



USP-APEC RHSC

Center of Excellence (CoE) for Product
Quality & Supply Chain Pilot Program:

Securing Medical Product Quality Through the Supply Chain

U.S. Pharmacopeial Convention (USP) | March 28–31, 2017 | USA



Welcome



Introduction of a Clinical and Retail Pharmacies Practices Toolkit: Attempting to address diversity in pharmacy settings

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Clinical and Retail Pharmacy Practices WG

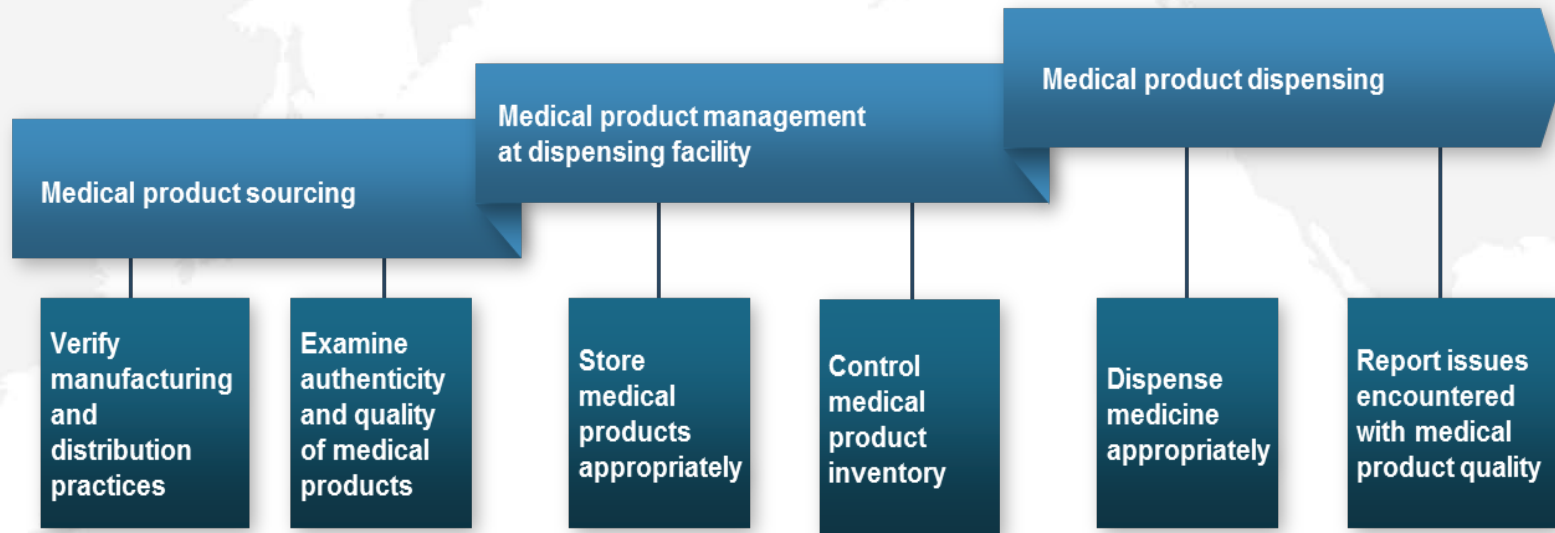
- Established by the Regulatory Harmonization Steering Committee (RHSC) in 2014
 - Develop a toolkit to support implementation of best practices towards ensuring the quality of dispensed medicines in clinical and retail pharmacies
- Comprised of experts from the Americas and volunteers from the United States Pharmacopeial Convention (USP), who contributed varied perspectives and experiences
 - Dr. Magaly Rodriguez de Bittner, Professor and Associate Dean, and Executive Director of the Center for Innovative Pharmacy Solutions, School of Pharmacy, University of Maryland, USA
 - QF Nora Gerpe, Technical Director, Pharmacy Services at the British Hospital, Montevideo, Uruguay
 - QF Susana M. Migliaro, Member of the National Certification Committee at the Pharmaceutical Association of Argentina (COFA), and Professor and Researcher at the John F. Kennedy University, Buenos Aires, Argentina
 - M.Sc. Damian Cairatti, Senior Director, International Regulatory Affairs, USP, USA
 - Dr. Victor S. Pribluda, Principal Program Manager, Promoting the Quality of Medicines Program, Global Public Health, USP, USA

Content of Presentation

- Clinical and Retail Pharmacy Practices WG
- The challenge: What best practices for what pharmacies?
- Addressing requirements in different realities
- What is the next step?

A challenge: What best practices for what pharmacies?

A framework that leaves some unanswered questions






- What to do when QA systems support is not available or regulations choose the long road?
- What happens when procurement ‘happens’ outside of the framework?
- Do we really need MORE guidelines?

Addressing requirements in different realities

Where to focus resources?

Requirements for best practice implementation

			
Dispenser training required	Low (no expertise and minimal training needed)	Medium (some pharmacy vocational education required)	High (pharmacist professional education required)
Technology required	None (can be done entirely manually)	Basic (access to internet sites or databases needed)	Advanced (specialized solutions needed)
Country resources required	Limited resources (e.g., independent pharmacies in remote locations)	Moderate resources (e.g., independent pharmacies in big cities)	Highly resourced (e.g., chain pharmacies in big cities)

Addressing requirements in different realities

Just some examples...

Guiding principles	Best practice examples	Dispenser training required	Technology required	Support infrastructure required	Example best practice country
Verify safe delivery of medical products	Check that vehicles for transportation and delivery of medicines are certified to deliver medical products				Peru
	Check for safe storage practices, particularly for temperature and light sensitive medicines				Mexico
Evaluate quality of medical products	Check expiration dates of medical products at point of receipt				Mexico
	Check for safe storage practices, particularly for temperature and light sensitive medicines				Mexico
	Manually compare product barcode numbers with online databases to verify that the pill count corresponds with records in database				USA (availability of QC centers)
	Send sample of medicine to be checked at national quality control center if suspicious of medicine quality				Peru

... to start now and here

What is the next step?

The CRPP Toolkit is a living document...
... that lives in the Roadmap for Supply Chain Security ...
... but is owned by the countries ...
... and countries input is part of the process!



