WHO Member State Mechanism on Substandard and Falsified (SF) Medical Products

online HANDBOOK on existing training resources and reference documentation for the prevention, detection and response to SF medical products

2019
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 SF 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.

Among the Mechanism's priority activities are to identify major needs and challenges and make policy recommendations, and develop tools in the areas of prevention, detection methodologies, and control of SF 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 SF 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 the WHO Secretariat, hosted in the 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 with 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 the current status of training resources for the prevention, detection and response to SF 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 SF medical products.

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 or 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 behaviours 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 the WHO Secretariat at 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, 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 such organizations and whether they comply with the necessary requirements to operate.

Available resources

- Jornada informativa sobre novedades en la fabricación y distribución de medicamentos y principios activos [Briefing on new developments in the manufacture and distribution of medicines]. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Spanish Agency for Medicines and Health Products).

- Postgrado de Vigilancia Sanitaria de Medicamentos [Postgraduate specialization in medicine surveillance]. Instituto Nacional de Higiene “Rafael Rangel” (National Institute of Health), Bolivarian Republic of Venezuela.
  http://www.inhrr.gob.ve/postgrados_vigilancia_sanitaria_id.php


- Pan American Health Organization. Virtual campus for public health.
  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 international nonproprietary names 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, for example: “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


- Education and resources by subject/Human drug approval and post-marketing. United States Food and Drug Administration. https://www.fda.gov/Training/learningportal/ucm417363.htm#humandrug


Compliance with current Good Manufacturing Practice

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 labelling. 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


• Curso Básico de Buenas Prácticas de Manufactura Centro para el Control Estatal de la Calidad de los Medicamentos [Basic course in good manufacturing practices of the Centre for the State Control of the Quality of Medicines], Cuba

• Curso de Buenas Prácticas de Manufactura de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica [Course in good manufacturing practices of the National Administration of Medicines Food and Medical Technology], Argentina


• Infographic good manufacturing practices – convergence. International federation of Pharmaceutical Manufacturers and Associations. [Link](https://www.ifpma.org/resource-centre/infographic-good-manufacturing-practices-convergence/)

• Good Manufacturing Practice guideline for pharmaceutical products: main principles. Ethiopian Food, Medicine and Healthcare Administration and Control Authority. [Link](http://apps.who.int/medicinedocs/en/m/abstract/Js22357en/)
Compliance with Good Distribution Practice

According to WHO, any comprehensive system for quality assurance must be founded on a reliable system for 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 for GMP. The distribution channel and supply chain need to follow quality assurance processes as well in order to ensure that patients are getting quality products.

Available resources


- Good Distribution Practice (GDP) guidelines. GDP Association.


  https://picscheme.org/en/publications
Compliance with Good Pharmacy Practice

According to the Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services, good pharmacy practice (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


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1 This page is password-protected. Please contact rapidalert@who.int should you wish to have access.
Maintaining a 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). [https://extranet.who.int/prequal/key-resources/prequalification-reports/whopirs](https://extranet.who.int/prequal/key-resources/prequalification-reports/whopirs)

**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-compliance detected, the product’s risk categorization, reported adverse events, results of laboratory testing or changes within the company. The risk-based approach might also be useful in planning and conducting investigative inspections.

Available resources


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 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

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


- Jornada informativa sobre el Real decreto de farmacovigilancia [Briefing on royal decree on pharmacovigilance 577/2013]. Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Health Products). 

  https://dec.usaid.gov/dec/content/Detail.aspx?vID=47&ctID=ODVhZjk4NWQtM2YyMi00YjRmLTkxNjktZTcxMjM2NDUy&rlID=NTAyMjM4

- Guideline to establishing a medicines quality monitoring program. United States Pharmacopeial Convention. 
  https://dec.usaid.gov/dec/content/Detail.aspx?ctID=ODVhZjk4NWQtM2YyMi00YjRmLTkxNjktZTcxMjM2NDUy&rlID=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 Health Assembly 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 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

- WHO Member State Mechanism. Existing technologies and “track and trace” models in use and to be developed by Member States. [http://www.who.int/medicines/regulation/ssffc/mechanism/en/](http://www.who.int/medicines/regulation/ssffc/mechanism/en/)


Authentication and detection technologies

According to Appendix 2 of Health Assembly 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 by NRRAs, industry representatives, government officers or even the public. These technologies 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. In contrast, 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


Inspections at borders

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

Available resources


- Regulatory procedures manual. Import operations and actions. United States Food and Drug Administration.


