriate.

Recommendation 7

Ensure active participation by policymakers to take a leadership role in preventing the manufacture and distribution of SSFFC medical

products. (*See Appendix A.4*)

Recommendation 8
Involve all stakeholders in creating solutions, including private sector organizations, governments (with representation from different functions, i.e. health product regulation, compliance and enforcement, technical expertise related to e-commerce investigations, and law enforcement), Internet commerce companies, consumers, and healthcare professionals.
Recommendation 9
The activities under the Internet Sales Toolkit should be closely aligned and coordinated with activities conducted pursuant to the APEC Single Point of Contact toolkit.

Appendix A – Detailed Recommendations

Each NRA should be clear whether the purchase of medicines via the Internet is a legal activity within its economy. The APEC Internet Sales Working Group recognizes and respects that this critical decision must be made internally within each APEC economy and does not advocate a position either way.

The recommendations below remain important to keep consumers safe from illegal online medical product sellers. APEC Economies where Internet sales are forbidden should utilize the suggestions below to educate their citizens about the restrictions on online sales. Those where online sales are permitted should focus on delineating between legitimate and illegal online sellers and educating consumers about the differences.

Regardless, all APEC economies should utilize the recommendations in this toolkit to improve enforcement efforts against illegal actors. Policies should be implemented that allow for NRAs to more efficiently investigate and prosecute actors engaged in the illegal sale of medical products on the Internet.

A.1   Public awareness

Public awareness is a key component of sustained success in combating illegal online medical product sellers. By raising public awareness, consumers will be aware of the risks inherent with purchasing medical products online.

NRAs and enforcement authorities, healthcare professionals, private industry, and consumers each fulfill an important role with respect to public awareness:

National Regulatory Authorities and Enforcement Authorities

NRAs and enforcement authorities play an important role in preventing SSFFC medical products sold over the Internet from reaching consumers in their respective APEC economies through rigorous interdiction efforts and investigations to secure the legitimate supply chain and deter against illegitimate channels for products sold by illegal online medical product sellers. Training of law enforcement officials related to the public health consequences of SSFFC medical products is an important component of this toolkit.

Training is necessary to explain the threat to law enforcement and empower officials to impose effective investigations and deterrents to criminals. Additionally, training is necessary to facilitate effective coordination with other relevant authorities and to ensure excellent communications to the public regarding cases of SSFFC medical products seized, arrests conducted, and prosecutions carried out. This form of public awareness can serve as a deterrent, both to those engaging in criminal activities or those considering purchasing unsafe medicines.

The ability to draw connections between a cybercriminal and the various components of the domain name system are critical tools for any law enforcement investigator: understanding Whois, IP addresses, name servers, mail servers, start of authority records and numerous other fields allow investigators to keep pace with, or stay a step ahead of, online criminals.

In this context, understanding the role that registrars and registries play and the contractual structure under which they operate is imperative for law enforcement. In particular, registrars and registries have the unique capabilities to "turn off" a domain name and make the portal through which most Internet users access a dangerous or illegal website inaccessible. Understanding how to make this happen and when it is appropriate - and what to do if it does not happen - is critical knowledge for any law enforcement official investigating cybercrime.

Private Industry

Private industry — including medical products manufacturers, retailers, Internet commerce companies, etc. — is also an important partner to help deliver the message on the threat to public health from SSFFC medical products sold over the Internet. In many cases, stakeholders in private industry are the first to communicate reactively or proactively regarding cases of counterfeit or falsified versions of their products. Likewise, many industry associations and individual companies are interested in promoting consumer safety and medical product safety awareness, through public-private partnerships or their philanthropic efforts. In many cases, industry is well-suited to initiate or support education campaigns, thereby helping campaigns reach a wide segment of the population.