Questions



Thank You

Background

- Roadmap for Supply Chain Security project
- Cases to illustrate two main issues in Retail/Community Pharmacies
 - Compounding
 - Dispensing/Best Practices
- **CLINICAL AND RETAIL PHARMACIES PRACTICES TOOL KIT**

Case #1: Compounding

Pharmacy XXYY

Equipment needed: Mortar and pestle, graduated cylinder, stirring rod

Drug Name	Route	Dosage Form	Concentration
Atenolol	Oral	Suspension	2mg/mL
Formula Qty: 250mL		Shelf Life: 90 days	

Ingredients	QS	Quantity	Units
Atenolol 100mg tablets <i>Sandoz</i>		5	Tablets
Glycerin USP		5	mL
Ora Sweet Sugar Free <i>Paddock</i>	X	250	mL

Auxiliary labeling/Storage: Refrigerate; Shake Well Room Temperature Stability=7 days (10mg/mL concentration)

Directions:

1. Crush tablets in a mortar and triturate to a fine powder.
2. Add glycerin and mix well. (Increase amount slightly if needed)
3. Add Ora-Sweet SUGAR FREE, geometrically, mixing well.
4. Transfer to graduated cylinder.
5. QS to final volume with remaining vehicle. Stir well.

Final Product Description: Thick, cloudy, white suspension. Maraschino cherry smell. *This description is for exact products and manufacturers specified below and may vary with substitutions.*

Why Compound

- Medications that are not available in the formulation
- A common and integral part of practice in hospitals and retail pharmacies, in low as well as high income economies.

Points of Discussion

- What are the issues outline in the case?
 - How do we assure that there is trusted source of raw material?
 - Sterile preparation?
 - Written documentation and records?
 - Labeling?
 - Expiration dates?
- Patient education and storage of product at home?

Case #2: Product Dispensing

- Patient with diabetes Type 2 comes to the pharmacy with a prescription for Insulin. This is the first prescription for insulin that this patient receives. He is overwhelmed and apprehensive, he is afraid of needles and is asking the pharmacist for help.
- RX:
 - Insulin glargine 10 U at bedtime
 - Insulin Lispro 2 u with meals

Points of Discussion

- Dispensing facilities, such as retail and hospital pharmacies, are the last stage in the medical products supply chain where interventions can be implemented to ensure patients receive good quality pharmaceuticals.
- Quality control measures implemented at dispensing sites, (e.g., retail and hospital pharmacies) serve as the last opportunity
 - Supply Chain
 - Product integrity
 - Storage condition

Points of Discussion

- Patient Education
 - Injection technique
 - Storage

Discussion: Strategies for implementation of best practices

- Ensuring the quality of medical products dispensed to patients is a complex endeavor that encompasses multiple processes and ensuing practices. While countries' ultimate goal is establishing comprehensive safeguards to guarantee the quality of medical products throughout the supply chain, it is necessary to realize the limitations imposed by country contexts and accompanying challenges.



Questions



Thank You

... and countries input is part of the process!

- From the three main processes occurring at dispensing facilities (receiving the product, managing the product within the facility, dispensing the product), which is the area that you consider in need for further strengthening in your jurisdiction?
- In your economy, do you think that public sector dispensing facilities personnel have the necessary resources to address the quality needs and develop quality measures and procedures?
- Do you think that in your economy the quality needs for compounding in pharmacies are properly addressed?

Internet Pharmacies Present Global Health Risks

- ▶ Unregulated internet pharmacies sell substandard and fake drug products.
- ▶ Substandard medicines represent a significant threat to global public health with tragic consequences.
- ▶ Multi-faceted global approach necessary across a diverse continuum of sectors.
 - Global distribution of falsified medicine in both resource-poor and developed countries
 - Products sourced from various countries using questionable manufacturing practices



Internet Pharmacies Present Global Health Risks

- ▶ Robust quality systems across the supply and distribution chain are essential, coupled with surveillance, cooperation, and awareness solutions
- ▶ Mitigation Roles:
 - Pharmaceutical supply chain/product quality standards; good distribution and pharmacy practices
 - Regulatory systems strengthening, including medicines quality monitoring and surveillance tools
 - Contributing to global discussions on illegal online drug sellers with evidence

Rogue Internet Pharmacy Sites

Overnight For Usa

Enter keyword...

Discount

Buy quality medicine
Take part in Bonus
Don't save on

20%
10%
30%

Categories List

- Antibiotics
- Bestsellers
- Cancer
- Cardiovascular
- Erectile Dysfunction
- General Health
- Men's Health
- Women's Health

Bestsellers

Viagra
Sildenafil

Viagra is often the first treatment for erectile dysfunction and pulmonary arterial hypertension.

Clomid
Clomiphene

Clomid is a fertility drug, and hereby the ovaries to stimulate ovulation.

Zithromax
Azithromycin

Zithromax is a macrolide antibiotic used to treat a variety of bacterial infections, including low respiratory tract, especially pneumonia.

Cipro
Ciprofloxacin

Cipro is a fluoroquinolone antibiotic used to treat a variety of bacterial infections (acute uncomplicated).

Anticonvulsants

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SPECIAL OFFER

VIAGRA 10 pills x 100mg + **CIALIS** 10 pills x 20mg
\$59.95 BUY NOW

ABOUT US

Our pharmacy company is a leader in delivering medications throughout the world. Each and every day our goal is to provide discount medications to anyone who is affected by expensive local prices. Our company is a professionally managed generic drugs distributor. We provide high-quality service supplying drugs all over the world.

Read more

For example: Viagra

0 items / Shopping cart \$0

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

SPECIAL OFFER

BESTSELLERS

- Viagra
- Cialis
- Levitra
- Trial Erection packs 1
- Brand Viagra
- Brand Cialis
- Dapoxetine
- Tadalafil
- Sildenafil
- Extra Super Viagra
- Extra Super Cialis
- Extra Super Levitra
- Malegra FXT
- Malegra DXT
- Viagra Professional
- Cialis Professional
- Viagra Super Active
- Cialis Super Active
- Kamagra Effervescent
- Viagra Soft
- Cialis Soft
- Female Viagra
- Propecia
- Zithromax
- Doxycycline
- Synthroid
- Accutane
- Clomid
- Nolvadex
- Lexapro
- Amoxil

Viagra \$0.36 for pill
ADD TO CART

Viagra is indicated for the treatment of erectile dysfunction in men.

