Introduction

In 2012, the World Health Assembly established the Member State Mechanism to address the issue of substandard and falsified (SF) medical products. This Mechanism aims at promoting the prevention and control of substandard and falsified medical products and associated activities, through effective collaboration among Member States and the Secretariat, in order to protect public health and promote access to affordable, safe, efficacious, and quality medical products.

One of the Mechanism's priority activities is to identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies, and control of substandard and falsified medical products in order to strengthen national and regional capacities.

To support the discussion of this prioritized item, a working group (WG) was convened in 2014. Its activities include the identification and/or development of training material for National and Regional Regulatory Authorities (NRRAs) focused on the prevention, detection and response to substandard and falsified medical products. Experts in this WG agreed, as a first step, to collect information about existing training material developed by Members States and other institutions, so to have a better understanding of what is already developed by different stakeholders. A survey was distributed in 2017 to collect information about existing training material, as well as to gather information on existing expertise and training needs.

Based on the information collected with this survey, members of the Working Group agreed that it would be useful to compile the information received in a user-friendly online “Handbook on existing training resources and reference documentation for the prevention, detection and response to substandard and falsified medical products”. This document is available for online consultation by Member States and WHO Secretariat, hosted in SF community of MedNet, WHO’s collaborative platform for scientific information exchange and sharing. To achieve a more robust description of the available resources, a new round of consultations to Member States and other stakeholders was conducted during 2017-2018.

This handbook is considered to be a “live document” that is to be updated on a periodic basis, to reflect current status of training resources for the prevention, detection and response to substandard and falsified medical products. It also includes reference documents that might assist NRRAs in forming a body of knowledge around the issue.

The main purpose of this document is to present information that might be taken into consideration by NRRAs when developing regulation, preparing actions,
implementing procedures or working in any aspect related to the prevention, detection or response to substandard or falsified medicines.

As a descriptive document with no technical content, this handbook was not subjected to approval by Member States, and the information presented is not endorsed by the Member State Mechanism nor by WHO. The content of the handbook corresponds to a compilation of information provided by Member States, International Organizations, Regional Organizations and Non-State Actors in official relations with WHO.

The structure of this handbook was developed taking into consideration the documentation approved by the Member State Mechanism, such as the “Guidance on Developing a National Plan for Preventing, Detecting and Response to Actions, Activities and Behaviors that Result in SF Medical Products”, the “Recommendations for Health Authorities to detect and deal with actions, activities and behaviours that result in SF Medical Products” and the “WHO Member State Mechanism on SF Medical Products - Working Definitions”, available online for consultation. ¹

If you wish to present any information to update this document, please contact WHO Secretariat (rapidalert@who.int).

Issuing of licenses (for manufacturing, distribution, etc.)

According to the Thirty-fifth Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, the organizations engaged in the manufacture, promotion, import, export, distribution, sale or supply of provisionally registered or licensed medicinal products must meet prescribed criteria or requirements regarding facilities, personnel and practices, intended to ensure the quality of the product up to the time of usage/consumption. These criteria and requirements must be specified in law and NRRAs must keep a record of who are those organizations and if they comply with the necessary requirements to operate.

Available resources:

- Jornada informativa sobre novedades en la fabricación y distribución de medicamentos y principios activos - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

- Postgrado de Vigilancia Sanitaria de Medicamentos - Instituto Nacional de Higiene “Rafael Rangel”

- Compilation of Community Procedures on Inspections and Exchange of Information

- PAHO virtual course: Medicines regulatory functions
  [https://www.campusvirtualsp.org/](https://www.campusvirtualsp.org/)
Issuing of marketing authorizations

According to WHO, a marketing authorization is an official document issued by the competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products - the register - and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a license or product license.