- Jornada informativa sobre la orden ministerial de control sanitario en frontera por la inspección farmacéutica - aplicación informática SIFAEX [Briefing on the ministerial order for border health control by pharmaceutical inspection – SIFAEX computer application] (Orden SPI/2136/2011). Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency of Medicines and Health Products).

- SADC guidelines on import and export procedures for pharmaceutical products. Southern African Development Community.
• Customs risk management compendium. World Customs Organization. 

• Pre-shipment inspection and testing agents. National Agency for Food and Drug Administration and Control, Nigeria. 
Code of conduct/ethics for regulators

According to the Regulatory Affairs Professionals Society, regulatory professionals have a professional and ethical responsibility to maintain the highest standards of professional conduct in exercising their professional duties, as they play a pivotal role in ensuring compliance with applicable laws and regulations in the development and commercialization of health care products. Observance of codes of conduct and ethical principles might help to prevent SF medical products from entering the legal supply chain.

Available resources

- Code of ethics. Regulatory Affairs Professionals Society.  
  http://www.raps.org/who-we-are/advancing-the-profession/code-of-ethics


- Código de conducta de los trabajadores del CECMED [Code of conduct for workers of the Center for the State Control of Medicines, Equipment and Medical Devices].  

- The European Medicines Agency code of conduct.  

- Ethics. United States Food and Drug Administration.  
  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 well-being, to enable informed decision-making and to adopt protective behaviours. In the context of SF medical products, communication and awareness activities targeting health professionals, the general public or other relevant stakeholders, including the issuing of public alerts, aim mainly at educating about and preventing the use of SF medical products.

Available resources

- Risk communication essentials. WHO Online course on risk communication. [https://openwho.org/courses/risk-communication](https://openwho.org/courses/risk-communication)
- Communication essentials for Member States. WHO Online course on risk communication. [https://openwho.org/courses/publichealthcom](https://openwho.org/courses/publichealthcom)
- Know your source: protecting patients from unsafe drugs. United States Food and Drug Administration. [https://www.fda.gov/drugs/resourcesforyou/healthprofessionals/ucm389121.htm](https://www.fda.gov/drugs/resourcesforyou/healthprofessionals/ucm389121.htm)
- BeSafeRx: Know your online pharmacy. United States Food and Drug Administration. [www.fda.gov/besaferx](www.fda.gov/besaferx)
- Alliance for Safe Online Pharmacies [https://buysaferx.pharmacy/](https://buysaferx.pharmacy/)
- National Association of Pharmacy Regulatory Authorities (Canada) [https://napra.ca/online-pharmacies](https://napra.ca/online-pharmacies)

• “Fight the Fakes” campaign. [http://www.fightthefakes.org]


Investigation of suspect incidents and intelligence activities

Investigation of suspect incidents includes 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 SF medical products, generally outside of the legal and regulated supply chain.

Available resources


- Pharmacrime 3. International Institute of Research Against Counterfeit Medicines.  

- Practical training on investigative techniques. International Criminal Police Organization (INTERPOL).¹

- Pharmaceutical Security Institute.  
  http://www.psi-inc.org/index.cfm

¹ There is no link available – please contact rapidalert@who.int should you wish to have further information.
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 SF 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

- Laboratory analysis. World Health Organization.
  http://www.who.int/medicines/regulation/ssffc/lab_analysis/en/

  http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf


- Sampling. United States Food and Drug Administration.


- International IP Crime Investigator’s College. International Criminal Police Organization (INTERPOL) and UL.
  www.iipcic.org


\(^1\) Upon request, INTERPOL can provide a password to follow the courses on this site.
practices for national pharmaceutical control laboratories]. (Pan American Network on Drug Regulatory Harmonization).


- The three-level approach: a framework for ensuring medicines quality in limited-resource countries.
https://dec.usaid.gov/dec/content/Detail.aspx?cIID=ODVhZjk4NWQtM2YyMi00YjRmLTkxNjktZTcxMjktMzNDBmY2Uy&rIID=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 WHO Global Surveillance and Monitoring System for SF medical products was launched in 2013. 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


- Protocolo de instrucciones de uso Sistema FALFRA – sistema “online” de intercambio rápido de informacion y alertas de medicamentos falsificados y fraudulentos en Iberoamerica [Procol of instructions for use of the FALFRA system – online system for rapid exchange of information and alerts on counterfeit medicines in Latin America]. Red de Autoridades en Medicamentos de Iberoamérica (Network of Medicines Authorities of Latin America). [https://www.redeami.net/docs/docs/cooperacion/medicamentos_falsificados/Protocolo_Uso_Sistema_FALFRA.pdf](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 SF medical products. This will allow for the adoption of different strategies and regulatory actions in the face of the problems and risks detected, taking into account the local context and the NRRA’s technical capacities.

