SUPPLY CHAIN SECURITY TOOLKIT for Medical Products

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Roadmap for Supply Chain Security

Member economies of the Asia Pacific Economic Cooperation (APEC) and non-APEC economies alike are adversely impacted by the international movement of substandard and falsified (S&F) medical products. As the medical products industry has become more globalized and specialized, economies must increasingly rely on the global marketplace to provide the medical products needed to keep citizens healthy and ensure that access to legitimate products is not disrupted. In an effort to address this modern issue, regulators, industry stakeholders, representatives from non-governmental organizations, international organizations, and academics from across the globe have come together as members of the "Roadmap to Promote Global Medical Product Quality and Supply Chain Security" ("Roadmap for Supply Chain Security") project, a collaborative multi-year project commissioned by APEC with oversight by its Life Science and Innovation Forum (LSIF) and the Regulatory Harmonization Steering Committee (RHSC). This work culminated in the development of this Supply Chain Security Toolkit. The Supply Chain Security Toolkit is intended to cover the entire supply chain and life cycle of medical products (i.e. raw materials to use by patients) and focuses on developing— and implementing through training programs— processes, procedures, and tools directed at enhancing global medical product quality and supply chain security. The Supply Chain Security Toolkit contains recommended best practices and tools to prevents and detect S&F medical products before they reach the consumer and to efficiently respond to incidents involving S&F medical products.

Comprehensive product quality and supply chain security requires a multilayer approach that includes prevention, detection, and response strategies and actions. The Supply Chain Security Toolkit is a comprehensive resource that addresses areas of vulnerability in the medical product supply chain. It contains recommended best practices and tools to prevent and detect S&F medical products before they reach the consumer and to efficiently and effectively respond to incidents involving S&F medical products. This section highlights the utility of the toolkit in in the prevention, detection, and response of S&F medical products.

In addition, the Supply Chain Security Toolkit can be used in conjunction with the World Health Organization's (WHO) guidance on developing a national plan for preventing, detecting, and responding to actions, activities, and behaviors that result in S&F medical products. This guidance is linked below.

📄 FINAL REPORT: APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security: Supply Chain Security Toolkit

📄 Prevention….Detection….Response

📄 World Health Organization: Guidance on Developing a National Plan for Preventing, Detecting, and Responding to Actions, Activities, and Behaviours that Result in Substandard and Falsified Medical Products

PREVENTION

Preventing Substandard, Spurious, Falsely Labeled, Falsified, Counterfeit (SSFFC) products from entering the supply chain requires, among other things:

- Improving transparency, accountability, and integrity of the supply chain by ensuring compliance with robust current good manufacturing, distribution, and pharmacy practices.
- Implementing track and trace systems and end-to-end product security and supply chain solutions to help ensure medical products are legitimate and enhance detection of illegitimate drugs.
- Ensuring robust import and export regulations to protect the legitimate medical product supply chain from entry of SSFFC products.
- Strengthening oversight of the sale of medical products on the Internet, including who may sell and what may be sold, in order to prevent the entry of SSFFC medical products into the supply chain.

DETECTION

Detecting Preventing Substandard, Spurious, Falsely Labeled, Falsified, Counterfeit (SSFFC) products in the supply chain requires, among other things:

- Incorporating detection technologies in order to improve surveillance and monitoring and identify products that are SSFFC.
- Improving surveillance, investigation, and actions against suspect SSFFC medical products.

RESPONSE

Responding to incidents of Preventing Substandard, Spurious, Falsely Labeled, Falsified, Counterfeit (SSFFC) products in the supply chain requires, among other things:

- Establishing a single point of contact (SPOC) program among the national medical regulatory agency, law enforcement, and others in order to facilitate coordination, communication, and information-sharing regarding incidents with medical products.
- Improving communication about incidents by reporting to the global surveillance and monitoring system for SSFFC medical products.