Healthcare Professionals
Because of their direct contact with the public, healthcare professionals play a critical role in protecting consumers from SSFFC medical products sold over the Internet by:

- Sourcing medical products only from legitimate suppliers;
- Raising public awareness among consumers to the presence of SSFFC medical products sold over the Internet and the threat that they pose;
- Responding to public reports by consumers of suspected SSFFC medical products; and
- Alerting consumers, colleagues, and health authorities to the confirmed presence of SSFFC medical products sold over the Internet.

Though healthcare professionals may find it difficult to dedicate large amounts of time to engaging in direct communication with consumers, effective training and education to HCPs, as well as the use of effective educational materials upon display in their place of practice, can help to ensure that professionals and consumers are more alert and responsive to the prevalence and potential health implications of SSFFC medical products. By displaying public awareness materials developed by NRAs, law enforcement and private industry (including posters, pamphlets, etc.) and raising the basic level of awareness for the public, healthcare professionals can play a crucial role in the solution.

Consumers

Consumers have a responsibility for the maintenance of their health and the safe use of medical products. As such, consumers are encouraged to source their medical products from reputable sources, to use those products according to the manufacturer's instructions, and to only use medical products that have been authorized for sale by the NRA where they live. Government should educate consumers to watch out for red flags that indicate the medical product is being sold by an illegal online medical product seller. For example, illegal online medical product sellers will allow consumers to purchase medical products without a prescription and/or offer deep discounts that are too good to be true. Consumers should be aware of the risks associated with sourcing medical products online. Should consumers experience any problems, including adverse reactions/malfunctions or should they have questions about the quality, safety, or efficacy of the medical products they intend to use, they are encouraged to contact their healthcare professional or their NRA.

Mechanisms to raise public awareness include:

a. Facilitate public speaking at key events;

i. Invite groups focused on the issue of illegal online medical product sellers to speak with media, at public events, or with policymakers.

b. Educate key stakeholders through online and traditional media (posters, pamphlets, TV, radio);

    i. Consumer education videos (e.g., the ASOP-CSIP joint public service announcement being displayed in New York City's Times Square);

    ii. Search engine advertising (e.g., the screenshot from a CSIP ad placed through Google's AdWords service);

    iii. Develop a newsletter (e.g., ASOP's bi-weekly newsletter shown below); and

    iv. Run a public education campaign national video contest (e.g., CSIP's Tongal campaign).

c. Direct education to consumers through discussions with their healthcare professionals and pharmacists;

d. News and media engagement - educate journalists about the issue;

e. Coordinate efforts among NRAs, law enforcement, media and industry in order to maximize the reach to the public;

f. Establish a government-sponsored hotline (telephone number and/or user-friendly website) for the public to report suspected SSFFC medical products;

g. Educate segments of the population, including remote or rural areas, where citizens have limited access to medical products and information;

h. Establish a public awareness task force to engage in training as an important element of effective public awareness campaigns; and

i. Conduct analyses of the volume of medical products sold online to better understand the scope of the problem.

A.2 Strengthen laws and policies to protect consumer safety

Few countries have adequate legal frameworks or policies specific to the issue of Internet sales of medical products. Legal frameworks provide an authority to which violators are held to account while policies help to provide direction on how goals and objectives will be achieved.

Below is a list of potential laws and policies to strengthen and to protect consumer safety:

a. Create or modify national laws that address the threat of SSFFC medical products specific to Internet commerce (such as requirements for online verification technology) e.g., the European Union Falsified Medicines

[Directive](#) that creates a 'common logo' for implementation by Member States;

b. Grant enforcement authorities the statutory authority to act against illegal online medical product sellers;
c. Encourage oversight and collaboration from all levels of government, including national, provincial/state and local governments;
d. Engage in increased international and domestic collaboration;
e. Ensure that sufficient enforcement activities take place at regular intervals;
f. Establish more stringent penalties for illegal sale of medical products via the Internet; and
g. Conduct law enforcement training programs on:
    i. How to apply a legislative and regulatory framework applicable for Internet sales of medical products;
    ii. How to coordinate across government agencies;
    iii. How to identify suspicious websites; and
    iv. How to use forensic IT techniques.

