UNITED NATIONS COMMISSION ON NARCOTIC DRUGS

AGENDA: ‘Discussing Measures to Control Drug Trafficking with Special Emphasis on Fraudulent Medicines’
Letter from the Executive Board

Greetings Delegates,

It is indeed an honour to welcome you to this simulation of the United Nations Commission on Narcotic Drugs (UNCND) at Amity International Model United Nations 2020. We sincerely hope that being a part of the conference is an intellectually stimulating experience for you as well as for us.

This simulation will be pondering the agenda “Discussing Measures to Control Drug Trafficking with Special Emphasis on Fraudulent Medicines.” For all procedural purposes of this meeting, we shall adhere to the UNA-USA Rules of Procedures. For all those participating in a MUN for the first time, or otherwise, please refer to the Rules of Procedures.

The purpose of this background guide is to equip you with the required knowledge about the committee as well as the agenda, therefore make sure you read and understand this background guide judiciously. However, at no point assume that only the content of the background guide can substitute for further research. Please also note that nothing written in the background guide can be quoted or used as proof for any claims/allegations in the committee.

Additionally, for this committee – and MUNs in general, we don't wish to know your research or the statistics you may read; we are particularly interested in what in the meaning of the statistics and numbers you may have read, and its analysis. Similarly, quoting the law or legal instruments has no impact on the debate in itself. Debating or discussing the law only has relevance when you can ponder upon its implications and implementation – whether successful or unsuccessful. Keeping that in mind, we cannot emphasize the need for analysis and evaluation in your arguments and speeches any further.

That being said, please feel free to get in touch with us via e-mails in case you have any questions or queries, or if you wish to seek any clarifications. We shall be happy to assist.

All the best!

Regards,
Siddhant Bajaj – President
Sambhav Sharma – Vice-President
Accepted sources of evidence

Evidence or proof is from the following sources will be accepted as credible in the UNHRC:

1. **State-operated News Agencies:**
   These reports can be used in the support of or against the State that owns the News Agency. These reports, if credible or substantial enough, can be used in support of or against any country as such but in that situation, they can be denied by any other country in the council. Some examples are:
   i. RIA Novosti (Russia) [http://en.rian.ru/]
   ii. IRNA (Iran) [http://www.irna.ir/en/]
   iii. BBC (United Kingdom) [http://bbc.co.uk/]
   iv. Al Jazeera (Qatar) [http://www.aljazeera.com]
   v. Xinhua News Agency (PR China) [http://www.xinhuanet.com/english/china/]

2. **Government Reports:**
   These reports can be used in similar ways as the State Operated News Agencies reports and can, in all circumstances, be denied by another country. However, a nuance is that a report that is being denied by a certain country can still be accepted by the Executive Board as credible information. Some examples are:
   ii) **Ministry of Foreign Affairs** of various nations like India [http://www.mea.gov.in/] or People’s Republic of China [http://www.fmprc.gov.cn/eng/].
   iii) **Permanent Representatives to the United Nations** Reports
   http://www.un.org/en/members/ (Click on any country to get the website of the Office of its Permanent Representative.)

3. **United Nations Reports:**
   All UN Reports are considered are credible information or evidence for the Executive Board of the NSG.
   iii) **Treaty Based Bodies** like the Antarctic Treaty System [http://www.ats.aq/e/ats.htm], the International Criminal Court [http://www.icc-cpi.int/Menus/ICC]
NOTE — Sources like Wikipedia [http://www.wikipedia.org/], Amnesty International [http://www.amnesty.org/], Human Rights Watch [http://www.hrw.org/] or newspapers like the Guardian [http://www.guardian.co.uk/], Times of India [http://timesofindia.indiatimes.com/], etc. are typically not accepted as PROOF/EVIDENCE. However, they can be used for a better understanding of any issue or on rare occasions, be brought up in debate if the information given in such sources is in line with the beliefs of a Government.

Further, the information submitted as evidence citing reportage from sources such as specified in this note may be at best, treated as having significance in terms of persuasive value - e.g. to cement one's assertions, but never as binding, indisputable fact.
About the Committee

Maintaining a coherent international strategy for narcotics control was a priority following the Second World War and the establishment of the UN, and in 1946, the newly formed Economic and Social Council (ECOSOC) established the Commission on Narcotic Drugs (CND) through resolution 9 (1) to advise it on drug policy. In the early years of CND, several drug protocols were established, the most significant being the 1953 Protocol for Limiting and Regulating the Cultivation of the Poppy Plant, the Production of, International and Wholesale Trade in, and Use of Opium (Opium Protocol). The Opium Protocol reaffirmed that opium and related substances could only be used for scientific or medical purposes, and mandated for the establishment of dedicated drug agencies in Member States that ratified the protocol.

The modern CND, however, is mainly defined around three treaties: the Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances (1971), and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988). The Single Convention was so named because it amalgamated and superseded all pre-existing drug control treaties. While earlier drug control treaties had largely been limited to controlling the supply of narcotics and limiting their usage to medical and research purposes, from the 1970s onwards demand reduction began to take a more prominent role in the language of international treaties. For example, the 1971 Convention on Psychotropic Substances requires signatories to take "all active measures for the prevention of abuse of psychotropic substances." The 1961 and 1971 Conventions, along with the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988), form the bedrock of the international drug control framework, of which CND is the central body.