Centers of Excellence

The "Roadmap to Promote Global Medical Product Quality and Supply Chain Security" was developed under the auspices of the APEC Regulatory Harmonization Steering Committee (RHSC). The RHSC established the Centers of Excellence (CoEs) model to link APEC/RHSC harmonization initiatives with training institutions and key players in the healthcare field, to maximize the use of public and private partnerships and other available resources. The CoE's role is to develop content and deliver quality trainings based on the toolkit materials developed by the members of the "Roadmap to Promote Global Medical Product Quality and Supply Chain Security."

To date, RHSC has endorsed two CoEs to conduct pilot programs on medical product supply chain security:

1. **United States Pharmacopeial Convention (USP).** USP's pilot program focuses on enhancing the implementation and sustainability of the RHSC's Supply Chain Integrity Roadmap best practices, covering compendial standards, good manufacturing practices, good distribution practices, screening technologies, and internet sales.

2. **University of Tennessee Health Sciences Center (UTHSC).**   UTHSC's pilot program focuses on protecting patient safety in the global marketplace through good distribution practices and product security measures.

Good Manufacturing Practices (GMP)

Appropriate manufacturing is essential for global medical product quality and supply chain security. The materials below identify best practices related to medical product supply chain security, providing current good manufacturing practices (CGMP) recommendations for stakeholders. These recommendations for best practices are intended to minimize divergent practices and opportunities for the introduction of substandard, spurious, falsely-labeled, falsified, or counterfeit medical products into the global supply chain.

The information and materials below are intended for industry stakeholders and National Medical Regulatory Authorities (NMRAs)-

1. Industry may use this information to adopt best practices;

2. NMRAs may use this information to strengthen laws and regulations; and

3. Industry and government may use for training purposes.

GMP Tools

Asia-Pacific Economic Cooperation

Good Distribution Practices (GDP)

To ensure supply chain security and integrity and maintain product quality, good distribution practices (GDPs) should be followed by all stakeholders as medical products move through the supply chain. The materials provide recommendations for the standardization and convergence of GDPs, focusing on supply chain security across industry, while accounting for evolving regulations.

The information and materials below are intended for industry stakeholders and National Medical Regulatory Authorities (NMRAs)-

1. Industry may use this information to adopt best practices;

2. NMRAs may use this information to strengthen laws and regulations; and

3. Industry and government may use for training purposes.

GDP Tools

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Good Import/Export Practices (GIEP)

Trade allows for the global distribution of new medical products, providing health benefits to patients around the world. However, inadequate and ineffective regulatory controls facilitate the movement of SSFFC medical products and have detrimental public health consequences. Materials and information are being developed with best practices related to good import and export practices.

Information and training materials are still under development.

GIEP Tools

Asia-Pacific Economic Cooperation

Clinical and Retail Pharmacy Practices (CRPP)

It is essential that quality control measures are implemented at dispensing sites, (e.g., retail and hospital pharmacies,) because they serve as the last opportunity to prevent patients from getting SSFFC medical products. Such measures should span from the time of purchase and receipt, to storage, and until the products are dispensed or administered. The information and materials below provide overviews of clinical and retail pharmacy practices across APEC economies, identifying best practices and resources required to support implementation.

The materials below are intended for industry stakeholders, National Medical Regulatory Authorities (NMRAs), and healthcare practitioner-

1. Industry may use this information to adopt best practices;

2. NMRAs may use this information to strengthen laws and regulations; and

3. Healthcare practitioners may use this information to improve patient care and outcomes

4. All may use for training purposes

CRPP Tools

Asia-Pacific Economic Cooperation

Product Security (PS)

Given the continued growth of threats to the global medical product supply chain, including substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products, cargo theft, intentional adulteration, product diversion, substandard products, and product tampering, holistic, end-to-end supply chain solutions are necessary to ensure the security and integrity of the supply chain. The information and materials below cover comprehensive supply chain security programs, managing upstream supply chain threats, mitigating the risks of cargo theft, audits of logistics service providers, monitoring marketplace threats to supply chains, responding to supply chain security breaches, and measuring the effectiveness of supply chain security systems. A good management system aimed at establishing standards through corporate policies, quality procedures, employee training, and the thoughtful selection of suppliers and distributors can assist firms in implementing effective product security measures.

