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SCHOOL OF GOVERNMENT

Fraudulent medicines in the shadow of the pandemic.

Examining the institutional capacity of global mechanisms against the rising trade in falsified medicines during the Covid-19 pandemic.

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List of Abbreviations

1. API – Active Pharmaceutical Ingredient
2. CCPCJ - Commission on Crime Prevention and Criminal Justice
3. COP – Conference of Parties
4. GDP - Good Distribution Practice
5. GMP - Good Manufacturing Practice
6. GSP - Good Storage Practice
7. MSM - Member State Mechanism
8. NMRA - National Medical Regulatory Authority
9. R&D - Research and Development
10. SDG – Sustainable Development Goal
11. TOR - The Onion Router
12. UN - United Nations
13. UNDP - United Nations Development Program
14. UNTOC – United Nations Convention against Transnational Organized Crime
15. UNODC - United Nations Office on Drugs and Crime
16. UNCAC – United Nation Convention against Corruption
17. WHO - World Health Organization

Chapter 1: Introduction

"[...] criminals will stop at nothing to make a profit. The illicit trade in such counterfeit medical items during a public health crisis shows their total disregard for people's wellbeing, or their lives"

- *Jürgen Stock, Secretary General of INTERPOL, 2020*

When the outbreak of Sars-Cov2 was officially declared to be a public health emergency with international scope on the 30th January 2020, it overshadowed another invisible danger that's been increasingly challenging global regulators and law enforcement in the recent decades. The illicit trade in falsified medicines gained popularity among transnational organized criminals due to its favorable characteristics: The margin of profit is high; the risk of prosecution is low and the target group broad and diverse. Good health and life saving medication are a universal need which becomes more accessible as more people escape poverty around the globe and form a growing middle class. Globalization and digitalization accommodate this demand through easy accessibility of products over the internet as well as the delivery of small parcels and large shipments across the globe. Unscrupulous criminal organizations do not refrain from exploiting this increasing interconnectedness and defraud consumers all around the world with ineffective and dangerous counterfeit, often without them even knowing. These innocent looking pills endanger human life for economic profit and make illicit trade in pharmaceuticals a silent but deadly crime that is likely to be boosted from the chaos and panic caused by the Covid-19 pandemic. Therefore, the aim of this research is to examine what issues and trends concerning illicit trade in falsified medicines are prevailing, how these are affected by the Covid-19 pandemic and which global mechanisms exist to enforce criminal justice and to foster public health and safety. To advance the vision of a healthy, safe, and just world, this thesis will attempt to answer the following exploratory research question:

RQ: To what extent can global mechanisms provide the institutional capacity to contain the effect of Covid-19 on illicit trade in falsified medicines?

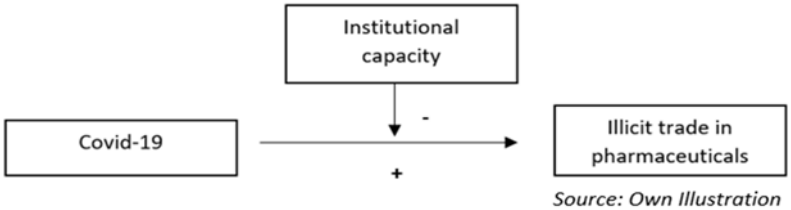
Scientific research into this topic is of high relevance as it is forecasted that the already threatening trend towards more falsification of medicines will be reinforced if the pandemic shock paralyses already fragile governance institutions. The detrimental impact of counterfeit medicine is continuous, multi-dimensional and increasing, and institutions need comprehensive up-to-date knowledge that can be transformed into action. Facing the challenges of a complex global pandemic, the already priorly insufficient regulatory framework is likely to not effectively contain the criminal engagement this opportunity enables. The large-scale production and distribution of fraudulent medicinal products as well as the Covid-19 pandemic are both rather recent and the scope of their mutual influence is yet unclear as the pandemic is still progressing. Therefore, the available body of research on their interlinkage is subject to temporal constraints and resembles a research gap that needs to be filled as soon as possible.

1.1 Research Design and Methodology

The following part will define the framework in which this research is conducted and briefly introduces the questions it seeks to address.

Due to the geographical interdependence of supply chains, regulators, and law enforcement, as well as the worldwide impact of the Covid-19 pandemic, the global level is selected as a spatial unit of analysis. The temporal unit of analysis is coined by the rapid globalization and digitalization of the past two decades in the pharmaceutical industry, which functioned as main drivers of illicit trade in medicinal products, as well as the onset of the Covid-19 pandemic as external shock affecting the aforementioned trade.

Figure 1. Defining the Variables



Source: Own Illustration

As illustrated in *Figure 1,* the illicit trade in falsified medicines is defined as a dependent variable as it is the variable whose behavior and characteristics will be observed. It is hypothesized that the Covid-19 pandemic as an independent variable exerts a positive influence on the dependent variable, therefore increasing the illicit trade in falsified medicines. Institutional capacity resembles an intervening/moderating variable and is characterized as a concept with two facets: one of global criminal justice mainly embodied through international law and surrounding law enforcement cooperation, and a facet of global public health and safety predominantly coined by regulatory and administrative health infrastructure such as the WHO. The suspected effect of the institutional capacity on the relationship between the independent and dependent variable is that it neutralizes the positive influence of the pandemic on illicit trade in falsified medicines. Due to the high notion on regulatory and legal affairs in this research, its goal can be best achieved by a comprehensive literature analysis of research articles and legal documents. Complementary statistical data retrieved from secondary sources will be further utilized to support the lines of argument.

The following section will introduce the different Chapters guiding throughout this research. Whereas the first three chapters are problem-oriented and describe the challenges of the interplay between pandemic and falsification of medicines, the last three chapters are solution-oriented and propose two frameworks to combat bogus medicines.

The first Chapter defines the topic, goal, methodology, definitions, and limitations of this research, and further introduces the societal relevance by outlining the grave consequences of trade in falsified medicines.

The second Chapter will describe the structures, actors and methods that enabled the rapid rise of the illicit trade in falsified medicines. The Chapter will provide the basic knowledge about the state of knowledge within the sector and equip the reader with the necessary background information to understand how the subsequent chapters will build up on each other.

The third chapter will link the knowledge on falsified medicines to the context of the pandemic response and analyze demand and supply from multiple angles to identify possible correlations between Covid-19 and blooming trade in falsified medicines.

The fourth chapter will pick up on the problem-oriented sections to transfer the insights into the solution-oriented global framework of criminal justice, by examining to which extent international law and institutions can provide the institutional capacity to effectively suppress illicit trade.
As criminal justice only takes effect after damage is done, the fifth chapter will explore how to increase further pandemic preparedness with regards to global public health and safety and resilient medical supply chains. Thus, the institutional system around pharmaceutical and medical regulation, prevention, education, and awareness, as well as pharmaceutical procurement and distribution infrastructure will be closely examined to identify efficient and effective regulations, good governance principles and best practice. Finally, the conclusion will wrap up the sub-conclusions on the provision capability of institutional capacity of the criminal justice dimension and public health and safety of medical supply chains and regulation.

1.2 Key concepts and Definitions

The following section will define the three key concepts upon which this research is based. Therefore, the following part will elaborate upon the different connotations of falsified medicines and other medical products. Subsequently, it will be defined which actions are considered to be covered by illicit trade, and lastly, it will be elaborated upon which factors constitute institutional capacity.

Defining falsified medicines

The lack of a harmonized set of definitions has long undermined international cooperation. To apply a harmonized and verified set of definitions, this thesis will orient its definitions in accordance with the recommended definitions of the United Nations Office on Drugs and Crime. Indeed, the long prevailing term SSFFC-Medicine (Substandard/ Spurious/ Falsely-labelled/ falsified/counterfeit) greatly reflects the different notions that complicate finding a proper definition.
In 2017, the World Health Assembly adopted a definition of “falsified medical products” that defines these as “[...] any medical product whose identity, composition or source is intentionally misrepresented” (UNODC 2019, p. 9). “Medical products” in this sense include medicines, excipients, active substances, medical devices, their parts and

materials, and accessories used in conjunction with medical devices. Whereas “medical products” play an important role within the pandemic effect of illicit trade, this research will mainly focus on ‘pharmaceuticals’ and ‘medicines’ which terms will be used interchangeably. According to the UNODC 2019 p.11, a “Medicine means any substance, or combination of substances: (a) presented as having properties for treating or preventing disease in humans or animals; or (b) that may be used in or administered to human beings or animals with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis”. The focus on the definition of “medicines” allows for effective exclusion of “medical devices” which can be also falsified. However, sometimes “medical products” are an important point of reference, for instance when speaking about Personal Protection Equipment (PPE), Covid-19 Testing Kits and similar applications of preventive or diagnostic nature.

Of further importance is the WHO Classification of medicines into “Substandard”, “Unregistered/Unlicensed” and “Falsified”. “Substandard” medicine is medicine which has been authorized but fails to meet quality requirements or product specifications. Whereas substandard medicines are not produced with criminal intentions, they still impose a significant risk to public health and safety. Substandard products are often the result of genuine manufacturing error or bad managerial oversight. Poor manufacturing practice can cause a too high or too low amount of the active ingredients, lacking the active ingredient or contamination with other substances or bacteria. Furthermore, repackaging and relabeling can lead to the intentional or unintentional circulation of expired products on the market and bad storage or transportation conditions can lead to a deterioration of product quality if conditions of temperature, light exposure or humidity are not met.

“Unregistered/unlicensed” medicines do not have approval or evaluation within one jurisdiction but may be permitted in another. Arising problems are that medicines might be not compliant while being in transit, are marketed in some jurisdiction for usages not intended within these or are acquired via online pharmacies and subsequently imported into countries in which they are not authorized. Differences in jurisdictions are a major obstacle for proper law enforcement activity as products are easily distributed over free trade zones and trade agreements that disable rigorous custom checks of small parcels.

“Falsified/Counterfeit” medicines are deliberately fraudulent and designed to deceive consumers and regulatory authorities to generate profits. They are often produced by criminal organizations which undertake great efforts to penetrate supply chains and avoid the detection of their goods. “Falsified” medicines are usually also “unregistered/unlicensed” and often “substandard”.

Finally, various other ways enable the illicit “diversion” of genuine medicines through the wrong actors and for the wrong purposes. Diversion of medicines occurs when it passes from a medical or legitimate source to an individual or group it was not intended for. Common ways on the individual level are the sourcing over friends and family, particularly after operations, from veterans or pensioners. However, other forms of diverting genuine medicine into illicit supply chains involve theft from the stocks of medical facilities or intercepting the medicines in transit between manufacture, central storage facilities and delivery to pharmacies and other dispensaries. This frequently happens in developing as well as developed countries. For instance, 71% of doctors and 83% of nurses in Costa Rica reported thefts of medical supplies from the hospital just as the Italian ‘National Medicines Regulatory Authority’ reports waves of medicine theft from hospitals and trucks (Kohler 2014, WHO 2017). In fact, formalized health infrastructure can be a direct or indirect part of the criminal actor constellation and facilitate the drug problem. “Doctor-shopping” or “double-doctoring” are common ways to acquire larger amounts of prescription drugs which can subsequently be sold prescription-free or used as precursor chemicals for other illicit drugs. This over-prescribing can be well organized as a fraudulent activity. In the US for instance, 3% of physicians are responsible for 62% of opioid prescriptions (Babor et. al 2014). In sum “Diversion of prescribed medicine occurs through various means and diversion via street markets is well established in several countries' ' (Coomber et. al 2013, p.90)

Defining Illicit Trade

“Illicit trade” will be used synonymous to “trafficking” in this research and describes all “[...]means of importing, exporting, storing, transporting, donating, dispatching, dispatching in transit, dispatching in free-trade zones, trans-shipping, distributing, brokering, offering, keeping for offer, selling, or supplying a falsified medical product,

whether on one's own behalf or for a third party" (UNODC 2019, p.11). Hence, this definition provides a broad applicability to grasp every stage of the products life cycle, from the production of inputs to the dispensing of outputs.