Available resources:


- Postgrado de Vigilancia Sanitaria de Medicamentos - Instituto Nacional de Higiene “Rafael Rangel” [Link](http://www.inhrr.gob.ve/postgrados_vigilancia_sanitaria_id.php)


- Article 58 of Regulation (EC) No 726/2004 - Regulatory and procedural guidance (allows the Agency's Committee for Medicinal Products for Human Use to give opinions, in co-operation with the WHO, on medicinal products for human use that are intended exclusively for markets outside of the European Union) [Link](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000157.jsp&mid=WCo0b01ac05800240d1)
• FDA Education and Resources (by Subject) / Human drug approval and post-marketing
  https://www.fda.gov/Training/learningportal/ucm417363.htm#humandrug

• Red PARF Documento Técnico N. 1. Requisitos armonizados para el registro de vacunas en la Región de las Américas y Guía para la preparación de una solicitud de registro sanitario

• Red PARF Documento Técnico No. 7. Recomendaciones para la Evaluación de Productos Bioterapéuticos Similares (PBS) (2011)

• Red PARF Documento Técnico No. 10. Requisitos para el registro de medicamentos en las Américas (2013)

• USP/PQM Guideline for Registration of Medicines
  https://dec.usaid.gov/dec/content/Detail.aspx?ctID=ODVhZjk4NWQtM2YyMi00YjRmLTkxN2ktZTcxMjM2ND8mY2Uy&rID=MzkwMzMx
Compliance with current Good Manufacturing Practices

According to WHO, Good Manufacturing Practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production, which may broadly be categorized in two groups: cross contamination/mix-ups and false labeling. Above all, manufacturers must not place patients at risk due to inadequate safety, quality or efficacy; for this reason, risk assessment has come to play an important role in WHO quality assurance guidelines.

Available resources:

- WHO good manufacturing practices (including training material)

- Pharmaceutical Quality/Manufacturing Standards (CGMP) - US Food and Drug Administration
  https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064971.htm

- National Institute of Public Health of Japan
  https://www.niph.go.jp/entrance/h29/course/short/short_shokuhin01.html

- APEC Supply Chain Toolkit - GMP

- Jornada informativa sobre novedades en la fabricación y distribución de medicamentos y principios activos - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

- Postgrado de Vigilancia Sanitaria de Medicamentos - Instituto Nacional de Higiene “Rafael Rangel”
  http://www.inhrr.gob.ve/postgrados_vigilancia_sanitaria_id.php

- Curso Básico de Buenas Prácticas de Manufactura del Centro para el Control Estatal de la Calidad de los Medicamentos - CECMED / Cuba
• Curso de Buenas Prácticas de Manufactura de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - ANMAT / Argentina

• Compilation of Community Procedures on Inspections and Exchange of Information

• PIC/S Guide to Good Manufacturing Practice (GMP) for Medicinal Products (including APIs) – PE 009
  https://pic scheme.org/en/publications

• IFPMA GMP Infographic

• USP/PQM Good Manufacturing Practice Guideline for Pharmaceutical Products
  https://dec.usaid.gov/dec/content/Detail.aspx?cID=ODVhZjk4NWQtM2YyMm00YjRmLTkxNjktZTcxMjM2NDBmY2Uy&rID=MzkzMzI2
Compliance with Good Distribution Practices

According to WHO, any comprehensive system of quality assurance must be founded on a reliable system of controlling the quality, safety and efficacy of a finished product delivered to a market. It is important that all manufacturing operations are carried out in conformity with the accepted norms of GMP. The distribution channel and supply chain need to follow quality assurance as well in order that patients are getting quality products.

Available resources:

- WHO distribution (starting materials, compounding, monitoring, finished products, procurement, storage and model guidances)

- APEC Supply Chain Toolkit - GDP

- Jornada informativa sobre sobre las nuevas Buenas Prácticas de Distribución de medicamentos de uso humano - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

- Postgrado de Vigilancia Sanitaria de Medicamentos - Instituto Nacional de Higiene “Rafael Rangel”
  http://www.inhrr.gob.ve/postgrados_vigilancia_sanitaria_id.php

- Compilation of Community Procedures on Inspections and Exchange of Information

- Comprehensive list of GDP guidelines
• European Commission Guidelines on Good Distribution Practice of medicinal products for human use

• PIC/S Guide to Good Distribution Practice (GDP) for Medicinal Products – PE 011
  https://pic_scheme.org/en/publications
Compliance with Good Pharmacy Practices

According to the Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services, GPP is the practice of pharmacy that responds to the needs of the people who use the pharmacists’ services to provide optimal, evidence-based care. To support this practice, it is essential that there be an established national framework of quality standards and guidelines.