Governance, Structure, and Membership

There are 53 members of CND, with 11 seats each reserved for African and Asian states, 10 for Latin America, six for Eastern Europe, and 14 for Western Europe and others. The remaining seats rotate between Asian and Latin American or Caribbean states every four years. Members must be party to the 1961 Single Convention on Narcotic Drugs, and “adequate representation” must be ensured for Member States that are either key producers of opium or coca leaves, key places where illicit narcotics are manufactured, or where the use of illicit narcotics is particularly concerning. Members of CND are elected by an organizational session of ECOSOC. CND is led internally by the Bureau and Extended Bureau of the Commission. The Bureau is composed of a Chairperson, three Vice-Persons, and a Rapporteur, who are elected at the end of each CND session for the following one. The Bureau also works with the UN Secretariat to prepare CND sessions, as well as undertake organizational work between sessions. The Extended Bureau includes representatives from the five main global geographic regions, in addition to the EU, China, and the Group of 77 developing nations.

CND, along with other bodies such as the Commission on Crime Prevention and Criminal Justice and the Commission on the Status of Women, is one of the functional commissions of ECOSOC. CND’s reports are considered at the substantive session of ECOSOC each year:
some are adopted and become ECOSOC resolutions, and some ECOSOC refers to the General Assembly, to potentially become General Assembly resolutions. Several smaller bodies report directly to CND, including the Sub-commission on Illicit Drug Traffic and Related Matters in the Near and Middle East that was formed in 1973, which exists to facilitate cooperation between governments in the region and to offer a focused regional perspective.

There are also the four Regional Meetings of Heads of National Drug Law Enforcement Agencies. These bodies, one each for Europe, Latin America, Africa, and Asia, exist to improve high-level coordination between regional drug law enforcement agencies.

Mandate, Functions and Powers
CND’s mandate is to “monitor the world drug situation, develop strategies on international drug control and recommend measures to combat the world drug problem, including through reducing demand for drugs, promoting alternative development initiatives, and adopting supply reduction measures.” Like many older UN agencies, the mandate of the CND has evolved over time. The original mandate, as set out in ECOSOC resolution 9(1) called for the new body to assist ECOSOC, supervise existing narcotics control treaties, and make recommendations on narcotic drug control issues. This means that CND has always had a functional, operational aspect to its mandate, in addition to a normative policymaking mandate. However, this division of roles was only clarified and formalized in 1999 with the adoption of ECOSOC resolution 1999/30, which requires CND to structure its agenda into two distinct sections: a normative section centered around policy issues and the upholding of treaties, and an operational section, where it exercises its role as the governing body of the United Nations Office on Drugs and Crime (UNODC).

UNODC itself was formed in 1997 by the merging of the secretariats of the UN International Drug Control Program and the Centre for International Crime Prevention. As a governing body, CND is responsible for administrative and budgetary matters of the UNODC, as well as strategic oversight. This means that while CND is not responsible for the daily operations of UNODC, it is recognized as the central drug policymaking organ of the UN, makes suggestions as to the direction of UNODC policy, and offers guidance on strengthening its programs during sessions concerning the first part of its agenda. Under the Single Convention on Narcotic Drugs (1961), CND is responsible for placing drugs into one of five schedules, depending on their harmfulness.

However, changes to drug scheduling can only be made on the recommendation of the World Health Organization (WHO). Drug scheduling changes can only be overruled by the ECOSOC plenary session. The Single Convention established the International Narcotics Control Board (INCB) and charged it to “limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs.” As such, it is the INCB that works directly with governments to ensure compliance with the convention, not CND.
The INCB focuses primarily on the regulation of legal drug markets, working with government agencies to ensure that controlled substance does not fall into the wrong hands. UNODC, meanwhile, focuses more on illicit drug markets, working with governments on demand reduction, police cooperation, and tackling organized crime. CND works closely with both bodies; as the governing body of UNODC, CND approves the International Drug Control Program Fund, which accounts for 90% of the UN for Drug Control Resources, and for the INCB, CND works in an advisory capacity.

**Recent Sessions and Current Priorities**

The 70th session of the UN General Assembly adopted the 2030 Agenda for Sustainable Development, which included 17 Sustainable Development Goals (SDG) to continue the progress achieved through the Millennium Development Goals. SDG 3, “ensure healthy lives and promote well-being for all at all ages,” includes in target 5 the aim of enhancing the prevention and treatment of substance abuse.

To fulfil this goal, in 2016, UNODC launched the "Listen First" Campaign, which promotes a better childhood as a basis to prevent drug abuse. In 2017, UNODC and the UN Entity for Gender Equality and the Empowerment of Women (UN-Women) created a roundtable to evaluate how the functional commissions can contribute to the goal of gender equality in order to contribute to the fulfillment of SDG 5, “achieve gender equality and empower all women and girls.” In 2016 the General Assembly held the UN General Assembly Special Session on the World Drug Problem (UNGASS 2016), which CND was tasked to organize. The goal of UNGASS 2016 was to define actions that should lead to the fulfilment of the Plan by 2019. In its outcome document, UNGASS 2016 made recommendations on demand reduction, prevention, treatment, availability, and access to controlled substances (medical and scientific purposes), supply reduction, law enforcement in drug-related crime and cross-cutting issues such as the role of women and youth. Member States reiterated their commitment to enhance cooperation on regional, interregional, and international cooperation by promoting alternative development, technical, and financial cooperation. Currently, CND focuses on the development of a subsequent policy following the Plan after 2019, which is to be adopted in its 62nd session.