A.3   Distinguish safe, legally-operating online medical product sellers from illegal online sellers

Some online pharmacies provide legitimate services supplying legitimate health products to consumers. The following recommendations enable APEC Economies to differentiate between legitimate and illegal actors:

a. Encourage the use of common terminology specific to Internet sales of medical products between national and international authorities;
b. Enforce against websites that are not operating legally and/or are not on the approved national registry; and
c. Meet with Internet commerce companies regarding their own policies to encourage voluntary action;
    i. One example of best practices is outlined in CSIP's Principles of Participation (*See Appendix B.2*)
If Internet sales of medical products are permitted, consider the use of a top level domain as a tool to publically identify legitimate online pharmacies. An example of one emerging *initiative*, amongst others is the *.pharmacy* initiative, found at www.safe.pharmacy. The .pharmacy top level domain will be available to pharmacies and other entities offering prescription drugs or prescription drug-related products, services, or information via the Internet, subject to their completion of the registrant application and approval process to establish compliance with all applicable laws and .pharmacy program standards. The application and approval process

includes vetting by NABP prior to registration to ensure that they meet all applicable regulatory standards, including those addressing pharmacy licensure and valid prescription requirements.

A.4   Actions for policymakers to address illegal online sellers

Policymakers across APEC Economies play a leadership role in setting the priority of addressing the illegal sale of medical products online. The following are a list of recommendations that can enable a clear and supportable course of action to addressing the issue:

a. Adopt laws that criminalize illegal online medical product sales;
b. Ensure adequate resources to enforce the Internet-specific laws;
c. Provide training for those officials responsible for enforcing those laws;
d. Support campaigns to raise awareness among healthcare professionals and the public of the threat of purchasing medical products online; and
e. Create opportunities for regional and global collaboration specific to illegal online medical product sales.

A.5   Alignment with Single Point of Contact Toolkit

The activities under the Internet Sales Toolkit should be conducted in close alignment and coordination with the APEC Single Point of Contact (SPOC) Toolkit. The SPOC mechanism is intended to provide a network both within and among economies involving the NRA, the customs authority, law enforcement and judicial authorities. The goals include

a. Collection and exchange of information and analysis related to SSFFC medical products;
b. Supporting the operational management of a signal of SSFFC products or suspicion of intentionality related to substandard products; and
c. Collaboration in risk management and investigation related to SSFFC medical products.

Appendix B – Resources

B.1   APEC Survey: Internet Sales of Medical Products

APEC Survey: Internet Sales of Medical Products

To gain an understanding of the extent of the issue of Internet sales of medical products across APEC Economies and to appreciate the extent of the efforts being taken to address this issue, the Internet Sales Working Group conducted a survey. This survey was intended to demonstrate where current gaps exist and enabled the development of informed recommendations.

Findings of the survey are listed below, first with an executive summary followed by excerpted findings. For more details and specific responses, please see the entire Survey results at (_____insert website here_____).

Executive Summary

- All ten Economies indicated that Internet sales of medical products represent a safety risk to their populations.
- All Economies indicated the need for training on how to apply their regulatory framework, how to coordinate across government agencies, how to identify suspicious websites, and how to use forensic IT techniques.
- All Economies indicated the need to strengthen their statutory authority to act, the need to increase international cooperation and work sharing, and the need to secure support from the private sector.
- The majority of Economies (all but one) indicated that they have no Internet-specific laws tailored to the sale of health products.
- All Economies found it difficult to verify the volume of trade of health products sold via the Internet, but most perceived an increase in recent years.

Excerpted Findings

Baseline Data and Trends
- All Economies indicate that Internet sales of medical products represent a safety risk.
- Citizens across all demographics were cited by all Economies as having

purchasing medical products via the Internet.