The information and materials below are intended for industry stakeholders and National Medical Regulatory Authorities (NMRAs)-

1. Industry may use this information to adopt best practices;

2. NMRAs may use this information to strengthen laws and regulations; and

3. Industry and government may use for training purposes.

PS Tools

Detection Technology (DT)

Various tools are available for stakeholders to use at different points in the supply chain to assure the quality and authenticity of medical products. Detection of substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products, and authentication of drug product and packaging, requires the use of numerous complementary features and modes of analysis, such as visual, chemical/forensic, and track and trace. The information and materials below highlight the capabilities and limitations of these technologies and provide guidance on the appropriate selection and application of detection technologies to help ensure the integrity of medical products along the entire supply chain.

DT Tools

Internet Sales (IS)

The growing trend of consumers purchasing their medical products on the Internet is worrisome because of the fraudulent pharmacy websites that offer for sale substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products. Often times the consumer is not receiving the drug they purchased, or it may be an incorrect dosage, sub-potent, super-potent, or contain no active ingredient at all. The information and materials below define the scope of the internet sales problem, present recommendations for combatting illegal internet medical product sales, and provide publicly available resource materials. The Internet Toolkit offers key definitions that pertain to internet sales of medical products globally to help national medical regulatory authorities distinguish between legally-operating online medical product sellers and illegal entities.

The information and materials below are intended for industry stakeholders, National Medical Regulatory Authorities (NMRAs), healthcare practitioners, and consumers-

1. Industry may use this information to adopt best practices;

2. NMRAs may use this information to strengthen laws and regulations

3. Healthcare practitioners may use this information to communicate risks to patients; and

4. Consumers may use this information to make more informed healthcare decisions

IS Tools

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Track and Trace Systems (TTS)

The ability to track and trace medical products is critical to curtailing counterfeiting and diversion in the legitimate supply chain. Global standards to identify, capture, and share product information that can enable the authentication and traceability of medical products from manufacturer to patient is essential. The information and materials below focus on best practices and resource materials for finished pharmaceutical products; however the same principles may be applied to other associated medical product supply chains as well.

TTS Tools

Asia-Pacific Economic Cooperation

Substandard, Spurious, Falsely Labeled, Falsified, Counterfeit (SSFFC) Surveillance and Monitoring (SM)

The existence of SSFFC medical products is an unacceptable and, to a significant extent, avoidable risk to patients and consumers, which undermines confidence in medical products, healthcare providers, and health systems. As such, it is essential for global communication and cooperation in identifying and monitoring for SSFFC medical products. With the globalization of trade in active pharmaceutical ingredients and finished medicines, the World Health Organization (WHO) recognized the need to establish a Global Surveillance and Monitoring System (GSMS) for SSFFC medical products. The information and materials below provide a visual tool to benchmark a minimum set of core functions needed to prevent, detect, and respond to substandard and falsified medical products and a website that is a reliable and up-to-date resource on this topic.

SM Tools

Asia-Pacific Economic Cooperation

Single Points of Contact (SPOC)

Due to the globalized nature of medical product supply chains, incidents involving substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products often affect more than one country. Therefore, a well-maintained SPOC network allows authorities to implement best practices, promote cooperation and information exchange for health authorities, customs, police, and other competent authorities at the national level, and international cooperation in the risk management of SSFFC medical products. The toolkit below provides recommendations for National Medical Regulatory Authorities implementing a SPOC system. This includes: 1) identifying officials at the national and international level for the purpose of coordinating regulatory, law enforcement, and judicial actions taken proactively and 2) reactively addressing incidents involving substandard, spurious, falsely labeled, falsified, and counterfeit medical products.

SPOC Tools