The main focus of the CND’s work, during its 60th session, was the improvement of reporting mechanisms and data collection for the evaluation of the implementation of the Plan. During the inter-sessional meeting of CND in September 2017, strategies to combat drug abuse were evaluated and reconsidered with regard to the goals set by UNGASS 2016. It was stressed that drug abuse is a health issue and should be dealt with by health ministries in Member States. Besides new forms of medical treatments, Member States also reported success in awareness campaigns through social media channels.

**Conclusion**

The international framework for controlling illicit substances is built primarily on the 1961, 1971, and 1988 Conventions, and CND is the central body tasked with upholding these treaties. Its dual role as both a normative policymaking body and as a functional committee, acting as a
governing body of UNODC with control of over 90% of the UN’s anti-drugs budget, makes it a committee of critical importance. As the 2014 review and UNGASS 2016 have shown, the 2009 Plan of Action was far from perfect as it failed from a lack of resources and commitment. In preparation for the 62nd session, the Commission continues to address the shortcomings of the Plan, as well as new challenges by focusing more on addressing the issues from different perspectives, such as health care. In preparation for the conference, delegates should bear in mind that this complex challenge will require a holistic approach that includes all aspects of the challenge posed by the world drug problem.
Agenda: Discussing Measures to Control Drug Trafficking with Special Emphasis on Fraudulent Medicines.

International Drug Trafficking
“The war on drugs, which started in the 70s, has not inhibited the production, traffic, or consumption of drugs in the world”, said Mexico’s President Enrique Peña Nieto when addressing the special session on drug policy of the United Nations General Assembly on April 19, 2016. His words were not stated without reason – in the 2015 World Drug Report, which was released roughly a year before, the United Nations Office on Drugs and Crime (UNODC) concluded, that in spite of the widespread efforts to control international drug trafficking more thoroughly, worldwide drug use and abuse is more prevalent than ever. The problems that need to be addressed are manifold; ever-increasing globalisation has led to numerous new trafficking routes, newly surfaced synthetic drugs defy current legal standards, and the measures undertaken to control this thus far have proven to be much less effective than what was to be hoped.

Due to the global aspect, which has allowed drug cartels to expand rapidly, the persecution and regulation of drug trade has become what has been called “an international game of whack-a-mole”. Though many drug producing countries and quite a few trafficking routes are known, the structures and the people behind transnational drug traffic remains elusive. Cracking down on specific areas of the problem has thus far mostly helped to create a vacuum, which is usually rapidly filled again. There are also many dissenting opinions on how this problem should be tackled: Traditional economic theory dictates that demand creates supply, and since the UN’s approach has so far been largely supply-focused, the international community has seen much criticism. There are also quite a few who argue that these traditional models do not apply to drugs, and that, to a certain degree, drug availability creates demand.

While some of the facets of the issue have long since been known, some others are newly surfacing. Some countries are known hubs of drug production, such as Afghanistan and the so-called “Golden Triangle” comprised of Laos, Thailand, Myanmar (and in some depictions also Vietnam) for opium, Colombia, Peru, and Bolivia for cocaine, or again Afghanistan and also Mexico for marihuana. But with new, synthetic drugs emerging, and because of the ever-shifting and uncontrollable nature of the trade and its routes, international legislation has found itself in something of a rut – some new substances remain in a “technically legal” grey area, and far too often the decisions agreed upon by international actors prove to be ineffective once they are actually put into action. Additionally, with some countries such as the Philippines resorting to rather extreme measures in combating drug use, the local side to what is a worldwide problem should not go unnoticed either.

With dissenting opinions as to whether increased stringency and force is necessary to tackle the issues at hand, or if legalisation, rehabilitation, and regulation should be the way of approach, the world finds itself confronted with a figurative behemoth of a task. There is little to no certainty as to which approach should be taken and which measures will prove to be effective in the long run, the negative implications of worldwide drug trade are as rampant as
never before, and the consequences are being felt. Whether your views are governed by trust in the traditional approaches, or whether you opt for a complete overhaul of the entire system – this is a problem that screams to be solved.

Drug trafficking is a global illicit trade involving the cultivation, manufacture, distribution and sale of substances which are subject to drug prohibition laws. UNODC is continuously monitoring and researching global illicit drug markets in order to gain a more comprehensive understanding of their dynamics. Drug trafficking is a key part of this research. Further information can be found in the yearly World Drug Report.

At current levels, world heroin consumption (340 tons) and seizures represent an annual flow of 430-450 tons of heroin into the global heroin market. Of that total, opium from Myanmar and the Lao People's Democratic Republic yields some 50 tons, while the rest, some 380 tons of heroin and morphine, is produced exclusively from Afghan opium. While approximately 5 tons are consumed and seized in Afghanistan, the remaining bulk of 375 tons is trafficked worldwide via routes flowing into and through the countries neighbouring Afghanistan.