- All economies found it difficult to verify the volume of trade of health products sold via the Internet, although most perceived an increase in recent years.
- Only two economies have a set definition of "Internet pharmacy".

Statutes, Laws, and Regulations

- The majority of economies cited that their NRAs were currently playing some role in providing oversight to the sale of medical products via the Internet.
- All economies indicated the need for training on how to apply their regulatory framework, how to coordinate across government agencies, how to identify suspicious websites, and how to use forensic IT techniques.
- All economies indicated the need to strengthen their statutory authority to act, the need to increase international cooperation and work sharing, and the need to secure support from the private sector.
- The majority of economies (all but one) indicated that they have no Internet-specific laws tailored to the sale of health products.
- Four of ten responding economies indicated that it is legal in their economies to purchase prescription medication online, while seven of ten responding economies indicated that it is legal to purchase non-prescription medication online.

Enforcement

- The majority of economies indicated they have enforcement agencies involved in investigating and prosecuting individuals violating domestic laws associated with Internet sales of medical products.
- NRAs in most economies cooperate with police and customs agencies, typically with one agency taking the lead.
- The majority of economies participate in some form of international collaboration, with Operation Pangea cited by 5 of 10 economies, followed by participation in the Permanent Forum on International Pharmaceutical Crime. Only 3 of 10 economies indicated they cooperate internationally on prosecutions.
- Six of ten economies perceive a rise in illegal activity, however most have little data to support said claims.
- All economies cite enforcement activities as insufficient in dealing with this issue, citing the need for new laws, definitions, and training specific to Internet sales.

Public Safety Controls

- Six of ten economies cite that prescriptions cannot be given online.
- Only four of ten economies require a prescription in order to fill an online order.

Public Education

- While 7 of 10 economies cited the development and distribution of public education materials, all economies cited the need to do more to inform the public about the risks of purchasing medical products online.

Internet Commerce

- Some economies cited private industry taking steps to provide protective practices, such as online verification technology. However only 4 of 10 require such practices.
- All economies cited having a complaint mechanism for product incidents.

B.2   Internet Commerce Company Voluntary Actions

Collaboration between public and private sectors is key to sustained success. One of the most direct ways for APEC economies to achieve their goals is through engagement with Internet commerce companies. Examples of Internet commerce companies include search advertising providers, social media platforms, domain name registrars, internet seller registries, payment system operators, and shipping companies. It is recommended that all APEC economies establish Model Voluntary Protocols for Internet commerce companies. In the absence of strong existing actions and commitments by the Internet commerce community in a given market, the APEC economy can look to Model Voluntary Protocols.

One example for Model Voluntary Protocols is the publicly available Center for Safe Internet Pharmacies (CSIP) Principles of Participation. These voluntary actions underscore the need for stakeholders to be willing to take voluntary actions that will enable all organizations involved to do more to make the Internet safer for consumers.

(*Note*: *To see the full document and to view CSIP's Principles of Participation, please visit: http://www.safemedsonline.org/wp-content/uploads/2014/03/CSIP-**Principles**-of-Participation.pdf.*)

The following recommendations represent various voluntary practices, by sector, taken by Internet commerce companies against illegal online medical product sellers.

<u>Advertising Service Providers</u>

Advertising Service Providers enable the placement of advertisements online. For example, Microsoft's Bing, Google, and Yahoo are search advertising providers that enable advertisers to place advertisements on sites across the web. Model practices for advertising service providers include:

- Suspension and Termination - Prohibit engaging in illegal activity and require compliance with applicable law, and maintain a right to suspend and/or terminate services if these provisions are breached.
- Public Statements - Have a "zero tolerance" policy that prohibits illegitimate websites from utilizing advertising services. For example, Bing, Yahoo, Facebook, and Google[6] have published advertising policies that prohibit illegal online medical product sellers from advertising on their platforms.
- Protections - Have controls in place regarding advertising by pharmacies. For example, require that online pharmacies (which advertise prescription medical products to customers in the United States) must be accredited by the National Association Boards of Pharmacy Verified Internet Pharmacy Practice Sites (VIPPS) program, and require advertisers to provide proof of accreditation prior to advertising.
- Enforcement Policies - Have an internal process in place to enforce advertising policies and remove or block known illegitimate websites. This process may also allow customers, users, or other interested parties to report suspected illegitimate websites for service provider review.