Cialis \$0.76 for pill
ADD TO CART

Cialis is indicated for the treatment of erectile dysfunction. Cialis works faster than other ED drugs and lasts for an extended period of time.

Levitra \$1.2 for pill
ADD TO CART

Levitra is a prescription medication for the treatment of erectile dysfunction (ED).

Trial Erection packs 1 \$3 for pill
ADD TO CART

Viagra 10 pills x 100 mg.
Cialis 10 pills x 20 mg.

Brand Viagra \$3.8 for pill
ADD TO CART

Brand Viagra is an oral medication for erectile dysfunction (ED) developed by the pharmaceutical company PRIZER. It helps most men with ED improve their erections.

Brand Cialis \$4.18 for pill
ADD TO CART

Brand Cialis is a medication used for treating men's erectile dysfunction (ED) and developed by the pharmaceutical company LILLY. Cialis works faster than other ED drugs and lasts for an extended period of time.

EVERY ORDER VIAGRA PILLS FOR FREE

FREE SHIPPING ON ALL ORDERS ABOVE \$200

ARTICLE

What are Allergies?

Allergies is very unpleasant condition. Bad cold, swelling, itchy red eyes ... When allergies increases fatigue, irritability increased, decreased

Need Help? 1-855-1-773

BEST SELLERS

SEARCH Viagra

SSL SECURITY with confidence 30 DAY MONEY BACK Super easy refund policy CHECKOUT

FOUND FOR "VIAGRA"

Sort by: Price highest first

Female Viagra
women's sexual health
from: US\$ 1.33
ADD TO CART

Sublingual Viagra
men's sexual health
from: US\$ 1.33
ADD TO CART

Viagra Oral Jelly (Generic)
men's sexual health
from: US\$ 1.41
ADD TO CART

Viagra Soft P...
men's sexual health
from: US\$ 1.41
ADD TO CART

Viagra Gold
men's sexual health
from: US\$ 2.33
ADD TO CART

Viagra®
men's sexual health
from: US\$ 2.33
ADD TO CART

Thyroid Health

Mental Health

Why do Consumers Buy Drugs Online?

- ▶ Convenience
- ▶ Cost
- ▶ Access
- ▶ Anonymity



Online Dangers

- ▶ Accessibility; Ubiquitous, global scope and reach, and growing use
- ▶ Transparency; Barriers to participate low
- ▶ Vulnerable Consumers; targeted marketing drives demand

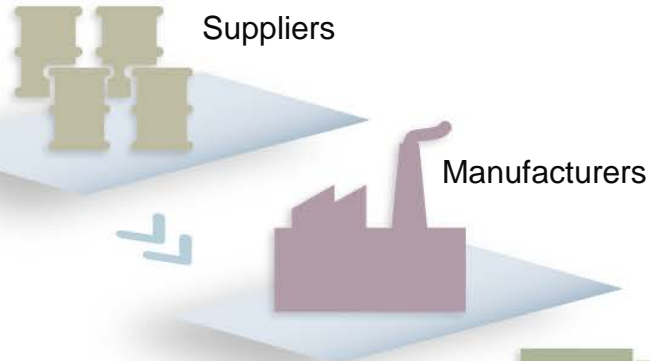


Why is this important?

- ▶ **Estimated 35,000-45,000** online pharmacies
- ▶ **Every day, approximately 20 new illegal online pharmacy websites** go live globally
- ▶ **65% of online search results** for prescription drugs leading U.S. consumers to illegal and unsafe websites
- ▶ **50% of the medicines sold online** by websites that hide their physical address are counterfeit



Integrity of the Supply Chain



A counterfeiting drug site used to produce fake Viagra and other drugs for export to the U.S. and E.U. (China).



Vials being washed only to be reused to hold counterfeit medications (Columbia).



Risks to Health and Safety

- ▶ Drug Safety (Quality)
- ▶ Patient Safety (Misuse, self treatment, denial and delay of care)
- ▶ Consumer Security (Personal data protection)

Heavy metals



mercury
aluminum
lead
cadmium
arsenic
chrome
uranium
strontium
selenium

Actual poison



PCBs
benzopyrenes
rat poison
boric acid
antifreeze

Common household items



road paint
wall paint
brick dust
floor wax
sheet rock
paint thinner

Drugs you didn't ask for



aminotadalafil
homosildenafil
xanthoanthrafil
pseudovardenafil
hongdenafil
sibutramine
haloperidol

No drugs at all



dextrose
dextrin
lactose
starch
saline
salt

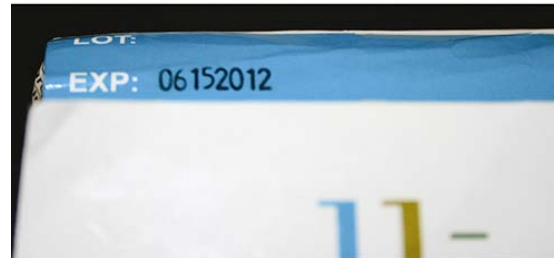
FDA Warns About Fraudulent Tamiflu



FDA Warns about Counterfeit Alli



Authentic alli Sample



Counterfeit alli Sample



Authentic alli Sample

Counterfeit alli Sample



Authentic alli Sample



Counterfeit alli Sample

FDA Warns about Extortion Scam by FDA Impersonators



Challenges

- ▶ Global reach and scope with minimal barriers to open and close commerce sites
- ▶ Plethora of participants; from public and private sector
 - Producers; manufacturers
 - Facilitators; source products, diversion
 - Service providers; spam & search, fulfillment and payment providers
- ▶ Crosses borders and jurisdictions



