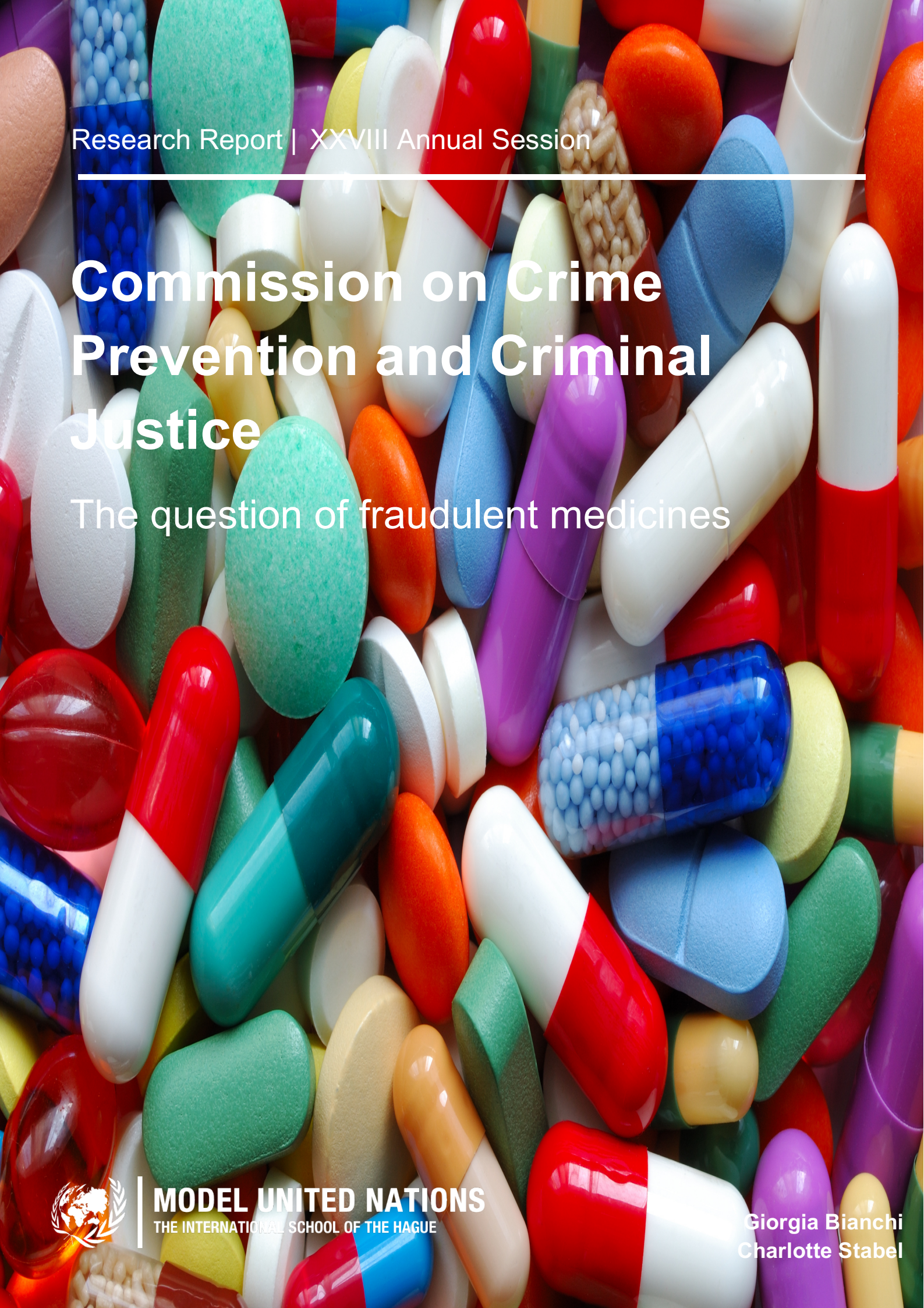

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Commission on Crime Prevention and Criminal Justice

The question of fraudulent medicines

MODEL UNITED NATIONS
THE INTERNATIONAL SCHOOL OF THE HAGUE

Giorgia Bianchi
Charlotte Stabel

Forum:	Commission on Crime Prevention and Criminal Justice (CCPCJ)
Issue:	The question of fraudulent medicines
Student Officer:	Giorgia Bianchi and Charlotte Stabel
Position:	Deputy president and President

Introduction

Fraudulent medicines are those which are produced and sold to a consumer with the purpose of falsely represent its origin, legitimacy, and efficacy. A fraudulent medicine will most likely contain improper amounts of active ingredients, undefined ingredients, and they may be sold with inexact, or even fake, packaging and labelling. Fraudulent medicines are associated to Pharma fraud. In order to try and minimise the negative effects of fraudulent medicine, drug manufacturers and distributors are continuously investigating in the various existing countermeasures, such as traceability and authentication technologies.