Defining Institutional Capacity

In order to evaluate to which extent the global level is capable of providing a framework against falsified medicines during pandemic situations, it is necessary to define how such a framework can be assessed. Institutional capacity is a broad term with varying definitions depending upon the context it is applied to. Whereas no universally accepted definition of institutional capacity prevails, they usually entail common elements at their core. For the purpose of this research, institutional capacity will be applied according to the definition of the United Nations Development Program (UNDP), which identified five basic pillars institutional capacity building is based upon. Namely, these are the (1) Capacity to engage stakeholders, (2) the capacity to assess a situation and define a vision, (3) the capacity to formulate strategies and policies, (4) the capacity to budget, manage and implement, and (5) the capacity to evaluate. Hence, these five points will be assessed within the context of criminal justice and public health and safety mechanisms at the global level within Chapter 4 and 5.

1.3 Societal Relevance

Illicit trade in pharmaceuticals and other medical goods is not a victimless crime. On the contrary, the broad range of detrimental effects that result directly or indirectly out of the illicit trade with medicines has comprehensive direct and indirect effects on communities and individuals. To illustrate the societal relevance of resolving this deceptive and deadly crime, the following part will briefly address trends and damages that result out of the production, distribution and consumption of falsified medicines based on a broad categorization into health-related aspects, economy-related aspects and institutional aspects.

1.1.1 Health-related damages

The perhaps most visible manifestation is the direct effect on patient health and wellbeing. Individuals might acquire falsified medicines directly over the internet due to

financial reasons and lacking awareness or through dispensing of genuine healthcare personnel if the counterfeit entered the legitimate supply chain at an earlier stage. Occurring health damages can be physical including higher mortality and morbidity, adverse health effects through toxicity and lacking efficacy, the failure to cure and prevent diseases, an overall higher prevalence of diseases and the progression of antimicrobial resistance.

Furthermore, associated psychological effects are a loss of trust in healthcare providers and governments as well as non-medical abusive consumption and possible addiction. While the overall scope of counterfeit trade in falsified medicines is difficult to estimate, it is evident that it occurs across low-, medium- and highly developed countries, although the concrete manifestations and damages are varying with the degree of technological advancement and supply chain resilience. The WHO estimates that on average 10.5% of medicines worldwide are counterfeit whereas others estimate the prevalence higher at 10-30% (Labaran & Hamma-Adama 2021). Indeed, global averages do not accurately depict the scope of the problem, as counterfeit prevalence can differ substantially by country, region and sub-region. While approximately 18.7% of medicines circulating in Africa are counterfeit (Schneider & Ho Tu Nam 2020) this number can range up to 70% in some African and Asian regions (O'Hagan and Garlington 2018). Indeed, in 2008 the European Alliance for Access to Safe Medicines reported that 70% of medicines in Nigeria and Angola were fake, 35% in Kenya, 10-35% in Russia, 20-25% in India and 13% in Cambodia.

Predominantly in the African region, due to in-effective antibiotics and malarial medication, an estimated 72.000-169.000 children die every year from pneumonia and 116.000 children die annually through ineffective malaria treatment (OECD 2020). But also, the Asian region is severely affected, as older reports from China revealed that 200.000-250.000 people died annually due to falsified medicines (EAASM 2008). Whereas falsified and substandard Antibiotics and Malaria medication can directly inflict harm through adverse or absent effects, they also promote antimicrobial resistance as they often contain a low amount of the correct active ingredients. Increasing resistance of diseases is evident in African regions where prevalence of substandard and counterfeit of the Anti-Malaria medicine 'Artemisinin' reached estimates of up to 90% (Kelesidis & Falagas 2015). Antimicrobial resistance

subsequently spreads from such hotspots across borders through travelers, a similar dynamic to the one observed with resistant and infectious Coronavirus mutations during the Covid-19 pandemic.

Whereas a lack of the active pharmaceutical ingredient or too low concentration thereof usually makes the treatment ineffective, pills can also contain dangerous substances that can be life threatening by themselves. Laboratory analysis performed by pharmaceutical company Novartis has revealed that falsified medicines can contain Heavy Metals (Mercury, Aluminum, Uranium, Arsenic, Lead, Chrome), Poisons (Rat poisons, Benzopyrenes, Boric acid, Antifreeze, BCPs), Chemicals (Road paint, wall paint, brick dust, floor wax, sheet rock, paint thinner) as well as various other non-declared API's and non-declared excipients.

The worrisome trend is that falsifications of medicines are rapidly rising in volume and in scope of targeted products over the past decade. "Every region has experienced an increase in pharmaceutical crime incidents since 2017, with a total of 145 countries involved" (OECD 2020, p. 20). By 2021, an all-time high of 1.992 different medicines across all therapeutic categories have been targeted by counterfeiters, with particular focus on medicines in the genito-urinary, central nervous system and anti-infective therapeutic categories (Pharmaceutical Security Institute 2021). More precisely, the most counterfeited medicines are Antibiotics (37%), followed by 'Sexual Impuissance treatment' (eg. Viagra), 'Painkillers' (eg. Opioids) and 'Anti-Malarial medication' (OECD 2020). Thus, an extensive range of treatments for serious diseases like Epilepsy, Multiple-Sclerosis, Malaria etc. is affected just as many 'lifestyle drugs' like sex enhancers. This reflects the indifference and apathy of counterfeiters in the application of their falsified products and the sole drive to falsify what is most profitable. In fact, virtually no product is spared. Indeed, even falsified contraception has been reported in 11 countries on three continents, and falsified abortifacients in eight countries (WHO 2017). Despite not being a potentially lifesaving medication, the sheer scale of the falsification depicts the recklessness in generating profits, as the seizure of 150.000 fake emergency contraceptives by the Nigerian customs authorities in 2013 illustrates (WHO 2017). Assumably, vaccines, testing-kits and other Covid-remedies will be targeted, as new market entrants are easy prey for counterfeiters because medical personnel are not familiar with them yet and have difficulties determining effectiveness and side effects

accurately. Hence, it is likely that the pandemic situation will be exploited by criminal organizations to take advantage of lacking knowledge about the new corona-virus strain, the public panic, and the unfamiliarity of medical personnel with available and upcoming treatments.

Economy-related damages

Whereas the health damages directly influence patient and global health, medicine counterfeit can further undermine the public good by hampering business and innovation. Pharmaceutical companies experience lost sales and employment, pay litigation costs and face increased monitoring and investigation costs. This diverts resources away from allocation into research and development (R&D) and diminishes governmental revenue through taxation.

The pharmaceutical industry doubled its global sales over the past two decades and is forecasted to reach global sales of $1.17trillion by 2021 (Hada & Mihalcea 2020). It further generates higher profit margins than any other industry (Babor et. al 2014), amounting to a gross profit margin of 76.5% under exclusion of costs for Research and Development (R&D) for big, fully integrated pharmaceutical companies (Ledley et. al 2020). Arguably, the forecast parallels the profitability for criminal organizations engaged in large scale production and distribution of fraudulent medicines even more, with the differences that these do not invest into the research for new medicines and do not pay taxes. On average, pharmaceutical industries are investing 17% of revenue into R&D of new drugs, whose development in turn averages a cost of $2.6billion. With estimated annual global sales of fraudulent pharmaceuticals ranging between $200-431billion, this translates into a loss of 6-28 new medicines per year (Miller & Winegarden 2020). These resources and innovation are harshly needed, especially since many long term effects of Covid still have to be fully discovered, understood and managed; and many treatments and operations of secondary-diseases that have been postponed during the height of the crisis have worsened and need to be answered coherently once the pandemic is over.

Companies themselves do not only lose sales but also experience substantial damages to brand reputation. A INCOPRO study has revealed, that 83% of consumers who experienced health damages through consuming a counterfeited brand would refrain

from buying the original brand again, and 76% have responded that they would be less likely to buy a brand that is known to be frequently counterfeited (INCOPRO 2018). This in turn reinforces lost sales and subsequently reduces government revenue as the taxable income is reduced. Plus, firms may be subject to liability and have to handle litigation costs or product recalls. To protect their brands and public health and well-being, the introduction of additional security measures vastly increases costs as well. The European Commission estimated that the introduction of anti-counterfeiting technologies, like unique identifiers, imposes an additional annual cost of 200-800 million € for the entire sector (manufacture, wholesale, retail, repository centrum) (OECD 2020). Hence, the strong necessity to constantly upgrade security technology diverts further resources away from other causes that could add more value to the real public good.

But not only the industry is affected by increased costs. For instance, as the European pharmaceutical industry loses estimated €9.6 billion in sales due to counterfeit annually, which represents 3.9% of its total value, the sales loss translates into a loss of EU governments revenue that amounts to €1.7billion annually (OECD 2020). Additionally, health care systems carry the financial loss of the repeated and failed treatment and in many cases additional treatment due to adverse health reactions. According to Tesfaye et. al (2020), the cost of additional care following treatment failure amounts to $200billion across all low -and middle-income economies. However, this only illustrates the financial damage carried by public entities. Over two billion people still lack access to governmental healthcare and many millions are at risk of being trapped into poverty by paying healthcare costs out of pocket (WHO 2017). Thus, it greatly affects countries struggling with governance and infrastructure that are particularly exposed during pandemic situations, such as African and South-East Asian regions. Considering that policymakers around the world are forced to make decisions under limited resources, limited time and limited information, in an environment of institutional fragility, it can be assumed that the vaccination roll-out within these countries will be a particularly attractive target for counterfeiters, as the high prevalence rate of falsified medicines prior to the pandemic already indicated a favorable business environment.

Institutional Damages

Various institutional damages beyond the economic and financial impact on public health systems are associated with illicit trade in falsified medicines. It undermines the integrity of the public procurement systems and medical practitioners, induces corruption, and causes conflicts between varying jurisdictions. Since falsified medications often intrude legitimate supply chains and are thus dispensed through official and trusted institutions, they can abuse the trust of citizens and consequently undermine their trust into democratic institutions and governmental or professional services. Aggravating such dynamics is the prevailing institutional corruption in the pharmaceutical industry, which through its untransparent entanglement of public and private actors as well as business practices already fueled public distrust before the pandemic struck.

Additionally, counterfeit imposes additional burdens on the regulatory systems, healthcare providers and criminal justice system, as its prevention and investigation further strains the availability of staff, resources and infrastructure.