Questions



Thank You

OVERVIEW OF INTERNET SALES TOOLKIT TO COMBAT ILLEGAL INTERNET MEDICAL PRODUCT SALES

US PHARMACOPEIAL CONVENTION
“SECURING MEDICAL PRODUCT QUALITY THROUGH THE
SUPPLY CHAIN”
MARCH 30TH, 2017

PRESENTED BY:
Katie Neckers, Esq.
Regulatory Counsel
United States Food and Drug Administration

Overview

- ▣ Background
- ▣ Methodology
- ▣ Internet Sales Survey
- ▣ Internet Sales Toolkit

Background

- ▣ **Problems with current 'buying online' practices**
 - Increasing number of consumers using the internet to purchase prescription drugs, and other medical products
 - Vast scope of products available for purchase without a prescription
 - Inadequate enforcement resources
- ▣ **Drug quality concerns**
 - Consumer receives wrong medication, ie. incorrect dosage form, sub-potent, super-potent, lack of active ingredient
 - Consumer could receive drug that could potentially cause serious side effects
 - Spurious Substandard Falsified Falsely Labeled Counterfeit (SSFFFC) medicines
 - The source of the product is unknown
- ▣ **Websites**
 - Misleading re: quality, source, authenticity of product
 - Deny or evade liability
 - Do not require a prescription

Counterfeit Rx drug sold on internet

FDA NEWS RELEASE

For Immediate Release: May 29, 2012

Media Inquiries: Shelly Burgess, 301-796-4651, shelly.burgess@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA warns consumers about counterfeit version of Teva's Adderall

Tablets purchased on the Internet contain wrong active ingredients

The U.S. Food and Drug Administration is warning consumers and health care professionals about a counterfeit version of Teva Pharmaceutical Industries' Adderall 30 milligram tablets that is being purchased on the Internet. Adderall, which is approved to treat attention deficit hyperactivity disorders (ADHD) and narcolepsy, is a prescription drug classified as a controlled substance – a class of drugs for which special controls are required for dispensing by pharmacists.

FDA's preliminary laboratory tests revealed that the counterfeit version of Teva's Adderall 30 mg tablets contained the wrong active ingredients. Adderall contains four active ingredients – dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate. Instead of these active ingredients, the counterfeit product contained tramadol and acetaminophen, which are ingredients in medicines used to treat acute pain.

Currently on the FDA's drug shortage list, Adderall is in short supply due to active pharmaceutical ingredient supply issues. Teva continues to release product as it becomes available. Consumers should be extra cautious when buying their medicines from online sources. Rogue websites and distributors may especially target medicines in short supply for counterfeiting.

The counterfeit Adderall tablets are round, white and do not have any type of markings, such as letters or numbers. Any product that resembles the tablets or the packaging in the photos below and claims to be Teva's Adderall 30 mg tablets should be considered counterfeit. The counterfeit versions of Adderall should be considered as unsafe, ineffective and potentially harmful.

Authentic Adderall 30 mg tablets produced by Teva are round, orange/peach, and scored tablets with "dp" embossed on one side and "30" on the other side of the tablet. Teva's Adderall 30 mg tablets are packaged only in a 100-count bottle with the National Drug Code (NDC) 0555-0768-02 listed.

Pictures of the counterfeit version of Teva's Adderall 30 mg tablets and packaging



Counterfeit OTC sold on internet

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration [A-Z Index](#) [GO](#)

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Drug Safety and Availability
Postmarket Drug Safety Information for Patients and Providers
Index to Drug-Specific Information
Approved Risk Evaluation and Mitigation Strategies (REMS)
Postmarketing Safety Evaluation of New Molecular Entities: Final Report
Drug Safety Communications
Drug Safety Information for Healthcare Professionals

UPDATED Public Health Alert: Counterfeit Alli containing sibutramine

1/23/2010

The U.S. Food and Drug Administration (FDA) is updating its warning to the public about a counterfeit version of Alli 60 mg capsules (120 count refill pack) being sold over the internet, particularly at online auction sites. FDA advises people who believe that they have a counterfeit product not to use the drug.

Alli is an FDA-approved over-the-counter weight loss drug that contains orlistat as its active ingredient. The counterfeit version of Alli does not contain orlistat; rather, it is made with varying amounts of sibutramine, a stimulant drug.

Although sibutramine is the active ingredient in another FDA-approved prescription weight loss drug, it is only to be used in specific doses and under the supervision of a physician. The counterfeit product is illegal and unsafe.

Additional FDA laboratory tests on the counterfeit product show that people may be taking 3-times the usual daily dose (or twice the recommended maximum dose) of sibutramine if they are following the dosing directions for Alli. Healthy people who take this much sibutramine can experience anxiety, nausea, heart palpitations, tachycardia (a racing heart), insomnia, and small increases in blood pressure. This excessive amount of sibutramine is dangerous to people who have a history of cardiovascular disease, and can lead to elevated blood pressure, stroke, or heart attack.

FDA recommends everybody check and make sure they are not taking counterfeit Alli. If they suspect they are taking the counterfeit product, they



Authentic alli Sample

Counterfeit alli Sample



Authentic alli Sample



Counterfeit alli Sample

Operation Pangea VIII Examples



Indonesian officers inspecting a warehouse.



UK's Medicines and Health products Regulatory Agency (MHRA) seizure of counterfeit condoms.



Blue Vallium tablets hidden in seashell seized by Norwegian authorities.



Italian Police and Customs authorities working together.



Authorities in Bosnia & Herzegovina seized Xanax.



Authorities inspecting a truck in Panama.

Operation Pangea VIII Examples



Seizure of illicit antibiotics by Swedish Customs.



Seizure of illicit medicines in the Netherlands.



INTERPOL San Jose in Costa Rica conducting inspections.



New Zealand's MedSafe and Customs seized testosterone hidden in fruit juice.



Seizure of slimming pills by Jordanian authorities.



Authorities in Malaysia conducted several awareness campaigns.