Fraudulent medicines constitute a large public health threat as they can fail to heal, and they may harm, or even kill, patients. In fact, low quality fraudulent medicine may cause numerous serious health complications, such as side effects or allergic reactions. Fraudulent antibiotics pose a prominent threat to the global population as they encourage the growth of drug resistant bacteria by having a low concentration of the active ingredients. This prominent threat has encouraged the international community to cooperate in order to enact a stronger response. Adding to this threat is the fact that the supply network for medical drugs functions at a global level, meaning that a collective effort is necessary in order to effectively identify and fight against the establishment of fraudulent medicines along said supply network.

Many different technologies can be used in order to fight against the issue of fraudulent medicines. For example, radio frequency identification is a method which utilises electronic devices to identify pharmaceutical substances by numbering the individual containers in which they are held. The U.S. Food and Drug Administration (FDA) is attempting to set up an ePedigree system to trace medical drugs from their factories to their final destination; pharmacies. This process effectively enables wholesalers and pharmacists to identify both the product and its dosage, hence preventing the forgery of drugs. However,

other technologies, such as energy-dispersive X-Ray diffraction and Raman spectroscopy, can be utilised to identify fraudulent medicines while they are still packaged.

Definition of Key Terms

Medicine

According to the World Health Organisation (WHO) a medicine is “any substance or combination of substances presented for treating or preventing disease in human beings or animals”.

Fraudulent Medicine

Fraudulent medicine, also referred to as falsified medicine, is a product which is produced and sold to intentionally deceive the consumer by faking its origin, authenticity or effectiveness. For example, if a vendor were selling pills without any medical effects labelled as paracetamol or any other painkiller, they would be selling fraudulent medicine.

Pharmaceutical

Pharmaceuticals, more commonly known as medicines or drugs is a substance used for treating or preventing diseases.

Active / Inactive ingredient

An active ingredient is the ingredient in a pharmaceutical substance that is responsible for achieving the wanted result. In a pharmaceutical substance there is also a certain amount of inactive or inert ingredients which do not help or increase the therapeutic action but are used for other proposes such as the colour, the fragrance, the flavour or the consistency.

Pharma Fraud

A term used to describe numerous illegitimate activities, including the manufacturing, marketing, and distribution of pharmaceuticals.

Substandard

Failing to meet their demanded or quality standards.

ePedigree

An ePedigree is an online document which withholds data on the history of a specific selection of drug. It meets the standard for a drug pedigree and while utilising an efficient electronic form.

General Overview

Causes

The idea of producing fraudulent medicines is enticing to many, due to the fact that they are not difficult to make and that production costs are low. In addition to this, criminals will most likely get away with this crime as the legal and illegal supply networks mix in markets which are not regularly regulated.

In addition to this, the profits made from the selling of fraudulent medicines is significant. In fact, in order to avoid arousing suspicion, criminals who sell fraudulent medicines make sure not to price them too low, and therefore opt to price them just below the price of the legal drug. However, in the wholesale market, fraudulent medicines can be priced with less care as these markets aren't frequently regulated and customers tend to be buyers for retails, rather than the general public, who may be complicit in the crime.

Anti-counterfeit Platforms

The world's first free-to-access anti-counterfeit platform was created in 2007 in Ghana. This platform depends on GSM networks in the same country to enable consumers to substantiate whether the medical drugs they purchased are legitimate by sending a free SMS message to the place of origin. In 2009, during a period of time in which the platform was still it its trial stages, the creators of the platform declared their partnership with Ghana's Ministry of Health and the Food and Drugs Board, Ghana's specialised agency in charge of drug safety, in order to develop the platform even further. A similar idea is being experimented in India.

In 2010, the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria established a show Sproxil's fight against fraudulent drugs in Nigeria. Similarly, in 2011, Kenya's Pharmacy and Poisons Board initiated an SMS-based anti-counterfeiting platform and supported the Sproxil solution. It was then reported that over 1 million consumers in Africa had used this platform in order to verify their medical drugs.