Available resources:


Maintaining public database of authorized products, marketing authorization holders and authorized companies

According to WHO, the regular publication of marketing authorization decisions and the existence of registers that detail which are the authorized products and companies in a given jurisdiction is helpful not only to procurement and distribution networks, but also to other Regulatory Authorities, once they present useful information about products and companies authorized by other regulators. In the context of detecting and responding to SF medical products, these databases might be especially helpful in the correct characterization of a suspected product or transaction.

Available resources:

- WHO Public Inspection Reports (WHOPIRs)
  http://www.who.int/immunization_standards/vaccine_quality/WHOPIRs_Vaccines/en/

- Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States
  http://www.who.int/medicines/regulation/ssffc/mechanism/en/
Risk-based inspections

According to WHO, all inspections shall be planned, performed, and, in the case of surveillance inspections, be at a frequency and level of detail that takes into account the nature of the products manufactured and the history of compliance of the respective site. A risk-based approach determines the frequency of inspections, taking into consideration elements of the history of the companies and their products, such as recalls, past non-compliances detected, the product’s risk categorization, reported adverse events, results of laboratory testing or changes within the company. The risk approach might also be useful in planning and conducting investigative inspections.

Available resources:

- WHO guidelines on quality risk management

- Manufacturer inspections - a risk-based approach to frequency

- A Model for Risk Based Planning for Inspections of Pharmaceutical Manufacturers - EMA

- Compilation of Community Procedures on Inspections and Exchange of Information

- PIC/S Recommendation on Risk Based Inspection Planning - PI 037
Risk-based post-marketing surveillance

According to WHO, regular sampling and surveying of both the regulated and unregulated supply chains is a way of identifying SF medical products. Different methodologies are used to sample the market and range from random sampling through to targeted sampling of particular products and outlets. It is important to optimize the use of resources by focusing surveillance activities on those products and venues that pose a higher risk to patients. Risk-based post-marketing surveillance might be a very effective tool in the detection of SF medical products.

Available resources:

- WHO Post market surveillance
  http://www.who.int/medicines/regulation/ssffc/pms/en/

- WHO Guidelines on the conduct of surveys of the quality of medicines

- Jornada informativa sobre el Real decreto de farmacovigilancia

- USP/PQM Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries
  https://dec.usaid.gov/dec/content/Detail.aspx?vID=47&ctID=ODVhZjk4NWQtMzYyMi00YjRmLTcxNjktZTcxMjM2NDNmYzUy&rID=NTAyMjM4

- USP/PQM Guideline to Establishing a Medicines Quality Monitoring Program
  https://dec.usaid.gov/dec/content/Detail.aspx?ctID=ODVhZjk4NWQtMzYyMi00YjRmLTcxNjktZTcxMjM2NDNmYzUy&rID=MzkzMDg4
Track and trace systems

Track and trace systems are used as a means of verifying that medical products move alongside the regulated supply chain, helping in the prompt detection of deviations and quick response from regulatory authorities. For that, they are one tool available in preventing the distribution of unauthorized medical products in the supply chain. According to the document “Existing technologies and “track and trace” models in use and to be developed by Member States” (Appendix 2 of WHA document A69/41), the term “traceability” is usually defined as the ability to identify the origin and the various stages of consumption goods production and distribution processes. The term “track and trace” is also used when describing traceability, which also includes the ability to track where a legitimate product is at any given time within the regulated distribution system operating within a harmonized region.