<u>Registries / Registrars</u>

Registries and registrars are involved in the provisioning and sale of domain names. From time to time, illegal online medical product sellers register domain names and then develop websites on these domain names to try and create a distribution channel for medical products in violation of federal and state laws. If given the proper notice information regarding these illegal activities, registrars and registries can take effective action to take down these websites and suspend the domain names from use.

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[6] Bing's advertising policy can be found here; Google's advertising policy can be found here; Facebook's advertising policy can be found here; and Yahoo's advertising policy can be found here.

Complaints about a domain's use for illegal activity, abuse, violation of existing laws of the stated economy in the jurisdiction in which they are located and to which they do business, or violation of ICANN's Registrar Accreditation Agreement should be sent directly to the relevant registries and registrars by regulatory authorities and law enforcement.

Model practices for registries and registrars include:

- General Policies - Registrars and registries should acknowledge the ongoing problem of illegal online medical product sellers and publicly support organizations and companies involved in combating the use of domain names for the illegal distribution of medical products and medicines by illegal online medical product sellers.
- Monitoring - Where permitted and consistent with company policies and procedures, registrars and registries should submit a list of domain names suspected of being used by illegal online medical product sellers to an online pharmacy verification provider to verify the legitimacy of the websites. After receiving written confirmation from a verification company that a domain name hosts a website that is used to market and distribute medical products and medicines in violation of applicable laws, registrars and registries should take prompt action to take down the illegitimate website.
- Suspension and Termination - Registrars and/or registries should immediately lock and suspend the domain names from use or resolution in the domain name system if a hosted website is determined to be operated by an illegal online medical products seller. Registrars / registries who do not take appropriate action where domain names are used for illegal purposes can be reported to the contract compliance division of the International Corporation for Assigned Names and Numbers (ICANN) https://forms.icann.org/en/resources/compliance/complaints/registrars/standards-complaint-form
- Public Statement - Registrars and registries should publish, on their respective websites, a "zero tolerance" statement or policy against illegal online medical product sellers and include specific provisions in their registrations terms and conditions prohibiting the use of domain names for websites distributing illegitimate medical products. Government officials may also participate in the appropriate ICANN Governmental Advisory Committee in an effort to educate registries and registrars about the problem posed by illegal online sellers.
- Reporting - Registrars and registries should also include contact

information for an "Abuse Contact" on their website so that users can report suspected illegitimate websites for further investigation by an online pharmacy verification provider.

A current list of companies globally that have been accredited by the ICANN to act as registrars in one or more top level domains can be found at http://www.internic.net/regist.html .

Payment System Operators

Below are model practices for payment system operators to address the sale of illegitimate medical products over the Internet[7]:

- Policies and Procedures - Maintain policies and procedures reasonably designed to prevent unlawful Internet pharmacy merchants from transacting through the electronic payment system, which may include policies and procedures requiring transactions to be legal in both the buyer's and seller's jurisdictions.
- Proactive Internet Monitoring - Employ third party firms and/or proprietary technologies to proactively monitor the Internet for merchants that attempt to process transactions involving illegal online medical product sellers.
- Investigate and Remediate - Maintain risk management programs to identify illegitimate Internet pharmacy merchants in order to terminate or remediate offending merchants in a timely manner.
- Under a four party model[8], the payment system operator would require the merchant's acquiring entity to investigate and subsequently terminate or remediate the offending merchant.
- Under a three party model[9] (or the PayPal model), the payment system operator would investigate and subsequently terminate or remediate the offending merchant directly.
- Third Party Agent Oversight - Payment system participants, utilizing Third Party Agents to sign up merchants on their behalf, should conduct due diligence on their agents in order to ensure compliance with the payment system operator's policies and procedures regarding the sale of illegitimate medical products.
- Stay Informed - Remain informed about legal and regulatory