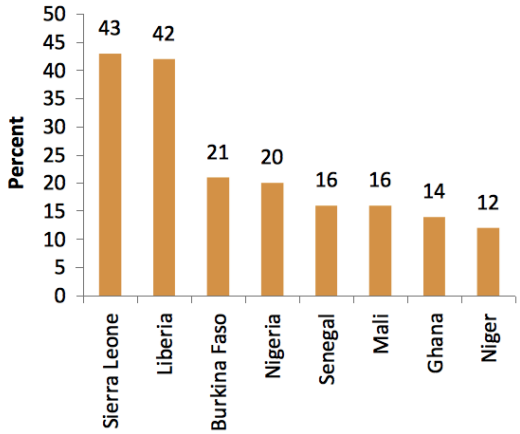
Another prominent and successful method of detecting fraudulent medicines is an ePedigree. Many states are asking pharmaceutical companies to produce and keep ePedigrees for each drug manage.

Packaging

The packaging of medicines is very important in terms of their legitimacy. For example, custom package seals, holograms, authentication labels, and security printing are all aspects which are of significant importance with regards to the security system. All these aspects facilitate the verification that the drugs enclosed within are exactly what the packaging states they are. Nevertheless, those who distribute fraudulent medicines often cooperate with package counterfeiters in order to trick consumers.

Anti-malarial medication

Malaria is a tropical disease caused by the bite of a mosquito infected with the Plasmodium parasite, which belongs to a group of one-celled organisms known as protozoa. The disease causes symptoms that typically include fever, nausea, headaches, vomiting and can be life-threatening if not treaty quickly. It is more present in tropical countries were the climate is warmer enabling the mosquitos and parasites to thrive. These regions include Sub Saharan Africa, South Southeast Asia, Latin America, and the Middle East. As the name indicates, anti-malarial medication is a drug designed to treat and prevent malaria. But in recent years the appearance of fake antimalarial drugs has become crucial health problem in developing countries. It has been estimated that fake anti-malarials contribute to nearly 450,000 preventable deaths every year. Africa. The illegal production, sale and distribution of fake drugs is a huge market estimated by WHO at more than US$35 billion and represents more than 15% of the pharmaceutical market worldwide with this proportion rising to more than 60% in developing countries, leading to a great number of deaths from untreated diseases such as malaria. The chart below illustrates the problem well as it shows the concerning high number of people who have been victim of a fake medicine or a member of their household. For example, in 2010, 42 percent of the population of Liberia, have been victims of those fake medicines. Combating counterfeit anti-malarials is a complicated task since the resources are limited and the techniques for the detection of fake anti-malarial are poor.



"Share answering "yes" to the question "Have you yourself or a member of your household been a victim of fake medicine?", *United Nations Office on Drugs and Crime (UNODC)*, 2010

Major Parties Involved

China

The State Food and Drug Administration cannot be held accountable for the regulation of pharmaceutical ingredients which are manufactured and sold abroad by chemical companies. This shortfall of regulations result in news coverage which was unfavourable for China, and the inefficient cooperation of regulatory agencies in China have hindered improvement. On May 6, 2005, a Chinese press agency named Xinhua proclaimed that the World Health Organisation had confirmed Rapid Alert System; the first online system for monitoring the activities of drug counterfeiters, due to the escalating severity of the issue of fraudulent medicines.

India

As claimed by the Outsourcing Pharma citing the European Commission, 75% of fraudulent medicines which are provided around the world have some origins in India. However, following a 2009 nationwide survey, the national regulatory authority for Indian pharmaceuticals and other medical devices stated that only 11 samples out of 24,000 samples were fake.

The trade in fraudulent medicines is facilitated by insufficient regulations, scarcity of drug inspectors, and a deficiency of laboratories which would enable the legitimisation of drugs.

Pakistan

In 2012, a fake medicine crisis released the scale of production of fraudulent medicine in Pakistan. Over 100 heart patients died following the distribution of degraded medicine by the Punjab Institute of Cardiology. Prior to this crisis, Pakistan did not have any regulatory administration, though a regulatory body was established in February 2012 as a response to this crisis.

United States of America

The USA has an increasing issue regarding fraudulent medicines. In 2007-2009, 149 American citizens died due to the use of Heparin, a contaminated blood thinner which was legitimately imported into the US. In 2012, 11 people were killed and 100 were sickened near Boston following the use of tainted steroids. The Food and Drug Administration is devoted to preserve the supply network against forgery and illegitimate drugs that enter the USA. To help prevent this, the FDA is warning health care workers that Medical Device King, a U.S. company which dispenses an illegal cancer drug, is fraudulent.

In 2005, the FDA held a Congressional hearing to assess this issue. It was stated that 40% of global annual prescription drug transactions were made in the US in 2007. In order to discourage advertising, a Protect IP Act was suggested in 2011. In fact, medical drug imports to the U.S. more than doubled in the years 2002 - 2010, with 80% of the active ingredients imported. These now make up 40% of finished medical drugs.