The Balkan and northern routes are the main heroin trafficking corridors linking Afghanistan to the huge markets of the Russian Federation and Western Europe. The Balkan route traverses the Islamic Republic of Iran (often via Pakistan), Turkey, Greece and Bulgaria across South-East Europe to the Western European market, with an annual market value of some $20 billion. The northern route runs mainly through Tajikistan and Kyrgyzstan (or Uzbekistan or Turkmenistan) to Kazakhstan and the Russian Federation. The size of that market is estimated to total $13 billion per year.

**Global heroin flows from Asian points of origin**

In 2008, global heroin seizures reached a record level of 73.7 metric tons. Most of the heroin was seized in the near and Middle East and South-West Asia (39 per cent of the global total), South-East Europe (24 per cent) and Western and Central Europe (10 per cent). The global increase in heroin seizures over the period 2006-2008 was driven mainly by continued burgeoning seizures in the Islamic Republic of Iran and Turkey. In 2008, those two countries accounted for more than half of global heroin seizures and registered, for the third consecutive year, the highest and second highest seizures worldwide, respectively.

In 2007 and 2008, cocaine was used by some 16 to 17 million people worldwide, similar to the number of global opiate users. North America accounted for more than 40 per cent of global cocaine consumption (the total was estimated at around 470 tons), while the 27 European Union and four European Free Trade Association countries accounted for more than a quarter of total consumption. These two regions account for more than 80 per cent of the total value of the global cocaine market, which was estimated at $88 billion in 2008.

For the North American market, cocaine is typically transported from Colombia to Mexico or Central America by sea and then onwards by land to the United States and Canada. Cocaine is
trafficked to Europe mostly by sea, often in container shipments. Colombia remains the main source of the cocaine found in Europe, but direct shipments from Peru and the Plurinational State of Bolivia are far more common than in the United States market.

Figure 1: Global heroin flows from Asian points of origin
Counterfeit medication

Introduction
Counterfeit medication or a counterfeit drug is a medicinal or pharmaceutical product which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. A counterfeit drug may contain inappropriate quantities of active ingredients or none, may be improperly processed within the body (e.g., absorption by the body), may contain ingredients that are not on the label (which may or may not be harmful), or may be supplied with inaccurate or fake packaging and labelling, as is the case with homeopathic products. Counterfeit drugs are related to pharma fraud. Drug manufacturers and distributors are increasingly investing in countermeasures, such as traceability and authentication technologies, to try to minimise the impact of counterfeit drugs. Antibiotics with insufficient quantities of an active ingredient add to the problem of antibiotic resistance.

A clear, widely accepted definition of "falsified medicines" is crucial for efficient and coordinated responses to this threat. However, until recently, the lack of a globally approved definition had impeded strong, coordinated national and international measures, as the meaning of "falsified" would vary between countries and international organizations.

To fill this gap, a working definition of "falsified medical products" was proposed and approved at the World Health Assembly 2017: "Medical products that deliberately/fraudulently misrepresent their identity, composition or source." Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, or reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product. Any consideration related to intellectual property rights (IP) does not fall within this definition.

Legitimate, correctly labelled, low-cost generic drugs are not counterfeit or fake (although they can be counterfeited) but can be caught up in anti-counterfeiting enforcement measures. In that respect, a debate is raging as to whether "counterfeit products are first and foremost a threat to human health and safety or whether provoking anxiety is just a clever way for wealthy nations to create sympathy for increased protection of their intellectual property rights". Generic drugs are subject to normal regulations in countries where they are manufactured and sold.

Counterfeit medicinal drugs include those with less or none of the stated active ingredients with added, sometimes hazardous, adulterants, substituted ingredients, completely misrepresented, or sold with a false brand name. Otherwise, legitimate drugs that have passed their date of expiry are sometimes remarked with false dates. Low-quality counterfeit medication may cause any of several dangerous health consequences, including side effects or allergic reactions, in addition to their obvious lack of efficacy due to having less or none of their active ingredients.

Since counterfeiting is difficult to detect, investigate, quantify, or stop, the quantity of counterfeit medication is difficult to determine. In 2003, the World Health Organization cited
estimates that the annual earnings from substandard and/or counterfeit drugs were over US $32 billion.

The considerable difference between the cost of manufacturing counterfeit medication and price counterfeiters charge is a lucrative incentive. Fake antibiotics with a low concentration of the active ingredients can do damage worldwide by stimulating the development of drug resistance in surviving bacteria. Courses of antibiotic treatment which are not completed can be dangerous or even life-threatening. If a low-potency counterfeit drug is involved, completion of a course of treatment cannot be fully effective. Counterfeit drugs have even been known to have been involved in clinical drug trials.

Several technologies may prove helpful in combating the counterfeit drug problem. An example is radio frequency identification, which uses electronic devices to track and identify items, such as pharmaceutical products, by assigning individual serial numbers to the containers holding each product. The U.S. Food and Drug Administration (FDA) is working towards an electronic pedigree (ePedigree) system to track drugs from factory to pharmacy. This technology may prevent the diversion or counterfeiting of drugs by allowing wholesalers and pharmacists to determine the identity and dosage of individual products. Some techniques, such as Raman spectroscopy and energy-dispersive X-Ray diffraction (EDXRD) can be used to discover counterfeit drugs while still inside their packaging.

Falsified medical products pose a considerable public health threat as they can fail to cure, may harm and even kill patients. These threats to public health have led the international community to call for a stronger and more coordinated response. Compounding this public health risk is the fact that the supply chain for medicines operates at a global level, and therefore, a concerted effort at the international level is required to effectively detect and combat the introduction of falsified medical products along this supply chain.