Available resources:

- Existing technologies and “track and trace” models in use and to be developed by Member States

- APEC Supply Chain Toolkit - Track and trace systems

- Pharmaceutical Industry Joint Position on Serialization and Product Verification - Helping to Secure the Legal Supply Chain for Greater Patient Safety
Authentication and detection technologies

According to the document “Available authentication technologies for the prevention and detection of SF medical products” (Appendix 2 of WHA document A70/23), authentication technologies comprise several solutions applied to the original drug, especially to the packaging, to enable the verification of genuineness of medicine samples, either by NRRAs, industry representatives, government officers and even the public. They also act as a deterrent to anyone considering production of SF medical products, once they make the production of a convincing falsified drug more difficult and costly. On the other hand, detection technologies are those used in the identification of SF medical products, ranging from a visual analysis of authentication technologies to a full chemical analysis in a laboratory setting.

Available resources:

- Available authentication technologies for the prevention and detection of SF medical products

- APEC Supply Chain Toolkit - Detection Technology (DT)

- Jornada informativa Dispositivos de seguridad: aspectos regulatorios y puesta en marcha en España - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

- EU Regulations - Tamper evident packaging

- Q & A document for EU Regulations on safety features for medicinal products for human use

- USP Technology Review Program
Inspections at borders

Inspections at borders include administrative and other safeguards aimed at ensuring that consignments of imported products are in conformity in all particulars with the relevant import license and that they remain secure within the distribution chain.

Available resources:

  http://apps.who.int/medicinedocs/en/d/Js5516e/22.html

- APEC Supply Chain Toolkit - Good Import/Export Practices (GIEP)

- Import Operations and Actions - US Food and Drug Administration


- Jornada informativa sobre la orden ministerial de control sanitario en frontera por la inspección farmacéutica - aplicación informática SIFAEX (Orden SPI/2136/2011 - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

- SADC guidelines on import and export procedures for pharmaceutical products

- Risk Management Compendium - World Customs Organization

- Pre-shipment inspection and testing agents
  http://www.nafdac.gov.ng/index.php/stakeholders/pre-shipment-inspection-and-testing-agents
According to the Regulatory Affairs Professionals Society, regulatory professionals have the professional and ethical responsibility to maintain the highest standards of professional conduct as they exercise their professional duties, as they play a pivotal role in ensuring compliance with applicable laws and regulations in the development and commercialization of healthcare products. Observance of codes of conduct and ethical principles might impair that SF medicinal products enter the legal supply chain.

Available resources:

- Code of Ethics - Regulatory Affairs Professionals Society  

- Regulatory Procedures Manual - US Food and Drug Administration  

- Código de conducta de los trabajadores del CECMED  

- The EMA Code of Conduct  

- FDA: Ethics  
  [https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm](https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm)
Risk communication and awareness campaigns

According to WHO, risk communication refers to the real-time exchange of information, advice and opinions between experts, officials and people who face a threat to their wellbeing, to enable informed decision-making and to adopt protective behaviors. In the context of SF medical products, communication and awareness activities targeting health professionals, regulated sector and/or public in general; including the issuing of public alerts, aim mainly at educating about and preventing the use of substandard and falsified medical products.

Available resources:

- WHO Course: Risk Communication Essentials
  https://openwho.org/courses/risk-communication

- WHO Course: Communication essentials for Member States
  https://openwho.org/courses/publichealthcom

- Know Your Source: Protecting Patients from Unsafe Drugs - US Food and Drug Administration
  https://www.fda.gov/drugs/resourcesforyou/healthprofessionals/ucm389121.htm

- BeSafeRx: Know Your Online Pharmacy
  www.fda.gov/besafex

- Canadian Online Pharmacies - Alliance for Safe Online Pharmacies
  http://buysafex.pharmacy/public-awareness-campaigns/canadian-online-pharmacies/

- S.A.F.E.D.R.U.G. Guide
  http://www.safemedicines.org/safedrug

- Counterfeit medical products and similar crimes: Risk communication (Book by Domenico Di Giorgio, Italian Medicines Agency - AIFA)
  https://www.researchgate.net/publication/263472806_counterfeit_medical_products_and_similar_crimes_risk_communication
- La venta ilegal de medicamentos por Internet. Conferencia nacional del proyecto Fakeshare - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) 