Available resources

- Full list of WHO medical product alerts.  

- WHO Member State Mechanism. 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/

- Counterfeit medicines in legitimate supply chains. International Federation of Pharmaceutical Manufacturers and Associations.  
Contingency plans and monitoring programmes

According to WHO, shortages of essential medicines 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 following transparent procurement practices, can assist in preventing SF medical products from penetrating supply chains and reaching patients. Developing contingency plans and monitoring programmes designed to avoid this situation can help to facilitate access.

Available resources

- Incident management system. WHO online course. https://openwho.org/courses/incident-management-system
• Know your source: Protecting patients from unsafe drugs. United States Food and Drug Administration. 
  https://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm

• From shortages to sustainable supply. International Federation of Pharmaceutical Manufacturers and Associations. 
  https://www.ifpma.org/resource-centre/from-shortages-to-sustainable-supply/

• Taking a leap toward global supply chain efficiency. International Federation of Pharmaceutical Manufacturers and Associations. 
Illegal distribution or supply of medical products via the internet

According to WHO, with internet connectivity globally increasing year on year, medical products are becoming more accessible online. 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 for storage and distribution.

Available resources


- Guía básica de investigaciones sobre la venta a través de Internet, de medicamentos falsificados o fraudulentos [Basic research guide about the sale of counterfeit or fraudulent medicines through the internet]. Red de Autoridades en Medicamentos de Iberoamérica (Network of Medicines Authorities of Latin America). [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)


• EU logo for online sale of medicines. European Commission.  
  https://ec.europa.eu/health/human-use/eu-logo_en

• Quick tips for buying medicines over the internet. United States Food and Drug Administration.  
  https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/default.htm

• What to expect from your pharmacy team - NHS  

• Dangers of buying medicines online - NHS  

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


• IFPMA-FIP Brochure: The threat of false friends. International Federation of Pharmaceutical Manufacturers and Associations.  
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

- Pharmaceutical crime operations. International Criminal Police Organization (INTERPOL)¹
  https://www.interpol.int/en/Crimes/Illlicit-goods/Pharmaceutical-crime-operations

- Illicit Trade Report 2017. World Customs Organization

  http://www.hma.eu/wgeo.html

- Pharmaceutical Security Institute.
  http://www.psi-inc.org/index.cfm

¹ INTERPOL is coordinating various regional and global operations, which bring together law enforcement and health regulatory agencies. Experience (such as planning meetings delivery and operations) and reports from the operations 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 among stakeholders of the existence of SF medical products is extremely variable - from health care 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

- Terms of reference for the Global Focal Point Network for SF medical products.  
  http://www.who.int/medicines/regulation/ssffc/mechanism/A69_41-en6-8.pdf?ua=1

- Supply Chain security Toolkit for medical products – Single points of contact. Asia-Pacific Economic Cooperation.  

- Rede de pontos focais da saúde para a prevenção e combate à falsificação de medicamentos e produtos médicos no MERCOSUL [Network of health focal points for the prevention of and fight against counterfeit medicines and medical products in MERCOSUL].  


- USP Public policy position on combatting substandard and falsified medicines. The United States Pharmacopeial Convention.  
• “Fight the Fakes”. Resources.
  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 are key. A legislative framework setting out clearly the requirements for compliance, and dissuasive sanctions for non-compliance, are important for preventing SF medical products becoming available in supply chains and ultimately reaching patients and consumers.

Available resources


General resources

The following programmes, 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 SF medical products.

- Pan American Health Organization. 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 [Conference for the discussion of tools and proposals for the prevention, detection and response to substandard and falsified products – training of the national workforce]

- PAHO Course - Acceso a fuentes de información y manejo de redes sociales¹

- BVS Course - Acceso y Uso de la Información Científica en Salud¹
  https://cursos.campusvirtualsp.org/enrol/index.php?id=142

- The Centre for Innovation in Regulatory Science.
  http://www.cirsci.org


  http://qualitymatters.usp.org


¹ This page is password-protected. Please contact rapidalert@who.int should you wish to have access.
• Pharmaceutical crime operations. International Criminal Police Organization (INTERPOL). ¹
  http://www.interpol.int/Crimes/Illlicit-goods/Pharmaceutical-crime-operations

• Falsified medicines. European Commission.
  https://ec.europa.eu/health/human-use/falsified_medicines_en

¹ INTERPOL provides e-learning courses to law enforcement and health regulatory agencies.