The 20th session of the Commission on Crime Prevention and Criminal Justice (CCPCJ) adopted resolution 20/6 on falsified medical products due to concern about the involvement of organized crime in the trafficking in falsified medical products. At the same time, resolution 20/6 highlights the potential utility of the United Nations Convention against Transnational Organized Crime (UNTOC) for which UNODC is the guardian, in re-enforcing international cooperation in the fight against trafficking, through, its provisions, \textit{inter alia}, on mutual legal assistance, extradition and the seizing, freezing and forfeiture of the instrumentalities and proceeds of crime.

As with other forms of crime, criminal groups use, to their advantage, gaps in legal and regulatory frameworks, weaknesses in capacity and the lack of resources of regulatory, enforcement and criminal justice officials, as well as difficulties in international cooperation. At the same time, the prospect of the comparatively low risk of detection and prosecution in relation to the potential income make the production and trafficking in falsified medical products an attractive commodity to criminal groups, who conduct their activities with little regard to the physical and financial detriment, if not the exploitation, of others.
Resolution 20/6 contains nine action points among which paragraph nine requests that UNODC, in cooperation with other United Nations bodies and international organizations, such as the International Narcotics Control Board (INCB), the World Health Organization (WHO), the World Customs Organization (WCO) and the International Criminal Police Organization (ICPO/INTERPOL), as well as relevant regional organizations and mechanisms, national regulatory agencies for medicines and, where appropriate, the private sector, civil society organizations and professional associations, assist Member States in building capacity to disrupt and dismantle the organized criminal networks engaged in all stages of the illicit supply chain, in particular distribution and trafficking, to better utilize the experiences, technical expertise and resources of each organization and to create synergies with interested partners.

While focus has been given to the health and regulatory aspect of this problem, it appears that less attention has been given to the issue from a criminal justice perspective. Given its expertise and work to build effective and transparent criminal justice systems and to support states to prevent and combat all forms of organized crime, UNODC can support the fight against the illicit manufacture and trafficking of falsified medical products in coordination with other stakeholders.

**Increasing Threat of Counterfeit Medicines**

Lifesaving drugs are not exempt from the trade in counterfeit medicines. The World Health Organization (WHO) is working with Interpol to dislodge the criminal networks raking in billions of dollars from this cynical trade. In 2009, 20 million pills, bottles and sachets of counterfeit and illegal medicines were seized in a five-month operation coordinated by the International Criminal Police Organization (Interpol) across China and seven of its south-east Asian neighbours; 33 people were arrested and 100 retail outlets closed.

Also last year, a series of raids in Egypt found counterfeit medicines worth hundreds of millions of dollars and exposed a criminal network feeding consumers across the Middle East. And in Europe, customs officers seized 34 million counterfeit pills in just two months in 2009; a haul that the European Union’s industry commissioner Guenter Verheugen said “exceeded our worst fears”.

An individual who receives a counterfeit medicine may risk a number of dangerous health consequences. The drug may:

- contain a different quantity of the original active ingredient
- contain totally different active ingredients
- contain toxic ingredients
- bear forged manufacturer's data on the packaging
- have been completely repackaged
- have been produced under conditions that do not conform with current Good Manufacturing Practice (cGMP)
• have not been transported and stored properly

No type of medicine, from expensive and groundbreaking treatments to everyday antibiotics or birth control, is immune. These medicines might have the wrong amount of the active ingredient (or none of it at all), or contain a different drug or other materials such as chalk or cornstarch. They can also be contaminated by bacteria or unknown impurities. Sometimes, a product isn’t up to snuff because it wasn’t manufactured or stored correctly. But often, they are intended to trick people.

Sometimes these drugs simply fail to deliver effective treatment, but they can also cause outright harm. And in the case of drugs meant to combat infection, having some but not enough of the necessary dose of the active ingredient actually helps contributes to antimicrobial resistance.

Counterfeit medicine is now a truly global phenomenon, and all countries of the world are affected as source, transit or destination points. The World Health Organization (WHO) estimates that up to 1 per cent of medicines available in the developed world are likely to be counterfeit. This figure rises to 10 per cent globally, but in some areas of Asia, Africa and Latin America counterfeit goods can form up to 30 per cent of the market.

Counterfeit Seizures CY 2017

Counterfeiting applies not only to 'lifestyle' medicines, including erectile dysfunction and weight loss medicines, but also to 'lifesaving medicines' including those used to treat cancer, heart disease and other serious illnesses. It's not just medicines. Fake medical devices also pose a risk. The term 'medical device' covers a wide range of healthcare products from contact lenses to condoms; syringes to surgical instruments; and wheelchairs to radiotherapy machines.
More and more people are buying medicines and medical devices over the Internet, through online pharmacies and auction sites. Unfortunately, a large number of these Internet sites are unauthorized, unregulated and trade in illicit or sub-standard products.

If an online supplier conceals its physical address, this is a warning sign that their products could be dangerous. The WHO estimates that 50 per cent of medicines available from such websites are counterfeit. In particular, buying prescription-only medicines from unauthorized or dubious sources significantly increases the risk of getting sub-standard or fake products. It is important to consult a healthcare professional for prescription-only medicines and to obtain the medicines from a regulated source.