- Programa "Medicina para Todos" - Dirección Nacional de Medicamentos / El Salvador 

- Medicamento verdadeiro - ANVISA 
  http://www.anvisa.gov.br/medicamentoverdadeiro/

- Fight the Fakes Campaign 
  www.fightthefakes.org

- ASOP EU Report on Fighting Fakes by Members States 

- Campaign from The French National Association of Pharmaceutical Students (ANEPF), the International Institute of Research Against Counterfeit Medicines (IRACM), the French Industrial Property Institute (INPI), the French Order of Pharmacists (ONP) and the National Anti-Counterfeit Committee (CNAC) 
  http://www.le-faux-medicament-kesako.com/
Investigation of suspect incidents and intelligence activities

Investigation of suspect incidents include field procedures and inspections by NRRAs as well as intelligence activities, carried out jointly or with the support of national and international stakeholders, with the aim at detecting and responding to substandard and falsified medical products, generally outside of the legal and regulated supply chain.

Available resources:

- Investigations - US Food and Drug Administration

- A Practical Guide for EU investigations on Falsified Medicines

- Practical training on investigative techniques - INTERPOL
  https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Skills-and-knowledge

- Pharmaceutical Security Institute (PSI)
  http://www.psi-inc.org/index.cfm
Detection of SF products

According to WHO, even the most tightly regulated supply chains will still be vulnerable to SF medical products. When SF products have penetrated the supply chain it is important to have strategies in place to detect them quickly. The detection of falsified medical products can be performed using a range of approaches, including routine inspections performed by NRRAs and enforcement agencies, targeted risk-based surveys, investigation of complaints, follow-up of reports on any suspicious observations in the supply chain and investigation of unexpected adverse events reported to have occurred with a specific product.

Available resources:

- WHO Laboratory Analysis
  http://www.who.int/medicines/regulation/ssffc/lab_analysis/en/

- WHO guidance on testing of “suspect” falsified medicines
  http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf (Annex 5)

- APEC Supply Chain Toolkit - Detection Technology (DT)

- Sampling - US Food and Drug Administration

- Global Pharma Health Fund - Minilab™ kit for rapid detection of SF products

- INTERPOL’s capacity building programme: module on falsified medicines
  www.iipcic.org


- Red PARF Documento Técnico No. 3. Guía de autoevaluación de buenas prácticas para Laboratorios Nacionales de Control Farmacéutico (2010)

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2 Upon request, INTERPOL can provide a password to follow the courses on this site.
• Red PARF Documento Técnico No. 6. Documento de Autoevaluación de Buenas Prácticas de Laboratorio (BPL) (2011)

  https://dec.usaid.gov/dec/content/Detail.aspx?ctlID=ODVhZjk4NWQtM2YyMi00YjRkLTkxNjkTcxMjMzNDBoYzUy&rID=MzkwNDcx
Removal of products from the market and safe disposal

According to WHO, upon confirmation of a medical product being substandard or falsified, a formal decision should be taken on its disposal, ensuring that it does not re-enter the market. Provision should be made for their appropriate and safe transport, and disposal should be done in accordance with international, national and local requirements, and with due consideration to protection of the environment.

Available resources:

Reporting of incidents to regional reporting systems and the WHO Global Surveillance and Monitoring System

The Global Surveillance and Monitoring System for SF medical products was launched in 2013, and its objective is to work with Member States in improving the quantity, quality and analysis of accurate data concerning SF medical products, and to use that data in the better prevention, detection and response to those products, in order to protect public health. Apart from the WHO global system, there are regional alert systems that work in a similar manner.