Africa

Efforts to control malaria in the continent of Africa have been threatened by the production and distribution of fake antimalarial medication. In 2011, as claimed by the World Health Organisation (WHO), 64% of Nigeria's imported antimalarial drugs were fraudulent. This is a prominent issue as Nigeria is Africa's biggest drugs market, and more than 70% of its medicines are imported from either India and China, which are considered to be the largest sources of fraudulent medicine.

In addition to this, it has been suggested that some pharmacists find themselves forced to purchase medical products from the cheapest suppliers, while they may not be the safest, in order to compete with illegal street traders.

Food and Drug Administration (FDA)

The FDA recognises reports of suspect forgery and fights against fraudulent medicines by cooperating with other agencies and the private sector in order to increase the protection of the nations' supply of drugs from the threat of fake medical products.

Interpol

The International Criminal Police Organization (Interpol) is an international organization based in the Netherlands, that facilitates the international police coordination. Since the manufacture, distribution of counterfeit medicines is not limited to a single country but it most of the time part of the actions of an organized international criminal activity, Interpol plays an important role I the matter. This illegal activity has increased over the years by the rise of the internet facilitating the sale of illicit goods because they can be bought easily and cheaply without any prescription. Interpol responses to this threat coordinating operations aimed to stop transnational criminal networks and training and educating agencies involved in the fight against pharmaceutical crime.

Timeline of Key Events

Timeline of events in reverse chronological order leading up to present day.

Date	Description of Event
1989	International Network for Rational Use of Drugs (INRUD) was created to establish effective way in which to ameliorate the way drugs are prescribed and used.
15 April 2011	Resolution on countering fraudulent medicines, in particular their trafficking.
21 July 2011	A new Directive was adopted by Member States as the EU attempted to increase the protection of consumers and patients with regards to fraudulent medicines.
14-15 February 2013	Technical Conference of Experts on the Trafficking in Fraudulent Medicines in Vienna.

Previous Attempts to Resolve the Issue

A new Directive was adopted by Member States as the EU attempted to increase the protection of consumers and patients with regards to fraudulent medicines. This Directive's main objective was to prevent the entrance of fraudulent medicines into the legal supply chain, consequently preventing them from reaching patients. It establishes new safety measures and amplifies the already existing control measures across Europe. These measures include a common EU logo for legally operating online pharmacies further helping the detection of websites claiming to sell real medicines, and other safety measures such as the packaging. These safety measures are crucial to the protection and health of the population because it helps them to identify if they are actually buying the medicines they need.

MEDICRIME Convention

In 2011, the Council of Europe created for the first time a binding international treaty in criminal law that obliges the parties to criminalise the manufacturing of counterfeit medical products. This is the first step to a harmonised international legislation on the topic and greatly helps to counter criminal organisation who operate across border. This convention entered into force in 2016 and has been ratified by five countries.

UN involvement, Relevant Resolutions, Treaties and Events

- Technical Conference of Experts on the Trafficking in Fraudulent Medicines, 14-15 February 2013 in Vienna.

- Countering fraudulent medicines, in particular their trafficking, 15 April 2011, (RES/20/6).

Possible Solutions

The issue of fraudulent medicine may be improved by improving general knowledge with regards to such drugs, by methods such as improving data collection, improving analysis, and deducing more methodical conclusions for remedial action. Not only should the knowledge on this subject be improved but the consumers should be more aware on the matter. Not everyone knows that medicines sold online can be falsified nor is everyone aware of the risk. By educating the general population and raising awareness the risk diminishes greatly and helps to further combat the trafficking of fraudulent medicines.

In addition to this, it could be wise to advise Member States to sign and ratify the MEDICRIME Convention, a convention drafted by the Council of Europe which constitutes a binding global tool in the criminal law field on the forgery of medical drugs and other issues regarding threats to public health. Furthermore, it could also be encouraged for other nations to create their own legislation by following and using the already existing convention as a guideline.

Moreover, the development of new technologies promises increased anti-counterfeiting measures. What makes these technologies efficient is that they don't require frequent and costly maintenance. Companies such as Clariant and KGaA are integrating these new technologies into anti-counterfeiting methods with distinct abilities such as the monitoring of high value product flows, the establishment of personalised data sets, and the reporting of attempts at forgery.

Appendices

MEDICRIME Convention

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UNODC – Trafficking in fraudulent medicine

https://www.unodc.org/unodc/en/fraudulentmedicines/introduction.html

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