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Opinions are divided almost evenly as to whether or not there has been a rise in the level of pharmaceutical crime activities during the past five years. However, the situation is clearer for some regions, such as Latin America. South and Central America indicated an increase in the number of active groups, cases, seizures and arrests since 2008. In both regions, clear signs of counterfeit production were stipulated, with finished illicit medicines or raw materials for illicit production exported to other countries in the region. For example, yearly illicit profits in one South American country were found to total almost one-third of profits made in the licit pharmaceutical market between 2008 and 2012; the sale of licit pharmaceuticals was estimated to be USD 100 million and the sale of illicit pharmaceuticals to total approximately USD 30 million.

Counterfeit and illicit medicines are also exported to other parts of the world via the Internet, with customs authorities from one South American country reporting almost 1,000 sales of medicines to countries in Asia from 2011 to the present. In 2012-13, an OCG in Guatemala established an underground supply chain in Latin America of local over-the-counter medicines.
Guatemalan authorities carried out raids and arrested several suspects. In Europe and North America, several investigations in Canada, Sweden and the US have linked the Hell’s Angels with the manufacture and distribution of counterfeit medicines, such as ED medication and steroids.

In Europe, OCGs have been involved in robbing trucks transporting various prescription medicines since 2010. There have been reports from some European Union member countries that the stolen products have been found in the legal supply chain. In Eastern Europe, it appears that OCGs are becoming increasingly involved in the manufacture and supply of doping substances, aimed primarily at amateur athletes and persons involved in body building. One country even indicated that amateur athletes are involved with criminal groups, a finding further substantiated by open-source cases that discussed the involvement of former athletes, coaches and owners of sports clubs in criminal rings. Counterfeits can be purchased from suppliers who advertise on business-to-business (B2B) e-commerce websites and then imported into countries where customs controls may be more lax.

In Slovakia, suspects recruited local alcoholics and drug addicts to receive shipments containing counterfeit pharmaceuticals. This is suspected to be a growing issue, with one questionnaire reply indicating an increase in the production of counterfeits in the region, whereas previously, finished products were almost exclusively imported. However, efforts are being made to counter this trend: for example, during Operation Pangea VI in 2013, Russian authorities investigated 145 illicit online pharmacies, arrested two suspects and seized 9,535 units of illicit medicines. In Asia there is a continuous demand for slimming pills, with an estimated 5 million slimming pills being consumed in Thailand alone each year.

Asia represents a large market with increased Internet connectivity and several strong developing economies, which are all lucrative factors for illicit online pharmacies and counterfeiters to take advantage of.

Recent Trends

1. Increased use of the Internet: The primary trend, as indicated in the majority of questionnaire replies, is the increasing use of the Internet to sell medicines. Only one European country indicated that the number of illicit websites registered in their country has decreased, due to enforcement action. Indeed, criminal elements are increasingly turning to the Internet to sell illicit products as it offers a high degree of security and anonymity for their actions. The profits earned from illicit online pharmacies are substantial, with one network in the US, active for five years, earning USD 55 million during two years of operation alone. Profits were laundered through the purchase of companies, often operating within the pharmaceutical industry, or through offshore banks in countries such as St Kitts and Nevis, and Panama. The increasing role of the Internet partly explains the augmenting involvement of informal networks, rather than traditional hierarchical groups, in pharmaceutical crime.

2. Prevalence of illicit ED medication: Another primary trend established from questionnaire replies was the increasing trade in ED medication, which has become a
target to focus on for many customs agencies. These medicines constitute the vast majority of medicines sold online, with destinations all across the globe. A large portion of cases extracted from open-source analysis further indicate the predominant rank of ED medication. Other lifestyle medicines and expensive medicines, such as those for the treatment of AIDS and cancer, are also reported to be sold in large numbers.

3. **Prevalence of doping substances**: The counterfeiting of doping substances also appears to be a growing and profitable field for criminals, especially in Eastern Europe. Three small international groups from this region were found to be involved in the production of counterfeit doping substances intended to be sold online or directly to athletes at sports clubs and gyms. One questionnaire reply exemplifies the clear involvement of small OCGs in trafficking steroids and doping substances across Eastern Europe. It was reported that, in cooperation with groups in at least two other countries in the region, raw ingredients were purchased from Asia and used in the production of counterfeit doping substances, which were subsequently sold in Europe and further abroad. Israel has reported that OCGs are smuggling steroids from Lebanon. Approximately two or three OCGs operate within Israel but control labs in the US. There is also a prominent courier network using foreign workers and ‘tourists’ from Moldova who smuggle in illegal substances, and in late 2012 there was a large seizure of anabolic steroids that were smuggled in from Moldova.

4. **Illicit medicines and narcotics**: The importation of opioid-based analgesic medicines for illicit use in the production of narcotics and/or substance abuse. Open-source analysis indicates that large markets exist for the abuse of opioids themselves. In the US, medicines such as oxycodone and hydrocodone are known to be diverted or stolen from pharmacies and sold without prescriptions. There are indications that large OCGs are trafficking in such medicines, with one well-established US-based OCG found in 2011 to be involved in the trafficking of counterfeit Vicodin, Oxycontin, Codeine, Xanax, and Percocet. More recently, a small Seattle-based group was dismantled for trafficking and distributing large amounts of oxycodone.