Available resources:


- Alertas de medicamentos falsificados y fraudulentos - Red de Autoridades en Medicamentos de Iberoamérica [https://www.redeami.net/web/subhomes/noticias_y_alertas/eami_conten_subhome_noticias_y_alertas.htm]

- Sistema FALFRA - Red de Autoridades en Medicamentos de Iberoamérica [https://www.redeami.net/docs/docs/cooperacion/medicamentos_falsificados/Protocolo_Uso_Sistema_FALFRA.pdf]

Assessment of alerts, reports and notifications received

The consideration, evaluation, classification and prioritization of alerts, reports and notifications received by NRRAs will assist in better detecting and responding to substandard and falsified products, allowing for the adoption of different strategies and regulatory actions in face of the detected problems and risks, Taking into account the local conjuncture and the NRRA’s technical capacities.

Available resources:

- Full List of WHO Medical Product Alerts

- Recommendations for health authorities on criteria for risk assessment and prioritization of cases of SF medical products
  http://www.who.int/medicines/regulation/ssffc/mechanism/en/

- PSI-IFPMA Infographic on falsified medicines in legitimate supply chains - SDCP & PSI Study
Contingency plans and monitoring programmes

According to WHO, shortages of essential drugs are becoming increasingly frequent globally, burdening health systems with additional costs and posing risks to the health of patients who fail to receive the medicines they need. Shortages of medical products are exploited by those that engage in the manufacture, distribution and supply of SF medical products. Anticipating and preventing shortages, and transparent procurement practices can assist in the prevention of SF medical products penetrating supply chains and reaching patients. The existence of contingency plans and monitoring programmes designed to avoid this situation and guarantee access.

Available resources:

- WHO Course: Incident Management System
  https://openwho.org/courses/incident-management-system

  http://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1

- Addressing the global shortage of medicines and vaccines

- FIP addressing global medicines shortages
  https://www.fip.org/Medicines-shortages

- Health Emergency Management Course - Health Canada

- Drug shortages listed by FDA
  https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

- Drug recalls listed by FDA

- Drug shortages listed by EMA
- Know Your Source: Protecting Patients from Unsafe Drugs - FDA
  https://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm

- IFPMA’s infographic: From Shortages to Sustainable Supply
  https://www.ifpma.org/resource-centre/from-shortages-to-sustainable-supply/

- IFPMA’s brochure: Taking a Leap Toward Global Supply Chain Efficiency
Illegal distribution or supply of medical products via the internet

According to WHO, with internet connectivity globally increasing year on year, medical products online are becoming more accessible. While in many countries it is legal to purchase medicines and medical products from properly authorized online pharmacies, with a prescription where necessary, many websites are offering medicines illegally, including SF medical products. NRRAs, law enforcement and customs undertake a series of initiatives to disrupt and remove illegal websites supplying medical products. What can look like a highly professional website providing quality medical products on your computer screen can be supported by a very different back office which fails to comply with the most basic of international standards of storage and distribution.

Available resources:

- SF medical Products - The Internet

- APEC Supply Chain Toolkit - Internet Sales (IS)

- Guía básica de investigaciones sobre la venta a través de Internet, de medicamentos falsificados o fraudulentos - Red de Autoridades en Medicamentos de Iberoamérica
  [https://www.redeami.net/docs/docs/cooperacion/medicamentos_falsificados/Guia_investigaciones_venta_internet_medicamentos_falsificados_fraudulentos.pdf](https://www.redeami.net/docs/docs/cooperacion/medicamentos_falsificados/Guia_investigaciones_venta_internet_medicamentos_falsificados_fraudulentos.pdf)

- La venta ilegal de medicamentos por Internet. Conferencia nacional del proyecto Fakeshare - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

- Buying medicines online - EMA

- EU logo for online sale of medicines
  [https://ec.europa.eu/health/human-use/eu-logo_en](https://ec.europa.eu/health/human-use/eu-logo_en)
• Quick Tips for Buying Medicines Over the Internet - US Food and Drug Administration
https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicinesSafely/BuyingMedicinesOvertheInternet/default.htm

• Avoid medicines scams - NHS Choices
http://www.nhs.uk/Livewell/Pharmacy/Pages/Miraclecures.aspx