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[7] These voluntary practices are intended to supplement, not replace, policies that payment system operators already have in place and are not designed to replace any law enforcement actions.
[8] In a four-party model, the payment system operator connects four parties in each transaction: card issuing banks, merchant acquiring banks or merchant acquirers, cardholders and merchants.
[9] In a three-party model, the payment system operator interacts directly with merchants and consumers, in addition to processing transactions, issuing cards and signing up merchants.

developments with respect to Internet pharmacy sales and adjust risk strategies as appropriate.

Shipping Companies

Carriers seek to keep consumers safe and help stop the shipment of medical products by illegal online medical product sellers. Model practices for shipping companies include:

- General Policies - Require each shipper to comply with all laws and regulations governing the dispensing, shipment or tender of shipment of prescription medical products.
- Training - Train delivery drivers, management, shippers, consumers, sales and marketing teams, security personnel, and other relevant employees and contractors how to spot red flags that may indicate the involvement of potentially illegal online medical product sellers. Teach that red flags, especially in combination with medical product packaging, may indicate that the shipper is an illegal online medical product seller. Consumers should not use foreign sites that do not require a prescription.
- Reporting - Accept reports, including anonymous reports, of potentially illegal online medical product shippers. Collect all information available regarding the shipper being reported, especially all websites associated with the shipper and the red flag(s) that led to the report being made.
- Investigating - Investigate any reports of potentially illegal online medical product shippers using the following steps and any additional steps as appropriate:
  a. perform Internet or other research on the shipper, including reviewing lists maintained by NABP and other verification and monitoring services;
  b. review the account's shipment history, volume, credit history, related accounts, and other relevant information about the shipper;
  c. interview personnel familiar with the shipper and/or shipments;
  d. consult with law enforcement; and
  e. Requests for licensure information from the shipper.
- Termination - When a carrier determines that a shipper is violating federal, state, or local laws or regulations governing the dispensing, shipment or tender of shipment of prescription medication, the carrier should terminate the shipper's account and suspend all pickup, delivery, and other services. The carrier should also take appropriate steps to report the shipper to law enforcement.

Some examples of red flags shipping companies should watch out for include:

1. Business location is not professional in security and appearance;
2. Package for the same consignee with different names;
3. The combination of pharmaceutical packaging and the use of COD;
4. Bulk Shipments through UPS Authorized Shipping Outlets or The UPS Store;
5. A Consignee appears to be "under the influence;
6. Customer requests driver meet on area to make pickup or delivery;
7. Consignee altered delivery points for pharmaceutical packages;
8. Consignee hesitant to provide identification;
9. Unusual displays of wealth at customer locations;
10. Delivery locations appear to be abandoned homes or businesses;
11. Significant changes in pickup or drop-off levels;
12. A new customer with a high volume of lightweight air shipments; and
13. Packages appearing to contain pharmaceuticals being shipped form residential addresses.