5. **Tenuous ties to terrorism Multinational**: OCGs are similar in structure to multinational companies. The OCG in country A can be responsible for the production of counterfeit medicines, while another OCG in country B can be in charge of the distribution process of the illegal pharmaceuticals. Various groups cooperate when there is a mutual gain. For example, in East Africa the counterfeit industry is sourced mainly from India and China. A report to the United Nations Security Council has also established links between OCGs operating in East Africa and the terrorist organization Al-Shabaab: “An opportunistic and mutually beneficial kind of ‘pax commerciale’ has been established between those criminal networks and al-Shabaab” 26. However, there is no conclusive evidence of an established connection between OCGs operating within the pharmaceutical crime area and terrorism.

6. **Increased trafficking of Tramadol**: During the past year, INTERPOL has become aware of a sudden rise in the importation of Tramadol into Western Africa. Tramadol is a weak opioid receptor known to be used as a recreational drug which is suspected to be increasingly used as a substitute for heroin, with seizures similar to those witnessed in West Africa replicated in other regions, such as the Middle East. Several cases from
May 2012 alone indicate the extent of the issue in the United Arab Emirates, with 91 million tablets seized at Jebel Ali Port at the beginning of May, followed by three further seizures which led to the arrest of 10 individuals involving in distributing Tramadol. However, so far no links to organized crime have been established in relation to these cases.

**Total Number of Incidents**

**CY 2013 - CY 2017**

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<th>Year</th>
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</tbody>
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**Corruption, enforcement and legislative elements**

Several roadblocks lie in the way of disrupting this criminal activity. The three main challenges relate to:

- Corruption
- Enforcement
- Legislation

Legislative and enforcement insufficiencies at both the national and international levels are major hindrances preventing countries from taking action. Furthermore, the corruption of those within the licit pharmaceutical industry by high-profit criminal enterprises is also a factor.

1. **Corruption**

Corruption was found to exist in several countries which responded to the questionnaire, with replies indicating varying degrees of corruption, from low levels at hospitals to higher levels at wholesalers, registered pharmacies and local markets. In particular, highly profitable online networks possess the financial pull necessary to corrupt those within the licit pharmaceutical industry.
Cases in the INTERPOL database system indicate that such networks have paid pharmacists to fill fraudulent prescriptions and physicians to review medical questionnaires filled by prospective patients. Further examples are found in open sources, including a recent case in India which pointed to the suspected involvement of 12 doctors at two hospitals with a criminal group supplying counterfeit medicines. The doctors are suspected to have knowingly prescribed prescription medicines in order to gain large commissions.

Likewise, criminals have been found to also be qualified pharmacists or doctors, holding positions within genuine pharmacies and diverting medicines or buying known counterfeit medicines in order to make private gains. Criminals are also known to operate the pharmacies themselves, as well as wholesalers, distribution companies and other facilities, leading to the development of criminal rings in which counterfeit and illicit medicines are moved through the legal supply chain. One example from 2012 highlights this issue, with two New York pharmacists found to be involved in purchasing almost USD 274 million worth of illegally obtained HIV and AIDS medication since 2008 through a distribution network run by another suspect. There are also indications that government and law enforcement officials have been corrupted in certain countries.

Government officials are known to have had direct involvement in criminal activities, helping to embezzle government medication as was the case in the Sialkot region of Pakistan in 2010. In a prominent case from a country in South America in 2009, illegally imported, expired and counterfeit medicines were knowingly supplied to a pharmacy and union-run healthcare centre whose deputy director was later arrested for his involvement. Thus, although not prominent or well documented at this time, corruption does occur within the licit pharmaceutical industry.

With the increase in the use of illicit online pharmacies, one can expect a future rise in the level of corruption of pharmacists and medical professionals at clinics and practices, notably through fictitious prescriptions and other medical documentation.

### 2. Enforcement

The degree of resources allocated to fighting pharmaceutical crime varies greatly from country to country. Several countries have large and well-established units dedicated to fighting pharmaceutical crime, while others proactively target criminal elements utilizing non-dedicated officers from various other units.

On the other hand, the inadequacy of enforcement is found to be chiefly caused by a lack of officers dedicated to working on pharmaceutical crime, or too few dedicated officers to cover the entire country. This is especially true with regards to the lack of dedicated IT crime units in many national police administrations.

### 3. Legislation

Most countries do not possess legislation directly addressing pharmaceutical crime. Rather than examining pharmaceutical crime as a specific type of crime requiring specialized legislation,
many countries continue to place it under the category of intellectual property crime or use existing criminal law on narcotics or fraud.

As a result, almost one-third of replies stated that countries do not possess the necessary legal apparatus to effectively target the issue, while others argued that penalties were far too low for the offences committed. Certain countries have specific laws related to medical products and pharmaceuticals, with strict penalties currently in place for criminal activities such as counterfeiting and trafficking of illicit medicines. Several countries also indicated that, although their national legislation is not currently sufficient, new specific legislation is being developed or will soon be adopted.

Additionally, several European countries have made positive comments in relation to upcoming the European Union legislation, which is found to be more specific and effective than current national legislation and will impose more stringent and proportionate penalties for pharmaceutical crimes.

**Intellectual Property Rights and Counterfeit medicines**

Intellectual property refers to creations of the mind: inventions, literary and artistic works, but also to symbols, names, images, designs and models used in commercial trade.