Methodology

- Stage 1 – Gap analysis via survey
- Stage 2 – Developed training material for APEC economies based on gap assessment – the “Toolkit”

Survey Background

- ▣ A survey was selected as the most appropriate methodology
 - Little existing guidance or policy across APEC Economies specific to Internet sales
 - Scope of the issue is not entirely clear, highly variant between countries
 - Unclear whether stakeholders in Internet sales of medicinal products fall within/outside current regulatory models
 - Rapidly evolving business model for Internet sales makes it challenging for National Regulatory Authorities to adapt

Survey Background

- While all APEC economies were invited to complete the survey, 10 economies participated:
 - Canada
 - Indonesia
 - Papua New Guinea
 - Philippines
 - Thailand
 - Chile
 - Japan
 - Peru
 - Singapore
 - U.S.
- Included both qualitative and quantitative questions
- 6 themes, 53 questions total
- Responses analyzed by the University of Tennessee Health Sciences Center

Survey Themes

- **Baseline Data and Trends**
 - Focus on the prevalence of the sale of health products via the Internet
- **Statutes, Laws and Regulations**
 - Capture the kinds of legislative and regulatory tools countries have regarding the sale of health products via the Internet
- **Enforcement**
 - Capture tools available to law enforcement agencies and nature of international cooperation among enforcement agencies
- **Public Safety Controls**
 - Capture information on consumer protection requirements
- **Public Education**
 - What educational campaigns are out there to raise consumer awareness
- **Internet Commerce**
 - Capture measures taken by private industry to facilitate legitimate online commerce

Survey Results- Baseline Data and Trends

- All citizens have access to and regularly use the Internet
- Most economies were unable to confirm the demographics making the online purchase
- Increase in illegitimate online pharmacies
- Only 2 economies have definition for “internet pharmacy”
- All economies agreed internet sales of medical products pose a health risk

Survey Results - Statutes, Laws, and Regulations

- 4 economies said it is legal to purchase prescription medicinal products via the internet
- Most economies have a national regulatory authority to oversee legitimate internet pharmacies and/or sales
 - 5 indicated the need for more statutory authority to act
 - Specialized training is needed
- Most reported there are no internet-specific laws to govern internet sales or the regulations were under revision
 - Some noted that existing law may be interpreted to apply to internet sales
- International cooperation is critical
 - Many legal and logistical barriers for information sharing
- Most internet pharmacies are not inspected as they are not conducting licensable activities

Survey Results- Enforcement

- All economies reported regular investigations of illegal activity related to internet sales
- 6 economies took actions to remove sites
 - Challenges include not having the capability to take down sites on own or requirement for long term investigation
- 7 economies engaged in international efforts such as Operation Pangea, Operation Storm, FAKESHARE
- 6 economies indicated a rise in illegal activities with the illegal sales of online medical products

Survey Results- Enforcement

- 3 economies cooperated internationally on prosecutions related to internet sales
- All economies reported current enforcement is insufficient and almost all economies reported a need for:
 - New laws and regulations
 - Cooperation from other governments and private sector
 - Create new and revise current definitions
 - Training (forensic information, joint training, etc.)
 - Data collection tools
 - Tools for faster detection

Survey Results- Public Safety Controls

- ▣ All economies require:
 - Valid license or certification for legitimate physical pharmacies
 - Health care professional prescription to fill an order in legitimate physical pharmacies
- ▣ Most of the economies require a health care professional to dispense medical products
- ▣ Less than half of the economies indicated that a prescription is required when filling an order via the Internet
- ▣ Most do not permit websites to prescribe virtually through chats or online questionnaire

Survey Results - Public Education

- ▣ Public education tools and awareness campaigns are present in most countries, however there is a need for more
 - Public education tools and awareness should be provided by the national regulatory authority, health care professionals, etc.
- ▣ Unclear whether health care professionals who obtain medicinal products online are knowledgeable of the products
 - Only 1 economy noted licensed products can be verified through a government agency

Survey Results - Internet Commerce

- Mixed responses for existing laws or regulations that apply to the role of internet commerce stakeholders
- Some internet commerce stakeholders adopted practices to protect consumers from illegal internet sales of medical products (i.e.: Google, Ebay, PayPal, industry associations)
- All have mechanisms to submit complaints and/or adverse drug reactions
- Three economies reported that internet commerce stakeholders are taking actions to support regulatory authority
 - Removing web pages after being notified of illegal online activities
 - Developed scheme to prevent advertisements that violate law

Summary Findings of Survey

- ▣ Survey results confirmed need for an internet sales toolkit
- ▣ Results helped shape the information included in the toolkit

Toolkit to Combat Illegal Internet Medical Product Sales - Overview

- ▣ Summarizes the scope of the illegal online pharmacy problem
- ▣ Makes recommendations to combat illegal internet medical product sales based on the survey results
- ▣ Provides public education resource materials
- ▣ Provides definitions of key terms

Toolkit- Definitions

- ▣ The Internet Sales Working Group crafted some key definitions that pertain to Internet sales of medical products
- ▣ Global harmonization of key definitions will help NRAs distinguish between legitimate, legally-operating online medical product sellers and from illegal actors
- ▣ Definitions cover the types of medical products sold online, penalties, healthcare professionals, and entities involved in the facilitation of medical product sales online

Toolkit- Recommendations

- ▣ **Rec 1-** Develop and deliver public awareness activities, including targeted education campaigns
- ▣ **Rec 2-** Strengthen laws and policies to protect consumers from medical products purchased online
- ▣ **Rec 3 -** Distinguish the safe, legally-operating online pharmacies that sell to consumers from the illegal online medical product sellers doing the same
- ▣ **Rec 4 -** Establish Model Voluntary Protocols for Internet commerce companies

Toolkit- Recommendations cont..

- ▣ **Rec 5** - Participate fully in INTERPOL's [Operation Pangea](#) and other cooperative international activities, including the [World Health Organization Member State Mechanism on SSFFC](#)
- ▣ **Rec 6** - Establish effective NRA, customs, and law enforcement coordination to remove rogue Internet sites using the Single Point of Contact (SPOC) system, as appropriate
- ▣ **Rec 7** - Ensure active participation by policymakers to take a leadership role in preventing the manufacture and distribution of SSFFC medical products
- ▣ **Rec 8** - Involve all stakeholders in creating solutions, including private sector organizations, governments officials, Internet commerce companies, consumers, and healthcare professionals

Toolkit - Public Education Resources

▣ *World Health Organization*

- Facilitates international collaboration to ensure the safety of medical products worldwide
- APEC economies should review the WHO's materials on counterfeit medicines at <http://www.who.int/medicines/publications/counterfeitguidelines/en/>

▣ *World Healthcare Professions Alliance "Be Aware" Toolkit*

- Can assist stakeholders in effectively raising public awareness regarding SSFFC medical products
- 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
- http://www.whpa.org/counterfeit_campaign_materials.htm

Toolkit - Public Education Resources cont.