• Buying drugs over the internet
https://www.canada.ca/en/health-canada/services/buying-drugs-over-internet.html

• NABPs: Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: March 2017

• IFPMA-FIP Brochure: Joining efforts to protect patients against online sales of fake medicines
Joint operations

To effectively respond to the emergence of SF medical products in a given market, field operations are also necessary. On-the-ground operations might be run on a national, regional or international level in order to disrupt transnational criminal networks involved in illegal activities. They might be directed at both physical outlets and internet suppliers, and include multi-agency efforts, supported by evidence. Usually, NRRAs count with the support of enforcement agencies to carry out field operations.

Available resources:

- Operations – INTERPOL³
  [https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations](https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations)

- Illicit Trade Report - World Customs Organization

- Heads of Medicines Agency - Working Group of Enforcement Officers
  [http://www.hma.eu/wgeo.html](http://www.hma.eu/wgeo.html)

- Pharmaceutical Security Institute (PSI)
  [http://www.psi-inc.org/index.cfm](http://www.psi-inc.org/index.cfm)

³ INTERPOL is coordinating various regional and global operations. INTERPOL through these operations brought together law enforcement and health regulatory agencies to operational activities. This experience can be shared (planning meetings delivery and operations). There are reports from the operations that can be shared with the agreement of the involved countries.
**Sensitization activities and collaboration among governmental authorities and with other stakeholders**

According to WHO, awareness amongst stakeholders of the existence of SF medical products is extremely variable - from healthcare professionals and supply chain professionals through to Police, Customs and the Judiciary, all need to be made aware of the existence, risks and impact of SF medical products. Ensuring close collaboration and open communication channels amongst national pharmacovigilance reporting centres, national medicines regulatory authorities, national poison centres and national quality control laboratories leads to the early detection of SF medical products. Furthermore, due to the global nature of the manufacture, distribution and sale of medical products, there is also the need for a global flow and exchange of information about SF medical products, especially among NRRAs.

Available resources:


- Partnerships - INTERPOL [https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Partnerships](https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Partnerships)


- Fight the Fakes Campaign Resources [http://fightthefakes.org/resources-library/](http://fightthefakes.org/resources-library/)
Developing / enhancing legal and regulatory tools

According to WHO, a fully functioning NRRA minimizes the risk from SF medical products entering the regulated and formal supply chain. The registration of medicines and systematic inspection of facilities engaged in manufacturing and distribution to ensure compliance with national and internationally recognized standards is key. A legislative framework setting out clearly the requirements for compliance, and dissuasive sanctions for non-compliance is important for preventing SF medical products becoming available in supply chains and ultimately reaching patients and consumers.

Available resources:

- WHO Regulatory Strengthening and Capacity Building

- PAHO virtual course: Medicines regulatory functions
  https://www.campusvirtualsp.org/

- The MEDICRIME Convention
  https://www.coe.int/en/web/medicrime/the-medicrime-convention

- IFPMA-Fondation Chirac MEDICRIME Infographic

- USP/PQM – A Risk-Based Resource Allocation Framework for Pharmaceutical Quality Assurance for Medicines Regulatory Authorities in Low- and Middle-Income Countries
General resources

The following programs, courses, documents and institutions are indicated as general resources that cover different regulatory aspects that play a role in the prevention, detection and response to substandard and falsified medical products.

- **PAHO** - Jornadas para la discusión de herramientas y generación de propuestas para la prevención, detección y respuesta ante productos subestándar y falsificados – Formación de fuerzas de trabajo nacionales


- **The Centre for Innovation in Regulatory Science** - CIRS [http://www.cirsci.org](http://www.cirsci.org)


- **USP-APEC RHSC Center of Excellence (CoE) for Product Quality & Supply Chain** [http://qualitymatters.usp.org](http://qualitymatters.usp.org)


- **Pharmaceutical Crime - INTERPOL** [https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime](https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime)


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4 INTERPOL provides e-learning courses to law enforcement and health regulatory agencies.