On a global level, trafficking in fraudulent medicinal products jeopardizes multiple efforts of the international community. The multitude of harms directly threaten the achievement of the Sustainable Development Goals (SDGs), especially SDG3 “Good Health and Well-Being” and SDG12 “Responsible Production and Consumption” **.** The high level of criminal organizations and corruption involved further undermine SDG16 “Peace, Justice and Strong Institutions”. Since in many countries, buying medicine is a privately carried cost in relatively poor households and can significantly threaten the economic situation and quality of life of families relying on them, the trade in falsified medicines has also indirect effects on SDG1 “No Poverty” and SDG10 “Reduced Inequality”. Because falsified medications de facto compete with the genuine pharmaceutical industry, they further affect SDG8 “Decent Work and Economic Growth” and “SDG9 “Industry, Innovation, and Infrastructure” by fostering unemployment, reducing sales and hindering R&D.

1.4 Limitations to the research

This research is subject to multiple limitations. Firstly, research concerning criminal activity is constrained through the availability of reliable data. Existing data on illicit goods such as counterfeit or narcotic drugs are usually estimates based on custom seizures, law enforcement interventions on manufacturing or storage facilities, testimonials, and other reports. Therefore, availability of verifiable knowledge is limited due to the difficulties of freely accessing reliable data upon subjects in the criminal sector. Furthermore, a temporal limitation through the rather recent emergence of illicit trade in falsified medicines that are distributed through the internet and its various associated components (social media marketing and small parcel delivery) persists as well. Similarly, the pandemic is a contemporary event that limits the availability and reliability of data, as new insights are produced on an ongoing basis. This particularly affects the chosen method of literature review as the rapid expansion of knowledge progresses with the unfolding of the pandemic in the form of frequently published research papers and news articles that update the body of knowledge on an ongoing basis. Lastly, the level of ambition attempting to make a multidimensional phenomenon tangible at the global level limits the detailed analysis of some sub-topics arising throughout the paper.

Chapter 2: Evolution of Illicit Pharmaceutical Trade

After the consequences of falsified medicines have been outlined in Chapter 1, Chapter 2 will elaborate on the underlying characteristics that foster the illicit industry and enable it to cause the described damages in the first place. Hence, this chapter will describe the trajectory of the development of the illicit pharmaceutical industry and the current forms, techniques, and processes involved in its criminal proceedings. The aim of this chapter is to introduce the characteristics of the trade with falsified medicines to elaborate in the next chapter how these react with the dynamics of the Covid-19 crisis. Therefore, the subsequent part will discuss the sub-question:

RQ: What are the relevant actors, structures and processes coining illicit trade in pharmaceuticals?

To answer this question, the development of the licit industry will be briefly addressed, the impact of e-commerce will be outlined and finally the market, product and governance characteristics presented, which make the falsification of medicines such an attractive business.

2.1 Historical Development of the Pharmaceutical Industry

The pharmaceutical industry emerged in the 19th century in the form of compounding pharmacies which produce medicines tailored to the needs of the customer individually and on the spot right before dispensing it. From this point, two distinct industry characteristics developed which coin the modern pharmaceutical supply chains up to today: (1) the patenting of medicines and (2) the rise of centralized manufacturing.

(1) Patenting of medicines

Patenting is the reason that pharmaceuticals are among the most Intellectual Property (IP) intense sectors in the world. Designed to preserve the incentives of companies to invest into R&D, governmental regulations grant the companies lengthy market exclusivity for their products, e.g., even up to 20 years in the US (FDA 2020). Consequently, the pharmaceutical industry is the 4th most IP intensive sector constituting 4.3% of trademark applications every year and accounts for 22% of all

R&D across all sectors (only topped by computer and electronics) (OECD 2020). A further distinction to make is the differentiation between “proprietary” -or “branded” medicines and “Generic” pharmaceuticals. The former is associated with the company that invested into the development of the medicine and thus holds a patent granting them market exclusivity. The latter is a medicine of similar composition and usage whose patent is expired, not granted, or licensed with the legitimate patent holder. Due to the high level of brand recognition is thereby also a major driver for counterfeiters to target such medicines as they raise consumer trust.

The range of products the pharmaceutical industry invented and developed grew with the industry over time, experiencing a particular boost of innovations throughout the 20th century. Whereas the 19th century was mostly centered around opium, alcohol, morphine and cocaine, the early 20th century was coined as the era of chloral hydrates and bromides. In the 1930s, barbiturates became a popular component in pharmaceutical treatments, followed by Benzodiazepines (e.g. Alprazolam, Lorazepam) in the 1960s/70s. Finally, the 1990s fostered the spread of serotonin reuptake inhibitors (SSSRIs) and psychostimulants (e.g. Ritalin) (Babor et. al 2014). Whereas the oldest forms of medicines like morphine, opium and cocaine are mostly associated to classical narcotic drugs, so called “designer” Benzodiazepines recently flood the street markets as novel psychoactive substances which are often counterfeit created by standard pill presses and induced with illicit opioids (Pergolizzi et. al 2020). Finally, psychostimulants and SSSRIs achieved a level so widespread and normalized that that their extensive marketing has turned the US and Europe into “psychopharmacological societies" where by neuro-enhancements “human subjective capabilities have come to be routinely reshaped by psychiatric drugs (Babor et. al 2014, p. 98). Hence, the innovation and patenting of medicines as well as their marketing are a driving factor picked up by criminal organizations to modify and profit from their effects and recognition.

(2) Centralized manufacturing

Naturally, the surrounding industry underwent major transformations throughout the century, adapting to the rise of healthcare and insurance systems as well as massive commercialization through the processes of globalization, profiting from advanced

production and logistics capabilities in increasingly interconnected markets and the usage of information and communication technology for marketing and public affairs. Nowadays, pharmaceutical supply chains and regulatory regimes rank among the most complex in the world. Because the development and production of pharmaceuticals requires a high degree of advanced technologies and strongly protected specialized expertise and knowledge, the headquarters of the biggest pharmaceutical companies are heavily concentrated in a handful of rich and developed countries. The top 50 pharmaceutical firms in 2017, which generated $653 billion in sales, are heavily located in OECD countries, hosting 16 in the US and 10 in Japan. Furthermore, 27,8% of sales were associated with firms in the EU (OECD 2020). Their supply chains however are fragmented throughout the global landscape. Like other industries, the pharmaceutical industry also sources inputs from economies that provide comparative advantages, such as cheap labor or resource availability. These are producing components and active pharmaceutical ingredients that are required for the production and development of the medicine and sending them to the manufacturer. The manufacturer assembles the product and delivers them to the wholesaler or centralized storage facility. From there, they are further processed by distributors or parallel traders, before they reach their point of dispensary (hospitals, pharmacies, doctors) where the product finally gets in contact with the consumer. Around this supply chain developed a range of other institutional actors somewhat involved in the process, such as insurance companies, patient organizations, Non-Governmental Organizations or Philanthropic Organizations as well as logistics and transport companies. Often, one or more parts of the supply chain are located within differing jurisdictions and thus subject to different rules and regulations. This makes the supply chain vulnerable for counterfeiters, as the ease of entering the supply chain increases with the number of joints, actors and regulations involved.

2.2 Characteristics of Illicit Trade in Pharmaceuticals

The high fragmentation of the regulatory landscape and the high number of joints and contacts included in the supply chain are facilitating a market entrance for criminal organizations.

History has proven time and again that these are more than willing to use this window of opportunity. The first evident case of falsification of medicinal products dates back to 1500 BC, when Queen Hatshepsut of Egypt sent out a team of experts to gather genuine medical plants after the market was flooded with fakes (WHO 2017). Over 2000 years later, the illicit market flourishes at new heights, pushed by the internet, modern production capabilities and peaking demand. According to a study of O'Hagan and Garlington 2018, Counterfeit drugs reached estimated annual global sales in the range of $200billion USD and are therefore the most valuable alternative illegal trade, worth more than the trade in Cocaine ($80billion USD), Opium and Heroin ($60billion USD), Human trafficking ($30billion USD), Arts and Cultural Artefacts ($5billion USD) and Small Arms ($1billion) combined. The driving factors behind the rapid ascent of illicit pharmaceuticals to the top of the list of illegal alternative products can be attributed to the interplay between market characteristics with advancements in production and distribution technology as well as institutional weaknesses (OECD 2008).

1. Market Characteristics

The potential market size for illicit pharmaceuticals is extremely large because health and well-being is a universally desired good. Hence, demand is only limited by access and affordability, which in turn are regulated through different constellations of public or private procurement regimes. Independent of the operating regime, health spending is associated with progressing economic development and forecasted to increase global health spending from $9.21 trillion USD in 2014 over $16.04 trillion USD in 2030 towards $24.24 trillion USD in 2040 (Global Burden of Disease Health Financing Collaborator Network 2017). If supply does not parallel this trend in rising demand in an affordable and accessible manner, criminal organizations are likely to take advantage of the disequilibrium and fill the resulting gap with fraudulent pharmaceutical products. This trend is possibly further fueled through the extreme inequality in the global pharmaceutical market. While overall opioid consumption tripled between 1994 and 2014, the consumption itself remained highly concentrated in rich countries. But stark differences occur even within the group of rich countries. For instance, the US consumes at least 10-times the amount of psychostimulants compared to other rich countries and consumes the vast amount of global supply of morphine, e.g. 73% of

oxycodone and 99% of hydrocodone (Babor et. al 2014). In 2018, over 87% of opioids were consumed by North America and Western Europe, representing only 12% of the global population (UNODC 2020). Such market imperfections are easy to exploit by criminal organizations by offering fraudulent products for lower prices or without prescription requirements in areas where they would otherwise not be available or affordable. Thus, rapid growth combined with rising inequality can be identified as a driver for demand creation of medicines from untrusted sources.

The rising demand is further supported by high profitability. Producing and distributing counterfeit pharmaceuticals can be extremely profitable because of the large volume involved, the high pricing of some brands, and the high cost of treating certain diseases or receiving treatment in certain national markets. On the production side, profitability can increase especially when the active pharmaceutical ingredient, which can account for 80% of the price of some medicines (WHO 2017), is either left out, substituted or in too low concentration. For instance, the profit margin for importing and selling 100.000 fraudulent pills of Viagra in the United Kingdom has a profit margin of 7,900% (OECD 2020). Putting the volume into perspective, four large operations by the World Customs Organization in major African ports between 2012 and 2017 seized an alarming amount of 869 million units of counterfeit medicines with an estimated value of €400 million (WCO 2017).

On the distribution side, large profitability also corresponds to the high level of brand recognition in the pharmaceutical market. Comparing generic with branded medicine, the latter can entail the 2-fold to 100-fold costs (Pichholiya et. al 2015). Thus, well-known companies based in the US and EU are particularly attractive targets for falsification as the revenue potential increases. Accordingly, well-known companies like Pfizer, Novartis and Roche include business risks associated to falsification in their annual financial reports, stating that counterfeit is a growing, industry-wide issue imposing serious risks to patient health and confidence as well as business integrity and sales resulting in potential product recalls and litigation costs (Pfizer Inc. 2020). However, while the high prices of some medicines like cancer treatments can yield high profits by defrauding a small number of consumers, the overwhelming targeting of cheap essential medications in Africa, such as malaria treatments, indicates that most

profit arises out of the quantity of fraud coupled with low regulatory defenses (Attaran 2010).