There are two branches to Intellectual property:

– **Literary and artistic property**, which applies to creations of the mind. On the one hand it covers copyright and concerns literary and artistic works such as novels, poems, films, musical works and works of art such as drawings, paintings, photographs, and sculpture; and on the other hand it covers other rights, that are similar to copyright, held by performing artists over their performances, by producers of sound recordings over their recordings, and broadcasters over their radio or television programs.

– **Industrial property** which protects technical discoveries (patents), ornamental creations (drawings and models) and distinctive signs (commercial trademarks, corporate signs, domain names, other names). With regard to drugs, it concerns above all the question of industrial property rights on trademarks and patents.

A drug is protected by industrial property law if a patent has been filed to protect it and if it possesses a distinguishing trade mark or a protected design and model.

A patent is granted to products that deliver innovation. It can be obtained for a drug as it can be obtained for any other kind of invention. A drug patent gives its owner a commercial exclusivity for a period of 20 years from the day of the application’s filing. In fact, the actual period of protection for the drug itself will be much shorter, since after the filing of the patent, the drug will still undergo almost 10 years of further research and testing before it can be commercially exploited.
To compensate for this, it is possible to obtain a “supplementary protection certificate” which extends the protection of the drug for up to 5 additional years.

The brand is defined as any sign (word, letter, logo, shape, colour, sounds, etc.) capable of distinguishing goods or services of a natural or legal person that can be protected by a trademark. In the pharmaceutical field, laboratory and drug names are protected by the law of trademarks. This law gives the holder an exclusive right to these names. These designations also allow the patient to recognize the product and thereby provide a guarantee of quality and safety. The brand differs from the International Non-proprietary Name (INN), which is the chemical name of the substance. A list of INNs is provided by the World Health Organization. Therefore, a drug is identified by a unique INN, but may be sold under different brand names.

The design and model are defined as any object whose shape, configuration or an external effect gives it a new and specific physiognomy which distinguishes it from other objects. This characteristic allows the object to be protected over a specified period. In practice, the term design refers to a two-dimensional design and model a three-dimensional creation. Designs and models refer to graphics and shapes that are not directly linked to the manufacturing process.

These industrial property rights are recognized internationally and have been discussed under the TRIPS agreements (“Trade-related aspects of intellectual property rights”). Various Intellectual Property offices register and ensure the protection of these rights at national, European Community (OHIM – Office of Harmonization for the Internal Market) or global level (WIPO – World Intellectual Property Organization).

“Drug counterfeiting is not a problem of intellectual property. It is first and foremost a problem of public health. This is the fundamental point. The problems of intellectual property may exist, but they are secondary to the problems of public health.” This sentence of Prof. Amor Toumi, Advisor to the WHO, recalls how intellectual property rights, alone, cannot apprehend the magnitude and the specificities of the issues raised by fake medicine trafficking which has become a global health scourge causing the death of millions of people. This is all the more true that the drug counterfeitters copy both brand name and generic products.

Yet, an intellectual property approach to drug counterfeiting is justifiable for three major reasons:

- Sometimes the only illegal thing about a fake drug seized in a batch during a customs control for example is that it violates an industrial property right. Thus, in many cases, only the legal approach on the grounds of a breach of an industrial property right can start a judicial proceeding.

- A fake drug without an active principle is a snare: it is only dangerous for health in that it deprives the patient of a real treatment or protection against a disease. Therefore as the manufacture and marketing of this kind of fake medicine is not specifically and legally recognised as punishable crime, the infringement of intellectual property remains one of the most reliable legal levers to stop the traffic.
The mechanism of suspension of release by customs authorities, as provided by articles 51 and seq. of the TRIPS Agreement is only possible in the case of suspected violations of intellectual property rights. As this mechanism has not been extended to false drugs, the Intellectual property approach is effective. It allowed customs to intercept more than 7 million fake medicines in Europe in 2009.

Let it be noted that the intellectual property rights defining the act of infringement do not make special provisions for drugs.

This means that violations of the right to intellectual property are independent of the issues related to the quality or safety of the product concerned. However, some countries, such as France for example, apply heavier criminal punishments in cases where the infringement of patents, trademarks, designs or models endangers “human or animal health or security.”

In the combat against fake drug trafficking, intellectual property rights should be considered as one of several effective legal means available (alongside prosecution for crimes of deception and forgery, the illegal practice of pharmacy, misleading information and advertising, etc.) to help save lives, and not, of course, as an end in and of itself.

Any infringement of an industrial property right is considered as counterfeiting. The manufacturing, marketing, detention, sale, offer for sale, import, export, use, production, reproduction, imitation, affixing, usage of an industrial property… without the consent of the owner of the copyright are considered prohibited by the law. In the case of drugs, counterfeiting most often takes the form of brand reproduction, i.e. an identical reproduction of a branded product. Sometimes, slight modifications or partial reproductions occur: the counterfeit is then an imitation leading to the likelihood of confusion in the mind of the public.

An infringement can also be the copy of a patent, which grants to its holder the monopoly to commercialise a product in compensation for the long years of research and the costs induced by its development. At the end of the period of protection, the patent falls into the public domain and becomes free of copyright.
Links for further Research

- http://www.psi-inc.org/index.cfm
- https://www.interpol.int/Crime-areas/Pharmaceutical-crime/The-dangers
- https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine/