

GHWP Annual Meeting

Proposal to Develop GHWP and APEC Initiatives to Combat Falsified Medical Devices Sold Through Internet Websites

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PERSONAL BACKGROUND STORY

- ▶ While I worked at the USDOC I was a member of the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT) Regulatory Committee. (2006 - 2008).
- ▶ At one meeting there was a discussion on African street markets.
- ▶ I made the comment they should be eliminated due to the high incidence of falsified medicines being sold.
- ▶ The response I received from an African member of the committee is something that I will always remember. Her response was



MY BACKGROUND AND CURRENT ACTIVITIES

- **Alliance for Safe Online Pharmacies (ASOP Global):** Treasury & Board Member (since 2014)
- **President, Gren International Health & Trade LLC:** (since 2014)
- **Health Industry Expert, USTDA Reverse Trade Missions:** Six RTMs; China, Turkey, Nigeria, Senegal, South Africa and Kenya (since 2016)
- **Former U.S. Government Senior Official:** Served as a U.S. Department of Commerce Office Director covering health industries (1991 – 2014).
- **APEC Harmonization Center (AHC):** Member Advisory Committee (since 2008)
- **Leading APEC Safe Medicine Activities:** Co-chair of Drug Det. Tech. Working Group (with China NIFDC) and Co-Chair Internet Sales Working Group (with Health Canada) (since 2014)
- **Led Medical Device Reg. Harmonization Initiatives:** APEC, ASEAN, Latin America, China, Russia, GHWP (1998 – 2014)

MY PAST GHWP ACTIVITIES

- Making a presentation today at the 26th annual GHWP meeting is very special to me.
- While I worked DOC, I was involved in establishing AHWP (1997) and I attended the meeting when the first AHWP Chair, Clarence Tan of Singapore, was elected.
- I also led an initiative through APEC Life Science Innovation Forum (LSIF), working with the Global Harmonization Task Force (GHTF), in organizing a series of med device reg. training workshops that took place in SE Asia and Latin America over a 9-year period.
- Many regulators and industry reps in this room participated in one or more of these training workshops.

PRESENTATION OUTLINE

- Global Falsified Medicine & Medical Devices Problem
- Operation Pangeia – Interpol
- WHO – Surveillance and Monitoring System
- APEC Regulatory Harmon. Steering Committee Work Combating Falsified Medicines (Supply Chain Security)
- Problems with On-line Buying of Medicines
- Alliance for Safe Online Pharmacies (ASOP Global)
- **Proposal to Develop a Toolkit to Combat Falsified Medical Devices Sold Through Internet Websites**
- Summary and Conclusions

WHAT ARE S&F MEDICINES (WHO)?

- **SUBSTANDARD:** Outside specification, excludes manufacturing errors but may include intentional or negligent errors.
- **FALSIFIED:** Deliberate intention to deceive.
- **Unregistered/Unlicensed Medical Products:** Medical products that have not undergone evaluation and/or approval by the regulatory authority for the market in which they are marketed/distributed or used in.
- **COUNTERFEIT:** Taken out of title due to Intellectual Property (IP) concerns, also confusion related to unauthorized generics.

I would recommend using these same terms for a falsified medical devices initiative.



BACKGROUND SUBSTANDARD / FALSIFIED MEDICAL PRODUCTS

- WHO International Medical Products Anticounterfeiting Task Force (IMPACT): Included drugs and medical devices (2006 – 2010)
- WHO Experts Group: Substandard, Spurious, Falsely labelled, Falsified and Counterfeit - SSFFC (2010 – 2017)
- As of May 29, 2017: WHO Member State Mechanism New Term - “Substandard and Falsified (S&F) Medical Products”
- WHO may consider doing more related to IVDs





Statement by
Former FDA
Commissioner
Scott Gottlieb

“If you're selling a drug with the potential for abuse and misuse through an online website, you're no longer in the business of selling widgets or books. You have a social contract to take voluntary steps to help address public health challenges.”

Applicable to medical devices as well!

Impact of COVID-19 - Medicines

- As demand for COVID-19 treatments and vaccines surged at the beginning of 2020, so too did the activity of illegal online pharmacies.
- Within a month of the WHO declaring the COVID-19 outbreak a pandemic, over 100,000 websites were registered with terms like “COVID,” “corona” and “virus,” and many are considered active malicious sites.
- In 2021, NABP released a report describing dozens of illegal online pharmacies actively selling prescription-only drugs to treat COVID-19, over 90% of which were registered anonymously.

Global Falsified Medical Devices Problem

- ▶ Coronavirus pandemic - The risk of falsified medical devices has increased dramatically.
- ▶ **Falsified medical devices - On the rise worldwide with regard to volume, level of sophistication and the number of economies/countries impacted.**
- ▶ 2010 - WHO reported that 8% of all medical devices in circulation are known to be falsified. Dated information and the actual numbers are likely significantly higher, but more recent global data is not available.
- ▶ **2020 - As Covid-19 spread around the world, many essential medical devices fell into short supply.**
- ▶ Surgical masks, and other PPE were particularly hard to come by with existing supply chains strained under this unprecedented demand.

Global Falsified Med Dev Problem

- ▶ In March 2020, a global operation by Interpol, Operation Pangea XIII, seized some 37,000 falsified medical devices, most of which were surgical masks.
- ▶ In September 2020, half a million counterfeit N95 masks were seized at Chicago O'Hare Airport.
- ▶ Customs officials stated that criminals are selling falsified medical devices (such as test kits) products through online marketplaces.
- ▶ Medical device companies rose to the challenge of supplying COVID-19 products in short supply during the pandemic.
- ▶ While there are significant global initiatives and research focused on falsified medicines, **there are extremely limited global activities focused on falsified medical devices.**

PROBLEMS WITH CURRENT “BUYING ONLINE” PRACTICES

- Increasing number of consumers using the Internet to purchase prescription drugs.
- **71% of consumers searching online for relevant health information.**
- Vast scope of medicines (and medical devices) available for purchase *without* a prescription.
- Consumer receives **wrong medication**, i.e. **incorrect dosage** form, sub-potent, super-potent, **lack of active ingredient**.
- Complex international problem, government cannot solve or stop the problem alone.
- Problem became much worse due to COVID-19.



FALSIFIED MEDICINES ONLINE

- ▶ According to the World Health Organization, **50%** of all prescription medicines sold online from websites that hide their physical address are falsified.
- ▶ Criminal trafficking of counterfeit medications make profits **ten times greater than that of illicit drugs**; generating between \$1-2.5 million in sales each month.



A counterfeiting drug site used to produce fake Viagra and other drugs for export to the US and EU (China).



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

FOCUS: THE INTERNET



- At any point, there are between 35,000 and 45,000 online drug sellers globally
- Every day, approximately 20 new illegal online pharmacy websites go live globally
- The Internet is inherently global, so this problem needs to be addressed worldwide

OPERATION PANGAEA - INTERPOL

- ▶ **INTERPOL** is the world's largest international police organization, with 192 member countries
- ▶ INTERPOL's role is to enable police around the world to work together to make the world a safer place
- ▶ Operation Pangea is an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the **dangers of buying medicines online**.
- ▶ Coordinated by INTERPOL, the **annual operation** brings together customs, health regulators, national police and the private sector from countries around the world



WHO SURVEILLANCE AND MONITORING SYSTEM

- ▶ In 2013, WHO launched the **Global Surveillance and Monitoring System** to encourage countries to **report incidents** of substandard and falsified medical products.
- ▶ The system provides technical support in emergencies, **links incidents between countries and regions**, and issues WHO alerts.
- ▶ As of November 2017, WHO had issued **20 global medical product alerts** and numerous regional warnings and has provided technical support in over 100 cases.
- ▶ WHO has **trained** a global network of over 550 regulatory staff in 141 Member States.

While the current focus is pharmaceuticals, this initiative could be expanded to include IVDs and other medical devices.

ABOUT ASOP GLOBAL

ASOP Global is dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers.

- ▶ **Educate** patients, caregivers and healthcare providers about how to stay safe when shopping for medicines online;
- ▶ **Influence** the policies of Internet commerce companies, local and national governments and law enforcement authorities;
- ▶ Conduct **research** on the Internet pharmacy market, consumer behaviors and trends; and
- ▶ **Collaborate** with partners and stakeholders to improve patient safety online.