B.3   Public Education Resources

Public education resources and statistics are key elements that should be used in public education campaigns. Below are a variety of credible resources on Internet sales have been developed by the WHO, the World Health Professionals Alliance, the US Food and Drug Administration the Alliance for Safe Online Pharmacies, Center for Safe Internet Pharmacies, and other relevant and credible organizations:

World Health Organization (WHO)

The WHO is involved in facilitating international collaboration to ensure the safety of medical products worldwide. APEC economies can use of the WHO's extensive online materials. In particular, APEC economies should review the WHO's materials on counterfeit medicines to garner a better sense of the problem and craft potential solutions. Those materials can be found through the WHO website at
http://www.who.int/medicines/publications/counterfeitguidelines/en/

World Healthcare Professions Alliance (WHPA) "Be Aware" Toolkit

The WHPA "Be Aware" toolkit can assist stakeholders in effectively raising public awareness regarding SSFFC medical products. The WHPA toolkit has been designed to help educate and improve the capacity of health

professionals to detect, report, and prevent use of SSFFC medical products, targeting three key audiences: health professionals, consumers, and public health advocates. A copy of this toolkit is available through the WHPA website at
http://www.whpa.org/counterfeit_campaign_materials.htm.

Fight the Fakes

Fight the Fakes is a campaign aimed at raising awareness about the dangers of fake medicines. The campaign brings together numerous partners to help inform the public about the public health threats posed. APEC Economies can find useful resources on the Fight the Fakes website at http://fightthefakes.org.

BeSafeRx Campaign

The US Food and Drug Administration has a campaign online that seeks to address consumers purchasing medical products online. This campaign can be found at www.fda.gov/besaferx .

The Alliance for Safe Online Pharmacies (ASOP)

ASOP is a global nonprofit dedicating to protecting consumer safety online. ASOP's website contains many resources that APEC Economies would find useful in fighting illegal online sales. Learn more at http://www.safeonlinerx.com.

The Center for Safe Internet Pharmacies (CSIP)

CSIP brings together numerous Internet commerce companies to help fight against illegal online medical product sellers. Through its Principles of Participation and other resources, CSIP is a model of voluntary private sector action. Learn more at http://www.safemedsonline.org.

Appendix C – Definitions

The below definitions apply to this toolkit:[10]

- **Active pharmaceutical ingredient (API)** - A substance used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
- **Administrative penalty** - A sanction, typically addressed through monetary means, as a way to punish non-compliance. These penalties may address specific incidents of non-compliance with an order made under legislation, such as refusing to comply with a recall order.
- **Consumer** - A person who purchases goods or services for personal use.
- **Criminal penalty** - Sanction, typically addressed through imprisonment and/or monetary means, as a way to punish a specific action. These penalties may address specific incidents against a specific action with an order made under legislation, such as taking a person's life.
- **Health care professional** - A person who is a member in good standing of a professional medical, nursing, pharmacists' or other health care professional association and entitled to provide health care under the laws of the jurisdiction in which the person is located, and other individuals who have the appropriate health care education and therapeutic expertise.
- **Illegal online medical product sellers** - Merchants who sell medical products over the Internet in violation of existing laws of the stated economy, regulatory requirements, and/or pharmacy standards in the jurisdictions in which they are located and to which they do business.
- **Internet commerce companies** - Private companies engaged in the facilitation of commerce via the Internet, including registries, domain name registrars, search engine advertisers, payment processors, and shippers.
- **Internet Pharmacy Accredited List** - List sanctioned by a National Regulatory Authority and/or Practice of Pharmacy Board of approved Internet pharmacies. For example, the National Association of Boards of Pharmacy provides the Verified Internet Pharmacy Practice Sites list of accredited sites: *http://www.nabp.net/programs/accreditation/vipps* .
- **Medical products** - Prescription pharmaceutical products, over-the-counter (OTC) pharmaceutical products, and/or active pharmaceutical ingredients (APIs).

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[10] This definition list has been adapted from the aforementioned APEC Internet Sales Survey.

- **Over-the-counter (OTC)** - Pharmaceutical products which do not by law require a prescription prior to dispensing.
- **Prescription** - Instruction written by a certified professional authorized by law in an economy to issue a medical product or treatment.
- **Registrar** - An organization that has an account with a Registry and provides the ability to buy and manage domain names.
- **Registry** - An organization which maintains a database containing the information regarding a particular registered top level domain name.