Multiple factors of globalization shape favorable conditions to produce and distribute counterfeit, like large-scale logistics (e.g., Cargo-Ships and port warehouses), small-parcel delivery methods and deregulated regional trade regimes with less customs and oversight (e.g., Free Trade Zones). The international supply chains of trade in counterfeit pharmaceuticals established itself among a pattern similar to the trade in illicit drugs, that is, the division into production, transit and consumption countries. Modelling the trade routes according to custom seizures, the main destinations for falsified medication in 2017 were North America (50%) and Europe (26%) (OECD 2020). However, economies in the African region are known to struggle with high volumes of falsified medications and arguably don't have the technical and institutional capacities to properly intercept and report incidents in contrast to technologically and democratically advanced economies. As improvements in reporting structures revealed over the past years, counterfeit prevalence appears to increase with the amount of allocated resources and scrutiny to detect (WHO 2017).

Examining the countries of provenance, 55% of seized counterfeit originated from India, 33% from China and 4% from the United Arab Emirates and 3% from Hong Kong. Thus, the Asian giants together constitute the source of almost 90% of counterfeit goods, and frequently ship their goods over transit countries such as Yemen, Singapore, UAE, Iran or Turkey (OECD 2017).

2. Product characteristics

Pharmaceutical crime substantially benefits from the possibility to produce with relatively low cost and distribute the products with a low risk of detection. If the active pharmaceutical ingredient is spared out, a simple pill press might suffice to produce a convincing design which can be impossible to distinguish by the mere eye of consumers and even trained customs and health care professionals. Criminal organizations often dispose of such equipment to produce other illicit drugs and hence can diversify their production easily. Indeed, one case of laboratory analysis of falsified Malaria medication in Southeast Asia revealed that the product contained Sildenafil (Viagra) and precursor chemicals used in the manufacture of MDMA, which indicates that the

same illicit laboratory engaged in the production of all three products (Newton et. al 2008).

Depending upon product and jurisdiction, authentic looking packaging of pills and labelling of the boxes can be reproduced with relative ease utilizing standard industrial printers. While regulators and companies made substantial efforts to secure the supply chain by adopting sophisticated labelling and tracking techniques, evidence has shown that criminal organizations evolve and quickly adapt to new regulations with professionally made labels, detailed, and expertly produced boxes and even falsified holograms and authentication devices (WHO 2017). However, especially in poorer and rural regions, sophisticated disguise may not always be necessary. Other practices disguising SSFFC-pharmaceuticals can be simpler, like repackaging counterfeit into original boxes that have been stolen out of hospital trash or manually changing the expiration date or batch number of products. Since counterfeit can easily enter at any point of the supply chain, it is hard to detect visually and requires lengthy laboratory analysis for forensic evidence, it is easy to conceal the operation to customs and consumers alike. Therefore, apart from occasional customs interceptions or targeted police efforts, fraud is usually only detected by healthcare workers when individual treatment repeatedly proves ineffective, results in adverse consequences or if health investigators detect strange regional patterns. But even when adverse reactions are detected, a lack of awareness and a low likelihood of occurrence can further delay timely intervention because other suspected causes -like outbreak of common, uncommon, or unknown diseases as well as soil or water pollution- are often ruled out first before suspecting counterfeit and starting a comprehensive investigation looking into patterns of drug consumption and dispensing. For instance, experts first suspected a dengue fever outbreak in Pakistan in 2011, when over 200 patients died and 1000 more got hospitalized, but spotted the pattern that all of them were treated at the same cardiac hospital, where a judicial enquiry tribunal determined contamination through poor manufacturing standards (Lahore High Court 2012).

3. Institutional characteristics

Weak governance, low awareness and a highly fragmented regulatory landscape incentivize criminals to engage in the supply provision of counterfeit pharmaceuticals as

limited technical capacity to exercise oversight and manage procurement undermine effective healthcare provision and thus create an easy arena with high demand. Non-availability of medicines constitutes a major push factor of demand which can be traced back to various reasons, including geographical isolation, war, natural disaster, terrorism, corruption, production errors further up the supply chain, bad central planning, inefficient import/export requirements, rapid changes in insurance-policy or uncontrolled price maximization of producers.

Whereas many of these events resemble external factors or unexpected policy outcomes, bad governance undermines their effective solution, often through the form of lacking cooperation between health authorities, customs and border control and judiciary systems.

An illustrative example is a case with falsified ephedrine in Afghanistan. With rising political conflict facing upcoming presidential elections, surgeons expected a rise in suicide killings and bombings and thus needed to stock up of the drug, which is a stimulant for the central nervous system. However, they faced difficulties in the procurement process as ephedrine is subject to import/export restrictions because it is also used as a precursor chemical for methamphetamine. Consequently, they tasked local suppliers who procured the drug without proper clearance. After doctors used the drugs for months, they spotted patterns of increased hypertensions in their treated patients. The WHO sent pictures of the drugs and packages to the assumable producer Bayer, who confirmed the counterfeit. As the medication was urgently required, the WHO mobilized emergency supply, which was then kept at the Afghan custom border, because the import requirements stated that the previous supply of (fraudulent) ephedrine had to be used completely before granting the new delivery. Consequently, the hospital has been without quality assured supply for over four months during times of crisis (WHO 2017). Other governance problems can arise out of too abrupt concluded or insufficiently phrased policies. For example, poorly worded policy reform in Africa decreased the availability of generic medicines (Attaran 2010) and changes in insurance policy in the US incentivized falsification of the breast cancer medication Avastin, because insurance companies crossed the medicine of their reimbursement list after a study revealed no real benefit, but the demand from patients and doctors persisted (WHO 2017).

Low risk of prosecution resembles an additional pull factor making falsification of medicines a particularly attractive crime as it decreases the risks associated with high potential to profit. Police forces generally lack expertise in the field of pharmaceutical crime as the investigations require comprehensive forensic analysis of computers and smartphones as well as lengthy laboratory analysis of the seized counterfeit medication. Thus, the investigations are very time consuming and resource intensive. On average, a forensic chemistry assay costs between 5.000-15.000 per test (OECD 2020). Time delays also frequently appear, as samples often need to be sent to different countries if the country of detection does not have the proper laboratories. Indeed, the level of enforcement is so low, that Egypt ranked among the top 10 enforcing countries in 2018 with making only one single arrest (Schneider & Ho Tu Nam 2020). The high heterogeneity across jurisdictions and the varying level of enforcement makes investigation of pharmaceutical crime a wicked issue since the supply chains usually cross multiple borders and are managed through complex ownership structures and foreign banks.

Apart from regulatory features, cooperation can be further undermined due to technical reasons, language barriers or diplomatic reasons when regions do not cooperate due to regional and political conflicts as investigations require a high amount of information sharing and therefore transnational trust (WHO 2017). Still, even in cases where cooperation, a legal basis and subsequent enforcement exists, the proportionality of the sanction does not necessarily reflect the severity of the crime. Whereas the global average for maximum imprisonment of smugglers of narcotic drugs is 25 years, counterfeiters of pharmaceuticals are often only imprisoned for trademark infringements with a global average maximum sentence of 6 years (OECD 2018). Often, perpetrators or the legal entities used for their crimes are only subject to civic or administrative penalties amounting to manageable costs of doing business. For instance, the largest personal fine paid in France amounted to merely 10.000€. In another case, a company sold over 5000 Malaria test kits and distributed over 8 million doses without having any license for manufacture and marketing was only charged with a fine of 11.000€ and suspended prison sentences of 12 and 5 months (WHO 2017).

Concluding, institutional characteristics are strongly favorable for illicit trade in pharmaceuticals as the combination of weak detection, weak legislation, weak

enforcement and weak sanctioning fails to disincentivize the engagement in pharmaceutical crime as the benefits outweigh the possibility of severe consequences.

2.3 The Internet Gateway

The offering of medicines over the internet resembled a milestone for the dynamics of illicit trade falsified medicines. Indeed, while the rise of online pharmacies resembles a revolutionary transformation for the legitimate pharmaceutical industry, it also benefited its illicit counterpart. Online pharmacies can either be associated with large retail stores and chains that additionally operate online, can be brick-and-mortar dispensaries that further have an online appearance or solely operate online. The pharmacies can either operate fully legitimate and compliant or by exploiting regulatory grey zones on the surface web, which is the part of the internet that is indexed by regular search engines.

Since the opening of the first online pharmacy Soma.com in 1999, the number of online pharmacies significantly increased due to the range of benefits they deliver for the customer. According to the OECD 2020, 30.000-35.000 online pharmacies have been online in 2016 and about 600 new online pharmacies launch every month. The success can be subscribed to various convenient features. Online pharmacies are 24/7 available, offer an extensive range of products, are easily accessible for people with physical disabilities, preserve privacy as no physical appearance and interaction is required and offer transparent, comparable and often cheaper prices. However, this convenience can quickly turn into exploitation and medicine fraud. A study of 116 online pharmacies in 2008 revealed that 62% of medicines bought online were either fake or substandard, 95.6% operated somewhat illegal due to lacking compliance, 94% did not have a verifiable pharmacist, 84.5% had no physical presence, 78.8% violated trademarks and 90.3% sold prescription-only medicine without requiring the prescription (EAASM 2008, Mackey & Nayyar 2016).

Regulation and effective rule enforcement of online pharmacies is a difficult task as they must be legally compliant with the legislation in the country they are located as well as the regulation in the destination country of the shipment.

Strikingly, 66% of countries did not have any legislation in place that explicitly allowed or prohibited online pharmacies, and of those that were decided, 19% prohibited it and 7% permitted it (WHO 2011). This lack of harmonization, enforcement and legislation

results in a large grey area that constitutes a major risk for transnational distribution of counterfeit and consumer health. Attempts to govern the safety of online pharmacies often include the application of specific technological, electronic, and cryptographic details embedded in the logo of the website, which subsequently redirect the consumer for a verification check to a registrar list of the responsible national or regional authority. However, checking the authenticity for consumers can still be a difficult task as seals and licenses themselves can be fraudulent or not in line with the jurisdiction of the purchaser (Mackey & Nayyar 2016).

The advent of online pharmacies on the legitimate surface web unfolded great potential for consumer targeting and global diversion of substandard and falsified drugs for large criminal organizations by running so called “Rogue Pharmacies”, unlicensed platforms mirroring the design of legit online pharmacies to defraud consumers. The underlying infrastructure operates through the interplay of internet service providers (e-commerce services, domain name servers, web hosting services, registrars, search engines) with marketing sources (illicit online pharmacy, affiliate sites, social media platforms) and utilize intermediate service providers such as payment processors and transport companies.

Whereas all major payment network companies have policies prohibiting the sale of illegal drugs, some rogue pharmacies disguise their activity by providing false codes to the banks indicating they sell different products. Apart from this practice, a small number of companies also deliberately support criminal endeavors and evade law enforcement cooperation. 45-52% of illegal online pharmacies are registering their domain names with 10 domain name registrars that do not enforce policies against illegal online pharmacies (OECD 2020) and a small number of banks are engaged in most of the payment processing on illegal pharmaceutical websites (McCoy et. al 2012). Overall, the illegal market appears to be highly concentrated in the hands of a few large criminal networks. According to a study of LegitScript 2016, only 3% of websites selling pharmaceuticals are the sole internet presence of individual prescription drug sellers, whereas 97% of online pharmacies can be linked to approximately 125-150 marketing networks under common control or central affiliation, e.g., criminal organizations controlling a network of distribution sites. Such websites are promoted via social media, e-mail and forum spam using botnets as well as other channels of

promotion such as search engine marketing, social media marketing, affiliate marketing and search engine optimization (Mackey & Nayyar 2016). Engaged criminal organizations further use these platforms to commit financial and data fraud by phishing and subsequently exploiting sensitive information.

In contrast to trade on the surface web, illicit trade in pharmaceuticals also takes place in the deep web, which is the part of the World Wide Web that is not indexed by regular search engines. The deep web is about 500.000 times as big as the surface web and contains a multitude of different databases, for instance from governmental, financial, professional, and educational institutions (Ranakoti et. al 2017). Hidden in this not-indexed part of the web are so called cryptomarkets -also called Darknet Markets (DNM)- that offer a quasi-unrestricted supply of goods and services, including medicines next to narcotics and alike. Put simply, a cryptomarket is "an online forum where goods and services are exchanged between parties who use digital encryption to conceal their identities" (Martin 2014). Cornerstones of this system are the TOR-network, third-party hosting, shipments via postal service, decentralized exchange networks and cryptocurrencies. The technical procedure is as follows. By utilizing the TOR-browser (The Onion Router), incoming connections are sent to anonymized servers and stripped of identifying information. Third-party hosting circumscribes the provision of infrastructure through administrators that resolve disputes and mediate transactions via an escrow payment system. Escrow payment systems function in the way that customers transfer their money to the admins, who release the money to the vendor after the customer receives the product. Within this process, the administrator charges a commission fee usually ranging between 2-4% (Aldridge 2017). The product is commonly sent via regular mail or courier services and safeguarded by the postal secret. Such small parcels are particularly difficult to intercept when they don't have to pass international customs borders. However, shipments are generally difficult to detect as vendors on cryptomarkets utilize advanced operational security techniques to disguise their shipment, such as double vacuum sealed bags, metal barrier bags, wrapping in card pieces and package designs such as regular business letters (Kamphausen & Werse 2019). In combating such DNM's, policymakers and Law Enforcement must be aware of unintended outcomes, as their efforts to get the DNMs under control pushes vendors to alternative paths like multichannel retailing (Child

2020). Mostly, these cover forms of direct dealing on untappable end-to-end-encryption messaging apps like Wickr, Signal or Telegram, which do not require to link to other information stored in the phone like contact lists and phone numbers (Child 2020). Hence, the companies behind these applications encrypt network traffic as well as data and server storage. Hence, communication is increasingly outsourced to private networks or common social media channels due to the high suspected density of Law Enforcement moles within the community and shifts frequent and big trade into more private and closed circles, which are only accessible after a sufficient level of trust was established on the cryptomarket as an introductory platform (Mounteney 2017). In sum, this last section has outlined two ways in which the digital space contributes to the distribution of counterfeit medicines, which is of relevance, as the next Chapter will elaborate further on digitalization-related factors accompanying the impact of Covid-19.

Chapter 3: The pandemic shock

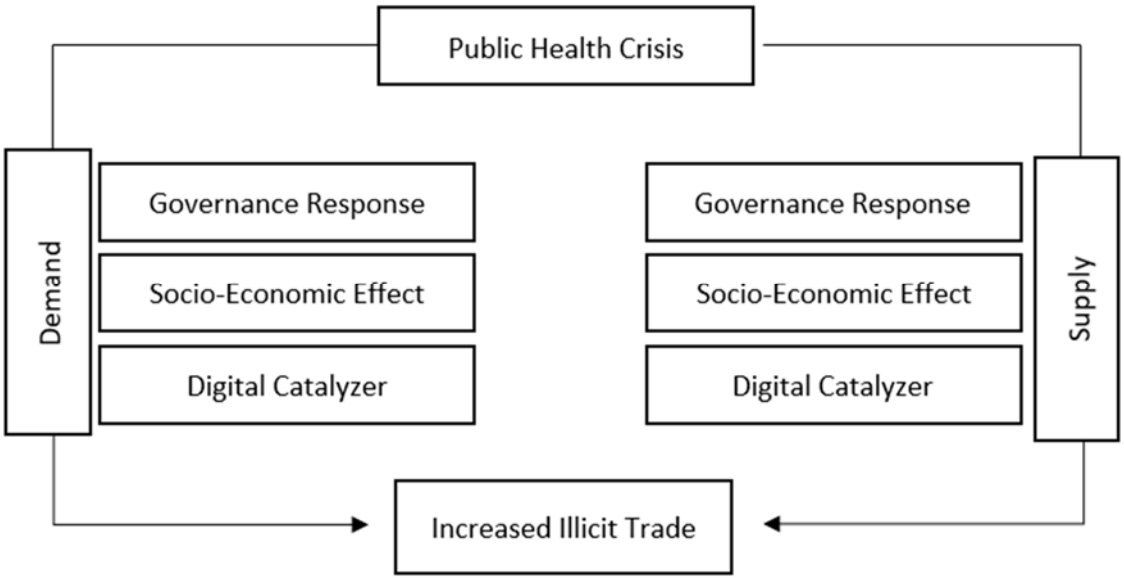
On the 30th of January 2020, the WHO declared the novel coronavirus disease spotted in China a public health emergency of international concern, which was officially declared a global pandemic on the 11th of March 2020 (WHO 2021). Since then, the Covid-19 pandemic affected virtually every country and brought grave economic, social and health consequences. As of June 2020, over 177million people became infected with the disease and almost 4million lost their life (Worldometer 2021). Aggravating the situation, organized criminal groups heavily engaged in counterfeiting of medicines and medical products like filtering masks, hand sanitizer, Covid-testing kits and other goods associated with the pandemic response, thus undermining effective measures to contain the virus. Whereas the beginning of the pandemic created a hitherto unseen global market for counterfeited Personal Protective Equipment and other medical goods like Chloroquine, it can be expected that the focus of counterfeiters will shift to vaccines and cyber scams of health authorities and patients, once a treatment is available (UNODC 2020a). To assess the effect of the Covid-19 pandemic on the trade with falsified medicines and other associated medical products, the following chapter will elaborate upon factors contributing to the rising demand of illicit pharmaceutical goods and subsequently upon factors that foster an increase in supply of these, by answering the following sub-question:

RQ: To what extent did the Covid-19 pandemic influence the illicit trade in falsified medicines?

To elaborate upon this question, factors of demand and supply will be categorized into economy-related, governance-related and digitalization-related factors as illustrated in *Illustration 2*. Notably, the strongly intertwined nature of all elements must be highlighted, as the categories mutually influence each other and thus occasionally overlap. Furthermore, a component of psychological distress will not be elaborated upon particularly but will be accounted for as a constant, subtle influence on the individual level throughout the analysis of the other categories.
However, the definition of demand has to be contextualized as it circumscribes rather a degree of susceptibility to purchasing falsified medicines, either intentionally by

attempting to source the medicines from alternative sources and channels or unintentional as a side-effect of increased demand for medicines in general. Supply on the other side covers all processes of production, manufacture and distribution as outlined in the definition for illicit trafficking in Chapter 1.

Illustration 2: Model of Demand and Supply Acceleration through Pandemic Shock



Source: Own Illustration

3.1 Factors increasing demand

Governance factors

On the individual level, mistrust in political representatives and health services might incentivize citizens to explore alternative challenges of medical procurement. Hence, the following paragraph explores to what extent corruption has been evident in the pandemic response, in which forms it occurred and how it might increase the demand for illicit pharmaceuticals.

Mistrust of citizens towards public officials due to corruption is a factor constituting an increase in the purchase of falsified medicines. In 2019, one year before the pandemic held the world in its grasp and greatly revealed institutional weaknesses, only 45% of citizens reported to have trust in their government and only 69% in their healthcare service (OECD 2020). This mistrust is not without reason as studies have shown. The

same year, a survey among health care professionals from 126 countries estimated that 29% of funds allocated for health care purposes are diverted illegally (World Justice Project 2020).

The pandemic provided a huge potential for economic exploitation through corrupt public officials that undermines the global public health response and fuels the crisis of democracy. "Corruption is prevalent across the COVID-19 response, from bribery for COVID-19 tests, treatment and other health services, to public procurement of medical supplies and overall emergency preparedness. " (Transparency International 2020a, p.8). Corruption experienced in relation to covid-19 can take either the form of high-level corruption concerning public procurement or low level corruption necessitating bribes for medical treatment to healthcare practitioners or to policemen in issues related to quarantine and border control. Even highly advanced and democratic market economies are no exception to this, as the unfolding "Maskenaffäre" (Mask affair) in the Christian Democratic Union (CDU) in Germany illustrates. Multiple parliamentarians are accused of brokering highly profitable procurement deals to companies they are somewhat associated with, thereby earning hefty payments for their lobbying efforts. For instance, Georg Nüßlein (CDU) evidently received 660.000€ through an offshore bank account in Liechtenstein for facilitating the deal. However, this is just one single case in a range of corruption scandals recently revealed which involved payments of multiple million euros to various parliamentarians and business associates (Becker et. al 2021). Thus, the problem of corruption is systemic, global and multilayered. Especially in the least prepared developing countries, corruption can prolong the effect and duration of the pandemic; and in countries under autocratic leadership, it can serve as a purpose to impose anti-democratic measures that further restrict access to information, transparency in public procurement and public accountability mechanisms. Overall, Transparency International reported that over 1800 citizens from over 60 countries contacted their Advocacy and Legal Advice Centers, seeking support in matters related to humanitarian aid, police corruption and health care, particularly affecting women (Transparency International 2020b). Thus, factors of mistrust and inefficiency due to corruption arguably incentivize people to take matters into their own hand and subsequently have a higher probability to fall for falsified medical products.

An additional factor are unintended knock-on effects of policies in other countries. Egocentric policy measures can create knock-on effects which can influence the consumption behavior in domestic or foreign markets by causing supply scarcities. History is very rich in examples in which medicine shortages lead to widespread falsification, such as of cinchona bark as leading malaria treatment in the 17th century and penicillin after World War 2 (Newton 2020). The strong heterogeneity of national and regional responses that limited the mobility of people and goods and thus created chaotic situations in ports and customs areas due to interrupted supply chains. Thus, the demand in some regions remained unserved either by the prevention of goods from flowing further down the supply chains (export restrictions) for the sake of serving populations closer to the production point or by inefficiency in transit arising out of complex documentation procedures associated with border crossing. Although such trade aspects undermine the production of medical supply, they arguably increase the demand simultaneously by creating supply shortages. As the Federation of German industries pointed out “No country produces all the products needed for medical care or the necessary intermediate products. If every country holds back its goods, no country will have all the (medical) products needed to cope with the pandemic" (BDI 2020, p.1). Thus, the diversity and multitude of trade responses might increase the demand by creating an overall uncertainty about the supply of medical products neither through global supply chains nor by the means of domestic production capabilities.
Hence, the governance reactions towards Covid-19 and a surge in corruption contributed to increased demand for falsified medicines.

Socio-Economic factors

To measure the socioeconomic impact of falsified medicines would require comprehensive data upon gross national income, life expectancy, literacy, levels of employment, social mobility, and on trust negotiation between households and governments (WHO 2017b). In the context of the pandemic, this list arguably can be extended by policy measures installed, welfare benefits, demographic characteristics vulnerable to Covid-19 and overall adherence to restrictive measures.
Thus, many factors can be related to social and labor circumstances of individuals within the public health crisis. During a pandemic, fear and panic might overshadow

rational thinking, and people with already little economic means are particularly exposed to infection risk, income reduction and unemployment. This might be attributed to the necessity to continue working, the inability to perform tasks in home offices due to the nature of low-skilled or manufacturing work, barriers to affordable healthcare services and the reliance on simple infrastructure that creates greater exposure, such as regular public transport usage. Whereas the aforementioned circumstances are short term effects, the socio-economic disadvantage might be even aggravated over the course of the pandemic. Indeed, the pandemic is threatening to push 90 million people into poverty, particularly affecting women, youth, less educated as well as informally employed or people in contact-intensive sectors (IMF 2021). Arguably, the combination of high exposure and little financial means might make these populations more susceptible for targeted pharmaceutical advertising, considering that promotion is usually performed by offering cheap prices and fast solutions. According to Büttner et. al 2006, consumer behavior towards online pharmacies is guided by perceived risk constituted out of probability and severity of financial and health consequences. Driven by the desire for health and safety, while simultaneously being necessarily highly exposed to the public sphere and facing limited spending capacity, such individuals might be more likely to resort to channels of alternative procurement of medicine supplies.

Accompanying conditions of low education, literacy and digital literacy possibly accelerate the problem, as even over 25% of surveyed students in healthcare training programs had difficulties to spot multiple signs of danger when asked to verify the credibility of displayed rogue pharmacies. (Ivanitskaya et. al 2010). The same study has shown that those who are likely to fall for rogue pharmacies are much more likely to share health information for decision-making with their friends and family, thus extending potential outreach and revenue.

The economic recession itself might trigger psychological distress that increases overall drug use. Such an association has been observed following past economic crisis (Barrat & Aldridge 2020) and might be particularly strong considering the severe impact and complex character of the Covid-19 pandemic, as the economic recession is only the repercussion to the public health disaster which in many cases might aggravate the grievance through personal loss. Furthermore, the economic crisis accompanying the

pandemic will limit the capacity of national states to effectively suppress drug demand and supply, as less funds for prevention, treatment and counter-narcotic programs are available (UNODC 2020c). As states usually allocate resources between 0.01%-0.5% of their GDP on drug policy expenses, mostly on supply reduction (EMCDDA 2019), the reallocation of funds towards other measures of the pandemic response might fuel the opportunity for falsification.

Lastly, the social and economic context of individuals can be further determined by their geographical location and its relation to the global medical supply chain. The high concentration of pharmaceutical companies in few advanced economies created knock-on effects in other countries. Whereas 44.5% of pharmaceutical companies are located in the US, 25% in Europe and 9% in Japan, Africa, Asia and Australia together account for only 17% (Babor et. al 2014). Thus, especially developing countries became dependent on imports in medicinal supplies, as they have been historically forced to liberalize their markets while lacking their own production capacities in medical goods, which restricted the access to the scarce supply of vulnerable populations even more (Bown 2020). Since populations in these countries have a constrained chance to receive essential medicines and equipment over market mechanisms and public procurement authorities, they might be less inclined to question legitimacy and effectiveness of the potentially fraudulent products they are offered.

Digitalization factors

While the digital sphere is commonly regarded as a major driver for illicit trade in pharmaceuticals, the following paragraph elaborates whether and to what extent this effect is catalyzed during pandemic situations.

Arguably, the higher exposure to the digital sphere influences consumer behavior as individuals spend more time online and increasingly utilize e-services.

The rise of e-health, social media and the growing access to the internet are associated with increased usage of online pharmacies (Mackey 2016). The usage of online pharmacies can add real value to public health and safety during a pandemic health crisis as they can provide patients with almost unlimited stocks of medicines, provide barrier free access and reduce contacts in public and commercial spaces as the delivery model avoids the creation of crowded situations on the way to the supplier and in the

premises of the supplier. Indeed, the number of people buying medicines in online pharmacies increased during the pandemic and numerous governments actively encouraged their constituents to do so (Sue Song & Lee 2021). However, the quantity of rogue pharmacies online arguably free rides on the new popularity and reinforced trust as well.

It can be hypothesized that people spent more time online during pandemic situations and thus got more in contact with online marketing of fraudulent medicines and fake information that favored the acquisition of the prior. Generally, too much exposure to media is known to be associated with increased fear, worry and poor mental health during public health crises (Sasaki et. al 2020). This sense of fear can be either due to the over-reporting in TV news or through increased time spent on social media.

One result of the Covid-19 crisis is that social media usage has grown rapidly as people seek ways to stay connected with the world during lockdown measures and similar restrictions on mobility. Surveys determined that WhatsApp usage increased by 40% in the initial stages of the pandemic and Facebook usage increased by 37%, these numbers even increasing to about 50% in later stages of the pandemic. Self-provided data from Facebook even reports an increase of 70% of complete time spent across its multiple platforms (Perez 2020).

Spam on social media or through emails has become a valuable instrument for criminal organizations to increase their outreach and market their products with low fear of detection or prosecution. Thus, social media and spamming has essentially become the marketing department of criminal organizations. While many people are at home during lockdowns and spend more time in the virtual sphere, criminals created a “infodemic” of spam content on social media sites to exploit the confusion and fear. A study of Mackey 2020 identified 1271 tweets and 596 Instagram posts associated with the illegal sale of Covid-19 relief, ranging from immunity boosting treatments to testing kits. The high propensity of fake news during the pandemic in combination with increased time spent online arguably fostered the exposure to offering of supply of falsified medicines. Fake news mostly originated from countries displaying a high uncertainty about the validity of online content (USA, Spain, Brazil, India) paired with relatively weak institutions (Brazil, Kenya, South Africa) (Newman et. al 2020). In times of crisis and natural disaster, proper policies must contain the spread of fake news to mitigate the

fear of people, manage rumors and stop the spreading of misinformation in order to exert pandemic preparedness and control. As citizens demand reassurance and predictability during the time of crisis, they become increasingly more upset the longer the state of fear and uncertainty is prolonged (Srivastava 2021). Therefore, increased consumption of traditional and social media in combination with mistrust, fear and bad governance might push citizens to resort to alternative channels of medicine procurement as well and thus increases the likelihood of getting in contact with counterfeited goods. But online advertising is not only limited to social media platforms and alike.

Increased internet pornography consumption during measures of quarantine and self-isolation might further foster exposure to targeted advertising of rogue pharmacies, which often place promotional banners and pay-per-click advertisements for sex enhancing products like Viagra on porn sites. It is estimated that 46-74% of men and 16-41% of women are active porn consumers in modern nations, and some large porn sites like “PornHub" generated over 115 million visits per day, resulting in 42 billion visits in 2019 alone. In countries with strict stay-at-home orders (China, Italy, France, Spain), porn consumption evidently increased by an average of 5 percentage points (Zattoni et. al 2020). Thus, increased traffic on web pages associated with advertising of rogue pharmacies might entail increased revenue for the latter since the outreach of the criminal enterprise enjoys the benefit of increased visibility.

3.2 Factors increasing supply

Governance factors

Policies that intended to mobilize supply and facilitate administrative procedures can create a backlash that enables the penetration of counterfeit in the legal medical supply chain and scaling up of falsified production Policymakers and politicians around the world faced a chaotic scenario to make decisions under limited time and information, as urgent and comprehensive responses were necessary while no knowledge about scale and duration of the public health hazard were available. To a large extent, actions included imposing economic and social lockdowns, mandating the wearing of Personal Protection Equipment (PPE) like filtering masks in public and commercial spaces, requiring improved hygiene practices like hand sanitizers and shutting down

international travel and commerce. The scarcity of necessary medical supply incentivized politicians to prioritize national interests and impose a range of trade policy instruments such as export bans, export licensing requirements and export quotas. Throughout 2020, a total of 701 policy measures in 135 customs territories imposed some sort of export restraints or import reforms mostly targeting medical supplies (Evenett 2020b). The high turbulence within the sector and the need to rapidly procure such medical supplies and protective equipment for own populations possibly fostered the willingness of regulators to compromise on Good Manufacturing Practice and lengthy bureaucratic procurement procedures, thus creating opportunity to penetrate supply chains with substandard and counterfeit goods. Indeed, after the WHO recommended ethyl or isopropyl as the basis for hand sanitizer, multiple countries lifted production restrictions to enable alcohol manufacturers to produce hand sanitizer. This created a huge opportunity for fraudulent products to circulate in the supply chain; Indeed, the FDA Punjab of India tested 25 samples out of 75 that have been collected and concluded that only three were not either substandard or misbranded (Hasen & Suleman 2020). This showcases how the simplification of administrative procedures, which could drastically improve the pandemic response if paired with transparency and oversight, can be either exploited by criminal organizations or simply result in detrimental outcomes.

Thus, when the fear of the virus is strong and oversight and verification mechanisms in the public procurement system are weak, falsified medication can rapidly spread as one example of early March 2020 in Africa has demonstrated. Only a month after declaring the Coronavirus a global pandemic, falsified Chloroquine which was advertised as a corona remedy has been seized in over 300 hospitals and pharmacies in Cameroon, Chad and Nigeria (Schneider & Ho Tu Nam 2020). Arguably, such outcomes are the result of governments promoting wrong and harmful narratives, eg. like former US president Donald Trump who advertised Hydroxychloroquine as a ‘game-changer’ despite scarce empirical evidence for its efficacy and safety to use as a treatment vof Covid-19 (Friedman 2021).

Socio-Economic factors

The following paragraph is elaborating upon to what extent the quantity of supply increased and how the prices of these supplies changed during the pandemic.

A major driver which is increasing the supply of falsified medicines and other medical products during the pandemic is the quantity of supply required and the high quality of the crime resulting from increased profitability. Already pre-pandemic, the seizures of medical goods surged every year, resembling an increase of 157% within the OECD area (OECD 2020). Thus, the trend has been vastly increasing even before the pandemic accelerated the demand drastically. Beginning in 2020, the OECD estimated a daily demand of 240million face masks per day to equip Chinese healthcare, manufacturing, and transport workers alone (OECD 2020b). Even though this number might be overestimated and accounts for the entire industry without lockdown measures, the need for medical and frontline workers worldwide is still immense. In March 2020, the WHO estimated that globally, medical and frontline workers have a monthly need of 89 million face masks, 30 million gowns, 1.59 million goggles, 76 million gloves and 2.9million liters hand sanitizer (Statista 2021).

Similar amounts account for the number of total Covid tests performed. By June 28, 2021, the United States alone performed almost 504 million, India 406 million, the United Kingdom 207 million, China 160 million and Russia 148 million tests. Hence, only the top 5 testing countries used a total of 1.425 billion covid tests. Three different types of diagnostic covid-19 tests were available, whereas the significantly cheaper test costing $2.55 just became available in mid-March 2021. Prior, the average price was $4-$4.20 dollars per test (UNICEF 2021). Applying the WHO estimate that 10.5% of global medicines are counterfeit to the total of 1.425 billion rapid tests at a price of $4, one gets the indicative amount of $586 billion dollars in falsified rapid diagnostic tests. However, this sample is reduced only to the top five countries which can have vastly different rates in counterfeit prevalence and control. Generally, accurate estimates are difficult to make as prices of medical goods are very volatile and dependent upon regions. The WHO noted that supplies can take months to deliver and prices for face masks are surging up to a sixfold increase (WHO 2020).

The global demand for extensive stockpiling and distribution of medical supplies which by far exceeded production capabilities enabled easy supply chain infiltration and

overvalued prices as this combines two conditions that are particularly attractive for counterfeiters. Criminal organizations are more than willing to cash in on the opportunity. The most recent Interpol-led Operation Pangea VIX in 2020 reportedly distorted activities of 37 organized crime groups by closing down over 2500 associated online appearances, stating that “the seizure of more than 34,000 counterfeit and substandard masks, “corona spray”, “coronavirus packages” or “coronavirus medicine” reveals only the tip of the iceberg regarding this new trend in counterfeiting.” (Interpol 2020). Indeed, it could be observed that criminal organizations adapted their counterfeiting with the transgression of the pandemic, strongly engaging in the counterfeit of PPE in the beginning, shifting over to testing kits and bogus medicines in its intermediary course and defaulting on vaccine falsification once vaccines have been developed and are distributed (UNODC 2020a). Again, the sheer volume of goods and rapid distribution taking place simultaneously around the world create favorable conditions to secretly flood the market with falsified vaccines.

Due to the socio-economic deterioration following the pandemic shock, people might have become more willing to engage in illicit activities in order to compensate for lost income and unemployment. Indeed, according to Barrat & Aldridge 2020, countries that provide less welfare payments may increase the demand for supplying various forms of drugs online. That is, because a multitude of people have been deprived of any perspective through the Covid-19 crisis and thus seek alternative ways to pay their bills and feed their families. When the state does not adequately fill the role as safeguard during times of crisis or does not provide any social contract by default, it is likely that newly unemployed or heavily indebted citizens feel the need to take their future into their own hands.

Digital factors

During the pandemic, the supply and distribution of drugs and falsified medicines strongly shifted into the digital sphere utilizing direct-to-consumer marketing.

The disruptive effect of border closures on drug supply chains and street markets may have a transformative effect shifting drug procurement towards the digital sphere. Whereas lockdown strategies increase the risks of dealers and buyers to get caught in analogous spaces, the closed borders can create local supply shortages.

As the time which is spent indoors and online increases, entry into and maintenance of cryptomarkets is more likely during Covid restrictions. This trend appears to account for vendors and customers alike. A UK survey of March-May 2020 revealed that 19% of purchases made on cryptomarkets have been made by someone new and that buyers tended to stockpile drugs in response to the lockdown (Barrat & Aldridge 2020). The European Monitoring Center for Drugs and Drug Addiction (EMCDDA) confirmed the two-fold trend in Darknet Markets, that dealers buying for physical resale are decreasing their activities anticipating difficulties on street-market due to lockdown restrictions, whereas consumers tend to increase their activity to stockpile drugs. However, the EMCDDA further highlights the necessity to triangulate data with other sources to fully understand the market reactions (stockpiling, price changes, increased or decreased usage) to Covid-19 (EMCDDA 2020). As counterfeiters generally benefit from growing e-commerce and lower potential losses, the trend was strongly towards shipments via postal and courier services. In the period 2014-2016 for instance, 69% of all customs seizures of attempted exports of falsified medicines into the EU were small parcels (OECD/EUIPO 2019).

In the wake of the pandemic however, the trend towards shipments in small parcels decreased drastically in 2020. Trafficking of counterfeit goods in small parcels decreased by striking 40% as opposed to the previous year, which according to INTERPOL can be attributed to the Covid-19 pandemic (Taylor 2020).

Additionally, supply in the digital sphere further might be increased through the additional possibility of performing more cyber scams that defraud public administrations and patients. Reportedly, charity and investment scams have been rising, as well as increased phishing of bank details and personal data through uploading self-executing phishing files and trojans over web pages that are displayed to the consumers as preferred online vendors due to the utilization of Search Engine Optimizations techniques (UNODC-ROSA 2020). Thus, the supply in falsified medicines is arguably also increased by the possibility to exploit the huge demand to commit further financial and data fraud.

3.3 Sub-Conclusion and Policy Recommendations

Much criminal activity can be observed especially in the beginning of the pandemic, because demand is high, and supply is limited. With the progression of the pandemic, supply adjusts to meet the demands and criminal activity subsequently drops (UNODC 2020a). However, criminal organizations adapt with the development as well and continue to exploit the psychological distress, socio-economic circumstances and regulatory loopholes or mishaps in order to reap the financial benefits of the crisis response.

To combat the chaos caused by the pandemic and its responses, the OECD recommended to improve transparency in procurement and negotiations to boost the confidence in international trade, keep the supply chains flowing by lifting unnecessary bureaucratic requirements, to not impose export restrictions or other unproportionate restrictive measures to not worsen the situation and to not resort to short-term thinking and ell-bow mentality (OECD 2020). These factors should be particularly considered in forecasting the next counterfeited item on the pandemic progression list, e.g., optimal preparation for the vaccine rollout, particularly in developing countries.

To further avoid knock-on effects of social and economic deterioration, welfare nets must be expanded to equip people with proper health care and/or the financial means to avoid quality assured medications. Targeted educational campaigns should warn about the dangers of procuring medicines online. Similarly, a stronger focus on prevention by education of cybercrime must be achieved through more awareness programs discouraging the sharing of data with unknown apps that specifically reach out to internet-dependent families, support of civil society to educate youth and children upon the dangers in the digital space

Prevention by regulation can entail better monitoring practices of cyber-fraud and particularly apps and websites that offer e-health services through a tailored agency and a common cyber-intelligence sharing center which reports cases and modus operandi to all governments as well as better tracking of online fund flows by instructing all banks to regularly share online transmission data with Financial Intelligence Units.

Furthermore, professionals themselves must be able to attend online courses free of charge and to attend regular webinars briefing them upon the latest trends and knowledge in their regions (UNODC-ROSA 2020).

Chapter 4: Institutional capacity – Criminal Justice

The following chapter will elaborate upon the question, to which extent institutional capacity at the global level is sufficiently equipped to provide an adequate criminal justice response concerning the illicit trade in falsified medicines. The criminal justice system can be defined as the system of law enforcement, including police, courts, lawyers, and other correctional entities that work on the basis of a legislative mandate throughout all stages of proceedings and punishment of a defined crime. Therefore, this chapter will analyze the legal-institutional framework exploring the following sub-question:

RQ: To what extent can mechanisms at the global level contribute to capacity-building in criminal justice responses?

At the global level, criminal justice is governed through cooperation of a multitude of different actors based on international law. At its core are the United Nations, mentionable through the UNODC, which administers the UN treaties and cooperates with a variety of enforcing parties like INTERPOL, EUROPOL, national police and regulators, the World Customs Organizations as well as their national subsidiaries. The central UN treaties are governed through the Conference of Parties representing the signatory member states, the International Narcotics Control Board and the Commission on Narcotic Drugs as specific expert committees. However, the most central actor leading the criminal justice response against falsified medicines is the UNODC, which was specifically empowered to combat illicit online pharmacies at the 20th session of the UN Commission on Crime Prevention and Criminal Justice (CCPCJ) in 2011 through the adoption of three resolutions: Resolution 20/4 "Promoting further cooperation in countering transnational organized crime", Resolution 20/6 "Countering fraudulent medicines, in particular their trafficking", Resolution 20/7 "Promotion of activities relating to combating cybercrime, including technical assistance and capacity-building".

4.1 International legal-institutional framework

(1) International Drug Control Conventions

The range of complementary and supportive treaties provide the basis for drug control at the level of international law. Three major treaties for international drug control are the *1961 Single Convention on Narcotic Drugs* (as amended in 1972), the *Convention on Psychotropic Substances 1971*, and the *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*. Whereas the first two predominantly codify internationally applicable control measures, the latter extends the control scope to precursor chemicals and consolidates measures combating organized crime, such as increased international cooperation through legal assistance and extradition and additional measures against money laundering.

The Single Convention on Narcotic Drugs is the foundation of the global drug control system and establishes a control bureaucracy which ensures that signatory governments establish restrictive measures that criminalize and enforce the unauthorized production and distribution of listed substances. Albeit Article 2 (5)b of the Convention exempts trafficking for the reason of "scientific and medical research" and Article 4 (1)c exempts "scientific and medical purposes", placing substances that can be non-medically abused under control can impose bureaucratic burdens on fragile states. For example, the case of Tramadol, which sparked debate as Egypt and some international organizations argued for its placement as controlled substance due to its potential for misuse, whereas the international experience suggests that controls rarely address public health issues and rather result in unintended consequences that are detrimental to the public good (Klein 2019).

(2) United Nations Convention against Transnational Organized Crime

Whereas the first three conventions define and regulate narcotic drug trafficking, two additional treaties strengthen the fight against transnational criminal activity in particular.

The *United Nations Convention against Transnational Organized Crime (UNTOC)* was signed in 2000, entered into force in 2003 and counts near universality with 189 signatory countries. The convention is the main legal instrument against organized crime at the international level and applies to the "prevention, investigation and prosecution" of offences established by the convention (Art. 5, 6, 8 and 23), other serious crimes (Art. 2) and protocol offences (Art. 1), when these offences are

transnational in nature and under involvement of organized crime groups. Whereas the trade in falsified medicines has long not been included specifically within the offences outlined by the treaty, they recently have been adopted through a resolution; reflecting a new stage of awareness of and response to the problem.

Acknowledging the gravity of trade in falsified medical products, re-enforced through the global pandemic, the recent Conference of Parties (COP) of the United Nations Convention on Transnational Organized Crime (UNTOC) in Vienna in October 2020 classified the trade in falsified medical products as a serious crime that represents a new dimension of transnational organized crime that is threatening the very foundations of our society (UNODC 1 2020). Subsequently, UNTOC Resolution 10/5 "Preventing and combating the manufacturing of and trafficking in falsified medical products as forms of transnational crime" called upon the international community to develop and implement effective and appropriate legislative frameworks and review current legislation with the objective to cover all forms of medical falsification under the scope of UNTOC.

This enables to criminalize all forms of corruption and money laundering associated to the counterfeiting; to strengthen international cooperation between countries and with international and regional organizations, having special regard to extradition, mutual legal assistance, joint-investigations, as well as seizure, confiscation and disposal property, instruments and equipment; to strengthen capacities and resources of regulatory authorities; to raise awareness domestically and in cooperation with other organizations; to voluntarily provide comprehensive statistics; encourages countries to participate in the WHO Member State Mechanism on Substandard and Counterfeit Drugs; and tasks the UNODC to collect data and drive cooperation through inclusion of all relevant stakeholders under equipment with extra budgetary resources.