INTEGRITY





Asia-Pacific Economic Cooperation

APEC Regulatory Harmonization Steering Committee (RHSC) Life Sciences Innovation Forum

- Internet Sales – Toolkit, Survey & Training Programs
- Detection Technologies – Toolkit, Guidance Document and Training Programs
- Single Point of Contact – Toolkit and Training Programs
- Supply Chain Roadmap
- Center of Excellence (CoE) Program

APEC Toolkit to Combat Illegal Internet Medical Product Sales

- ▶ 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
- ▶ **ASOP Global and Health Canada** led a 2022 Working Group that resulted in an Updated Toolkit

Initiative to Combat Falsified Med Dev Sold Through Internet Websites

- Goal - To establish APEC and GHWP initiatives and a toolkit focused on combating falsified medical devices sold through illegal internet websites.
- Combatting illegal online sales of falsified medicines has been a priority APEC Regulatory Harmonization Steering Committee (RHSC) initiative for many years, however, combatting falsified medical devices is not included in this initiative.
- The APEC RHSC has an Internet Sales Working Group under the APEC Roadmap for Medical Product Supply Chain Security.
- The Internet Sales Working Group has developed a Medical Products Internet Sales Toolkit during 2015 which has been updated during 2022.

Initiative to Combat Falsified Medical Devices Sold Through Internet Websites

- The APEC Internet Sales Toolkit focuses on prescription medicines and notes that there are also problems with illegal online sales of IVDs and other medical devices.
- For falsified medical devices sold through internet websites to be addressed by APEC RHSC, a new and separate initiative would need to be developed.
- GHWP could serve a useful role of examining this topic, and if there is support from GHWP regulators and industry reps, to recommend this as a new GHWP and APEC RHSC medical devices initiative.
- There is a **Medical Devices Priority Work Area under APEC RHSC**, which would be an appropriate place to address the problem of falsified medical devices sold through internet websites in APEC.

Initiative to Combat Falsified Medical Devices Sold Through Internet Websites

The APEC medical device **Priority Work Area** includes the following eight Centers of Excellence:

- Sichuan University (SCU), China
- Pharmaceuticals and Med. Dev. Agency (PMDA), Japan
- Nat. Institute of Med. Dev. Safety Info. (NIDS), Korea
- Soonchunhyang University (SCH), Korea
- Taiwan FDA, Chinese Taipei
- University of Southern California (USC), U.S.
- Northeastern University (NEU), Boston, U. S.
- **Pilot CoE - Centre of Regulatory Excellence (CORE), Duke-NUS Medical School, Singapore**

Initiative to Combat Falsified Med Dev Sold Through Internet Websites

- Establish a GHWP Working Group of government and industry reps to explore if there is support to proceed.
- I will be working with GHWP and APECMed to establish this WG, and we anticipate 3 meetings, the first by video call within the next month, the second in-person meeting in Singapore (Spring/Summer 2023), and the third meeting by video call following the Singapore in-person meeting.
- In coordination with APACMed organize 3-4 days of Singapore in-person meetings for further exploration of development of an initiative to combat illegal medical devices purchased through internet websites.

Initiative to Combat Falsified Med Dev Sold Through Internet Websites – Phase I Activities

Examples of possible Singapore meetings include:

- APACMed
- SE Asia GHWP government and industry reps
- Singapore Health Sciences Authority (perhaps also including other GHWP regulators)
- INTERPOL Regional Office in Singapore
- Duke-NUS CoRE (Pilot APEC CoE)
- US Pharmacopeia (USP) Singapore Office
- US Embassy Staff Singapore

Initiative to Combat Falsified Medical Devices Sold Through Internet Websites – Phase 2 Activities

- Continue activities of the Working Group to draft a toolkit to be considered for AHWP and APEC
- Coordinate with appropriate APEC RHSC Medical Devices CoEs and involve them in the toolkit development process
- Develop a data base on the extent of substandard and falsified medical devices in the global market
- Possible update presentation at the 2024 GHWP annual meeting

SUMMARY AND CONCLUSIONS FALSIFIED MEDICINES

- **Past 25 years** - significant global progress combatting falsified medicines and there are significant international activities and programs
- There is expanding evidence that **falsified medical devices is also a growing global problem.**
- There is also a need to develop similar activities for medical devices, but a new initiative will be required.
- The proposed phase 1 & 2 activities I outlined will move this proposed initiative forward.
- **My crystal ball forecast - 2000, 2020, 2040.**

Question? Thank You!



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