- ▣ *Fight the Fakes*
 - Aimed at raising awareness about the dangers of fake medicines
 - Brings together numerous partners to help inform the public about the public health threats posed
 - <http://fightthefakes.org>
- ▣ *U.S. Food and Drug Administration's BeSafeRx Campaign*
 - National campaign to raise awareness among consumers of the dangers of buying prescription medicines from fake online pharmacies
- ▣ *Alliance for Safe Online Pharmacies - Global*
 - Global nonprofit dedicating to protecting consumer safety online
 - <http://www.safeonlinerx.com>
- ▣ *Center for Safe Internet Pharmacies*
 - Brings together numerous Internet commerce companies to help fight against illegal online medical product sellers

Questions?

THE ALLIANCE FOR SAFE ONLINE PHARMACIES (ASOP GLOBAL)

APEC RHSC – USP Center of Excellence (CoE) for
Product Quality & Supply Chain Pilot Program:
“Securing Medical Product Quality Through the
Supply Chain” - March 30, 2017

Libby Baney, JD

Executive Director, ASOP Global

Principal, Faegre Baker Daniels Consulting

Counsel, Faegre Baker Daniels, LLP

ASOP Global's Support for APEC RHSC Supply Chain Activities

- * **Member of APEC Internet Sales Working Group**

- * ASOP Global is a member of this Working Group and the USP CoE program this week is an excellent example of global cooperation and collaboration

- * **Support the APEC Internet Sales Tool Kit**

- * The Tool Kit has been developed during 2015 and 2016 and is a significant achievement and provides good guidance to APEC economies on how to cooperate to combat illegal Internet drug sales

- * **Continued APEC Engagement**

- * ASOP Global is excited about continued collaboration as APEC economies work together to implement the Internet Sales Tool Kit
- * We look forward to continue working with the Supply Chain CoEs during 2017 and 2018

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- ✓ Amgen
- ✓ Allergan
- ✓ Blink Health
- ✓ Boehringer Ingelheim
- ✓ Consumer Health Information Corporation
- ✓ Consumer Online Foundation (India)
- ✓ Eli Lilly & Company
- ✓ European Alliance for Access to Safe Medicines
- ✓ Generic Pharmaceutical Association
- ✓ International Pharmaceutical Federation
- ✓ Italian Medicines Agency
- ✓ Healthcare Distribution Alliance
- ✓ Johnson & Johnson
- ✓ LegitScript
- ✓ MedExpress
- ✓ Men's Health Network
- ✓ Merck
- ✓ National Association of Chain Drug Stores
- ✓ National Council on Patient Information and Education (NCPIE)

- ✓ NeedyMeds
- ✓ NOVA ScriptsCentral
- ✓ Partnership at Drug-Free.org
- ✓ Takeda Pharmaceuticals
- ✓ The Gerontological Society of America
- ✓ UPS
- ✓ U.S. Pharmacopeial Convention
- ✓ Visa Inc.

OBSERVERS

- ✓ American Association of Colleges of Pharmacy
- ✓ Federation of State Medical Boards
- ✓ National Association of Boards of Pharmacy
- ✓ National Association of State Controlled Substance Authorities
- ✓ National Health Council
- ✓ Partnership for Safe Medicines
- ✓ Pharmaceutical Research and Manufacturers of America (PhRMA)
- ✓ RX-360

ASOP Global works in the US, EU, India, Canada and Asia to:



Educate

Provide consumers, providers and policymakers about how to stay safe when shopping for medicine online.

Influence

Influence policy with policymakers, Internet commerce companies, law enforcement and NGOs.



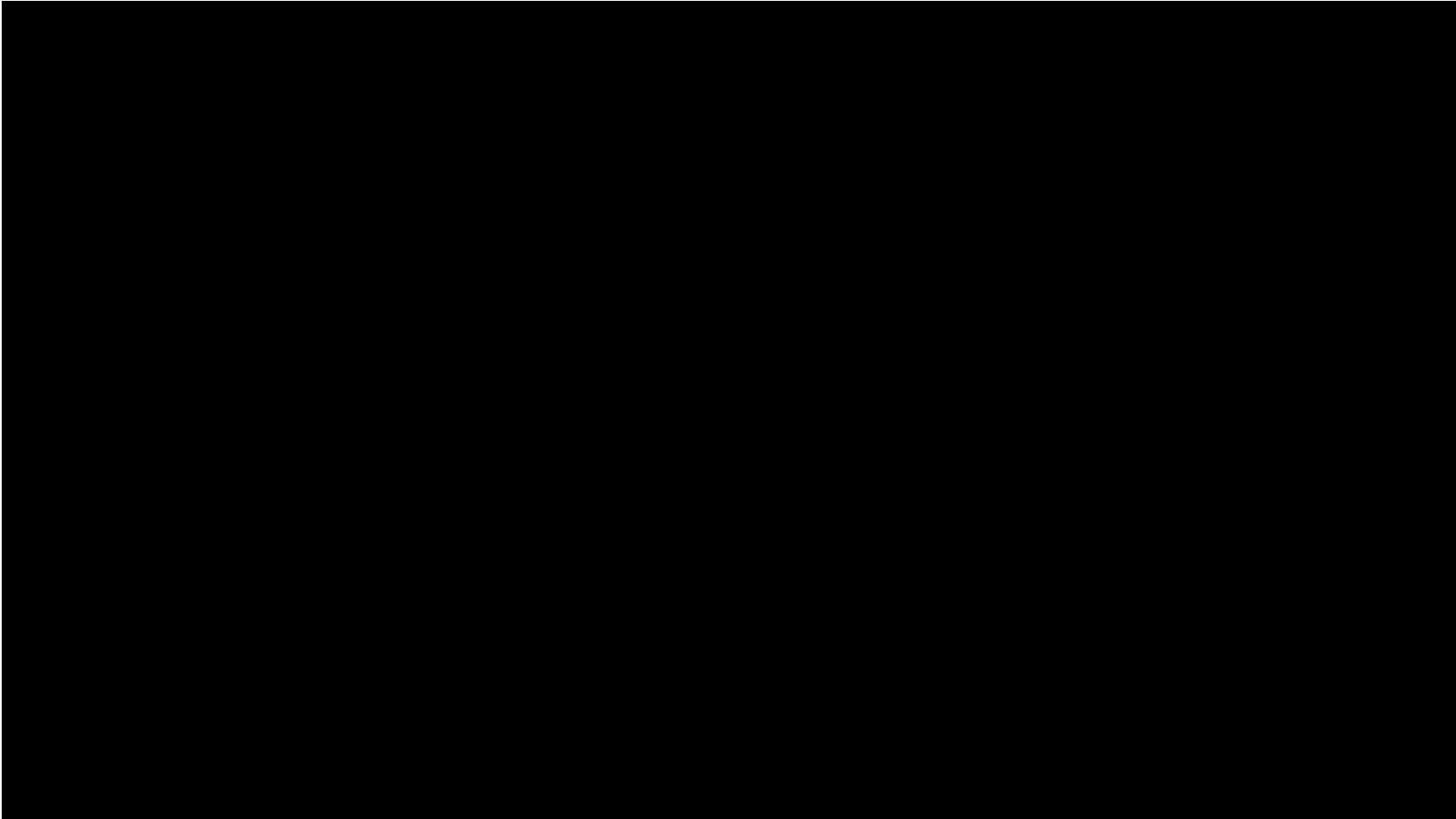
Research

Development of credible data and information on Internet pharmacies, trends and illicit online drug sellers.

Collaborate

Work alongside US and international partners to raise awareness and improve patient safety online.





ASOP Global – LegitScript Online Pharmacy Market Spotlight Reports

- **United States: 65%** of search results for prescription drugs facilitate the sale of unapproved and dangerous drugs.
- **Canada: *Bifurcated supply chain.***
 - ✓ Legitimate, Health Canada-approved medications **only** to Canadian consumers.
 - ✓ Consumers outside of Canada, drugs are sourced from India, China and elsewhere.
- **Russia: 51%** of search results display unapproved and dangerous medications.
- **China: 93%** of online drug sellers were either “rogue” or “unapproved”.



LegitScript | ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES | July 2016

ASOP GLOBAL – LEGITSCRIPT ONLINE PHARMACY MARKET

SPOTLIGHT REPORT: THE UNITED STATES

Abstract

The information presented in this report, compiled and analyzed by LegitScript at the request of the Alliance for Safe Online Pharmacies (ASOP Global), provides an overview of the Internet market for prescription drugs in the United States. This analysis summarizes the state of regulations and regulatory action in the US, and also assesses the risk presented to US Internet users who search for a prescription drug or pharmacy online. Data used in this analysis includes US search engine results for a range of prescription drug queries.

As detailed in this report, LegitScript finds that almost two-thirds (65%) of search results for prescription drug terms facilitate the sale of unapproved and dangerous medication to the US populace, leading to so-called “rogue” internet pharmacies, most of which are operated by Russian or Eastern European organized criminal networks. A substantial portion of these illicit results are also represented by “so-called Canadian” online pharmacies that may have a business or pharmacy license in Canada, yet do not usually source the medicines sold to US residents from a real, licensed Canadian pharmacy. Note

Conducting Research

	OTC sold online	Prescription Medication sold online		OTC sold online	Prescription Medication sold online
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Australia	✓	✓	Germany	✓	✓
Brazil	✓	✓	Indonesia	✓	✓
Canada	✓	✓	Ireland	✓	✗
China	✓	✗	Italy	✓	✗
France	✓	✗	Japan	✓	✗

Conducting Research

OTC sold online

Prescription
Medication sold
online

OTC sold online

Prescription
Medication sold
online

South Korea



Thailand



Netherlands



Turkey



Russia



UK



Spain



CONDUCTING RESEARCH

ASOP Global's Continuing Education Program

- Over 1,100 U.S. physicians and pharmacists took the course.
- **1%** of participants regularly discuss the risks of online pharmacies with the patients.
- After the course, **81%** of participants said that they would change their methods of treatment as a result of the course.
- Providers reported a **10-fold increase** in expected frequency of discussions regarding illegal online drug sellers.



CONDUCTING RESEARCH

Sponsoring Research

- Dr. Tim Mackey of UCSD Global Health Policy Institute.
- Non-medical Use of Prescription Medications (NUPM), including opioids, benzodiazepines and amphetamines.
- **45,000** tweets promoting NUPM through the sale of Rx drugs through online pharmacies in a two week period.

Exploring trends of nonmedical use of prescription drugs and polydrug abuse in the Twittersphere using unsupervised machine learning

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HIGHLIGHTS

- A methodology using unsupervised machine learning analyzed 11 million tweets filtered for commonly abused prescription opioid drugs
- Analyses identified 2.3 million tweets with content relevant to nonmedical use of prescription medications/drugs (NMUPD)
- Twitter content was associated with a high degree of discussion (approximately 80%) about polydrug abuse involving multiple types of substances
- The methodology can filter large volumes of twitter data with minimal human intervention to identify macro NMUPD themes and trends

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ABSTRACT

Introduction: Nonmedical use of prescription medications/drugs (NMUPD) is a serious public health threat, particularly in relation to the prescription opioid analgesics abuse epidemic. While attention to this problem has been growing, there remains an urgent need to develop novel strategies in the field of “digital epidemiology” to better identify, analyze and understand trends in NMUPD behavior.

Methods: We conducted surveillance of the popular microblogging site Twitter by collecting 11 million tweets filtered for three commonly abused prescription opioid analgesic drugs Percocet® (acetaminophen/oxycodone), OxyContin® (oxycodone), and Oxycodone. Unsupervised machine learning was applied on the subset of tweets for each analgesic drug to discover underlying latent themes regarding risk behavior. A two-step process of obtaining themes, and filtering out unwanted tweets was carried out in three subsequent rounds of machine learning.

Results: Using this methodology, 2.3M tweets were identified that contained content relevant to analgesic NMUPD. The underlying themes were identified for each drug and the most representative tweets of each theme were annotated for NMUPD behavioral risk factors. The primary themes identified evidence high levels

EDUCATION & AWARENESS: UNITED STATES



CENTER FOR MEDICATION
SAFETY ADVANCEMENT



IS THE MEDICINE YOU BOUGHT ONLINE SAFE?

Know The Facts Before You Buy!

96% of websites selling prescription medications online to U.S. consumers are **ILLEGAL**.



50% of medicines sold online from sites that hide their physical address are **COUNTERFEIT**.

89% of illegal online pharmacies **DON'T REQUIRE A PRESCRIPTION**.

Counterfeit drugs often contain **NO ACTIVE INGREDIENTS** and/or contain mercury, concrete, boric acid, paint, anti-freeze and other **DEADLY POISONS**.

65% of search results for prescription drugs lead U.S. consumers to **ILLEGAL AND UNSAFE WEBSITES**.



Buying prescription medicines from illegal online pharmacies increases your risk of **CREDIT CARD FRAUD AND IDENTITY THEFT**.

HOW TO STAY SAFE

ALWAYS visit www.BuySafeRx.pharmacy **BEFORE** you order prescription drugs online to verify that the site is legal and safe. You also can trust websites ending in .pharmacy since these sites have been approved by the National Association of Boards of Pharmacy.

NEVER order from online pharmacies that don't require a valid prescription; offer "too good to be true" prices; don't have a licensed pharmacist available for consultation; ship from other countries to the U.S.; or don't have a physical street address.



ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES



The screenshot shows the ASOP Global website with the following elements:

- Header:** ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES and Buy SafeRx logo.
- Navigation:** Home, About ASOP Global, Public Awareness Campaigns, FAQs, In The News, For the Media, Resources, Share Your Story, Contact Us, and social media icons for Facebook, Twitter, LinkedIn, and YouTube.
- Hero Image:** A large image of a red and white capsule on a prescription form with a large 'Rx' symbol.
- Text:** "The Alliance for Safe Online Pharmacies (ASOP Global) is a non-profit organization founded in 2009 to combat illegal online drug sellers and make the Internet safer for patients worldwide through advocacy, research and education."
- Target Audience:** Three categories: Consumers (with a photo of people at a table), Providers (with a photo of a doctor and patient), and Policymakers (with a photo of the U.S. Capitol).
- Video:** "ASOP Global 2015 Overview Video" featuring Libby Baney, J.D., Founder and Executive Director of ASOP Global.
- Call to Action:** "Report Unlawful Online Medicine Sales" with instructions to report illegal online drug sales to the U.S. Food and Drug Administration.
- Verification Tool:** A "Verify your online pharmacy" tool highlighted with a red circle. It includes a text input field with "www.example.com", a "Verify" button, and the text "Powered by LegitScript".
- Infographic:** A graphic titled "IS THE MEDICINE YOU BOUGHT ONLINE SAFE? Know The Facts Before You Buy!" with statistics: "96% of websites selling prescription medications online to U.S. consumers are ILLEGAL", "50% of medicines sold online from sites that hide their physical address are COUNTERFEIT", and "89% of illegal online pharmacies DON'T REQUIRE A PRESCRIPTION." It also features a "DANGER!" sign and a crossed-out Rx symbol.

EDUCATION & AWARENESS: EUROPEAN UNION



**Fighting Fakes by Raising
Public Awareness**



- Public awareness campaigns have proven effective in tackling the “demand” created consumers turning to the Internet.
- Recent law enforcement initiatives, such as Interpol’s Operation Pangea, confirm the continuing issue of illegal online drug sellers.

GLOBAL INFLUENCE – CHINA

International Symposium on Drug Supply Chain Security & Combatting Counterfeit Drugs

October 28, 2016 in Beijing, China



ASOP | ALLIANCE FOR SAFE
GLOBAL | ONLINE PHARMACIES

FAEGRE BAKER
DANIELS

GLOBAL INFLUENCE – INDIA

International India Forum on Patient Safety and Access to Safe Online Pharmacies

March 1–2, 2017 in Delhi, India



सत्यमेव जयते

Government of India



24X7 toll free 1800-11-4424

**PATIENT SAFETY AND ACCESS
INITIATIVE OF INDIA FOUNDATION**

a Partnership for Safe Medicines India Initiative



**International Alliance of
Patients' Organizations**

A global voice for patients

Associate Member

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**FAEGRE BAKER
DANIELS**

GLOBAL INFLUENCE

ASOP Global's Canada
Working Group



Work with the Asia-Pacific
Economic Cooperation



**Asia-Pacific
Economic Cooperation**

COLLABORATE

80

ASOP | ALLIANCE FOR SAFE
GLOBAL | ONLINE PHARMACIES

 pharmacy®


ASOP EU
Alliance for Safe Online Pharmacy



 THE PARTNERSHIP FOR
SAFEMEDICINES.org
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS.


European Alliance for
Access to Safe Medicines

**FIGHT THE
FAKES**
SPEAK UP ABOUT FAKE MEDICINES


International Alliance of
Patients' Organizations
A global voice for patients
Associate Member

**PROJECT
MADE**
Health delivered.

KEY TAKEAWAYS

- Everyone has a role to play to address illegal online drug sellers
- APEC CoE Supply Chain activities play an important role
- The APEC Internet Sales Toolkit is an key global document
- Education is critical – consumers, healthcare providers, policymakers, and intermediaries need the facts
- Continued multisector collaboration and leadership needed to promote patient safety online

Continue alongside ASOP Global in this fight!

THANK YOU! QUESTIONS?

Libby Baney, JD

Executive Director, ASOP Global

Principal, Faegre Baker Daniels Consulting

Counsel, Faegre Baker Daniels LLP

Practice Focuses:

- Global Medication Safety
- Internet Policy
- Telemedicine & Telehealth
- Pharmaceutical Supply Chain
- Pharmacy