The motion to define trade with falsified medical products as a "serious crime" is a crucial step towards effective enforcement and tackling of the issue at the global stage. Trafficking falsified medicines is a prime example of an offence that is transnational in nature, as the globalized supply chains and exploitation of jurisdictions reflect that the offence is committed in more than one state while the offence is substantially planned, prepared, directed and controlled in another state. Furthermore, criminal organizations

(Russian Mafia, Chinese Triads and Columbian Drug Cartels) as well as terrorist organizations (Hezbollah, Spain Separatist Organization ETA) are evidently major producers of counterfeit that create a substantial effect in another state for the realization of financial or material benefit (as according to Art. 3.2) and further use this revenue to finance their other illicit endeavors (Miller & Winegarden 2020).

The convention also establishes multiple provisions for international cooperation. The possibility to pose extradition requests (Art. 16) harmonizes requirements with other treaties and agreements and obliges parties to either extradite or prosecute its own nationals. Given the low enforcement rate and international supply chains of counterfeit pharmaceuticals, this is a valuable advancement in the tackling of counterfeit pharmaceuticals as it forces state parties to act and enforce these laws as soon as the new definition of trade with falsified medical products as a "serious crime" covered under the convention is entering into force.

Furthermore, the provision of mutual Legal Assistance (Art. 18) enables investigators to request evidence and statements from persons, to effect the service of judicial documents, to execute searches, seizures and freezing, to examine objects and sites, to provide information, evidentiary items and expert evaluations, to provide originals or certified copies of governmental, banking, financial, business or corporate records, and to trace the proceeds of crime as well as its instrumentalities, property and other things of evidentiary purposes. According to Art. 18.1, "States parties shall afford one another the widest measure of mutual legal assistance…". This implies that state parties must have legal powers necessary to produce and deliver assistance, including the establishment of a central authority to receive, execute and transmit legal assistance requests. This is a crucial operational element in the prosecution of pharmaceutical crime, as the transnational nature often undermines effective investigation. Furthermore, state parties cannot refuse mutual legal assistance on the basis of bank secrecy, which facilitates the investigation into rogue pharmacies, who often utilize the low regulatory standards of certain jurisdictions to store their profits with locally registered banking providers or establish their own headquarters in these to disguise the true nature of their activities.

Other Forms of Cooperation are enshrined in Art. 19, 20, 21, 26 and 27 and circumvent joint-investigations, the usage of special investigative techniques such as electronic

observations and undercover operations, the transfer of criminal proceedings, additional measures to enhance cooperation with law enforcement authorities such as the sharing of criminal record databases for evidence and forecasting, and general law enforcement cooperation between agencies which concerns the sharing of information about whereabouts of criminals defined under the convention.
Concluding, UNTOC provides the legal basis for a broad range of tools and instruments which can be applied to the fight against falsified medical products in a targeted manner as of the passing of resolution 10/5 to define the aforementioned as a serious crime.

(3) United Nations Convention against Corruption

Since corruption is a major driver undermining the pandemic response and facilitating untransparent procurement procedures in medical goods, the *United Nations Convention against Corruption (UNCAC)* will be examined as well. UNCAC is also called the MERIDA convention, was adopted in 2003 and entered into force in 2005, counting 186 signatory countries. The convention requires its state parties to criminalize four basic offences in their domestic legislation, namely: the participation in an organized criminal group (Art. 5), the laundering of proceeds of crime (Art. 6), Corruption (Art. 8) and Obstruction of Justice (Art. 23). The convention further prescribes preventive anti-corruption policies (Art. 5), the establishment of anti-corruption bodies (Ar.t 6), the recruitment, management and training of public officials (Art. 7), lays out procedures for conflicts of interest, Codes of Conduct and Asset Declarations (Art. 7 and 8), for Public Procurement and Management of Public Finances (Art. 9) and finally how Anti-Corruption Education can be structured (Art. 13). Therefore, Article 5-9 and 13 do not only resemble criminal justice elements but add preventive properties which can enhance further pandemic preparedness as transparent procurement is a major factor in the fight against falsified medical products. Corruption itself is criminalized extensively and within many forms, thus giving the possibility to sanction wrongful behavior. Mandatory offences enshrined in the convention are the Bribery of National Public Officials (Art. 15), the Active Bribery of Foreign Public Officials (Art. 16), the Embezzlement, Misappropriation or Other Diversion of Property (Art. 17), the Laundering of Proceeds of Crime (Art. 23), the Obstruction of Justice (Art. 25) and Participation in such offences (Art. 27, para. 1).

These treaty provisions are a valuable tool to investigate suspicious procurement practices, pre-purchase agreements or untraceable stocks of PPE and other medical supplies. Bribery of foreign or national officials arguably represents a major point of entry into the legitimate supply chain for criminal organizations who want to profit from the huge demand arising out of the pandemic.

Indeed, the lack of transparency concerning secretive contracts and clinical trials is worrisome. Analysis of 183 different contracts for 12 different Covid vaccines between drug companies and governments revealed that only 7% of contracts have been published through official channels and only 0.5% have been published without redactions, often blacking out entire pages entailing information of critical public interest (Transparency International 2021). Whereas the lack of transparency is of direct concern about criminal involvement, it further fuels citizen suspicion, misinformation, and conspiracy theories, and thus additionally resembles a push factor in demand for alternative or self-procurement. To monitor for corruption during Covid-19 in procurement processes, one should look for high proportions of contracts awarded to single bidders, large differences between contract awards and final contract amounts, higher prices of products than industry averages, significant price differences between and within regions and hospitals, a high number of new companies immediately tasked with contracts (UNDP & PRAIA 2020). Furthermore, countries are advised to establish a dedicated oversight body that monitors all the pandemic spending, track all these Covid-related spending on a central webpage, employ dedicated and specialized investigators and prosecutors, release bi-monthly reports with pandemic information and ensure that all these information are easily accessible to the public (Stephenson 2021).

The convention also provides a range of optional offences that countries are merely advised to criminalize in their domestic legislation. Such are the Passive Bribery of Foreign Public Officials (Art. 16), Trading in Influence (Art. 18), Abuse of Functions (Art. 19), Illicit Enrichment (Art. 20), Bribery in the Private Sector (Art. 21), Embezzlement of Property in Private Sector (Art. 22), Concealment (Art. 24) and the attempt and preparation of UNCAC offences (Art. 27, para. 2-3).

Whereas the mandatory offences vastly increase the institutional capacity to respond to the involvement of criminal organizations, the optional offences are particularly suitable

to tackle institutional corruption within the legitimate pharmaceutical industry. Especially abuse of functions, trading in influence and illicit enrichment can often be attributed to the intertwined nature of legislators and CEO's. A great example of institutional, systemic corruption are the United States. Combined, administrators and officials of the Trump administration received a known minimum of $40.000.000 through stock shares and other forms of financial assets from the pharmaceutical industry, which additionally donated $1.535.000 for Trump's 2017 inauguration. Subsequently, Alex Azar, former top executive of the pharmaceutical company Eli Lilly became secretary of Health and was thus in charge of the FDA. During his oversight at the pharmaceutical company, he increased the prices of the insulin drug Humalog by 345% from $74 per vial to $269 dollars per vial while simultaneously cashing in multiple millions in salary and bonuses (BPBF 2020). This is just one of many examples showcasing the dependence on money, knowledge and influence that tie legislators to pharmaceutical interests. Whereas this form of institutional corruption is not necessarily associated with illicit trade in pharmaceuticals directly, it can fuel it indirectly by increasing prices for pharmaceuticals to absurd heights and thus pushing consumers to seek alternative procurement.

(4) The MEDICRIME Convention

Further cooperative ground for INTERPOL, EUROPOL, UNODC, WCO and WHO is the MEDICRIME convention. It was established by the Council of Europe, is ratified by 15 countries and legally entered into force in 2016. The convention resembles the first international binding instrument in the field of criminal law that is tailored to target counterfeit medical products and similar crimes that impose a threat to public health (Council of Europe 2021). Thus, it is greatly suitable to provide definitions and measures which can be adopted in national legislations. However, the MEDICRIME convention has been ratified by only three African signatories (Burkina Faso, Guinea, Benin) and no compliance mechanism in place (Klein 2019).

The Convention seeks to ensure public health by criminalizing certain acts, protect victims of pharmaceutical crime and promote national and international cooperation (Art. 1). Signatories to the convention are obliged to criminalize the manufacturing, supplying, offering to supply and trafficking in counterfeit medical products, as well as

their parts, accessories, active substances and materials, within their domestic law (Art. 5, 6). It furthermore requires the criminalization of falsification of documents (Art. 7) as well as similar crimes involving a threat to public health (Art. 8). Such similar crimes are targeted at intentionally commercial activity of unauthorized medical products, non-compliance of conformity requirements and usage of documents outside their designated use within the medical product supply chain. Hence, the similar crimes enshrined in Art. 8 can differentiate and account for substandard and unlicensed trade with products out of the genuine supply chain, therefore creating stronger liability also in the absence of evident criminal intent. According to Art. 12, such crimes shall be punishable by proportionate, effective, and dissuasive criminal and non-criminal monetary sanctions. Evaluating current sanction regimes, this Article is of high importance as punishments are evidently not dissuasive nor effective if measured against the increase in trafficking. Whereas judges must take into account the individual circumstances of each case, it is imperative that sanctions must be equal to sanction for other serious crimes, as falsification of medical products does not only impose serious risks and damages towards the legal market and consumer trust in the integrity of supply chains but also to the rule of law and stability within states (UNODC 2019). While previous punishment provisions often only circumvented civil and administrative fines which can be accounted as manageable business costs, the MEDICRIME convention provides the legal basis to increase such sanctions.

Whereas natural persons might face deprivation of liberty and extradition, legal persons might be temporarily or permanently disqualified from commercial activity, placed under supervision and be subject to a judicial winding-up order. Confiscation, seizure and possible destruction of the means of the crime as well as the proceeds of the crime must be enabled by signatories to the treaty. Interestingly, Art. 12 Nr. 3 c) further states that each party shall “take any other appropriate measures in response to an offence, in order to prevent future offences”, thus granting extensive legal leeway. For instance, states can mobilize resources more easily to establish education programs or foster the involvement of civil society to encounter the dangers and profitability of crime. Central is further the notion on the Aggravating Circumstances enshrined in Article 13. These specifically state the abuse of confidence in professional capacity, confidence in manufacturers and suppliers as well as the usage of large-scale distribution and

information systems (Art. 13 b) -c)). Thus, these paragraphs are a strong instrument against illicit online pharmacies and ensure corporate liability, which is further specified in Article 11. However, other aggravating circumstances are related to the damages to physical and mental health, as well as to the nature of the perpetrator as a member of a criminal organization or iterative perpetrator.

Due to the definitions applied, the scope of the convention is rather flexible, as it refers to the counterfeit of "medical products", which ultimately circumscribe medical devices and any medicines for human and veterinary use that according to the convention have properties for treating or preventing a disease, that restore, correct, or modify a physiological function or that is used in medical diagnosis (Art. 4). Thus, the convention is greatly able to cover the different goods in counterfeit that transgressed over the course of the pandemic (from PPE over testing kits to vaccinations).

Furthermore, the convention calls for increased professional capacity in the investigation of these crimes through provision of more resources and training (Art. 16) as well as increased national and international cooperation and information exchange (Art. 17, 21, 22).

Lastly, the convention covers general and procedural provisions for prevention and protection of the victims (Art. 18, 19, 20, 22).

4.2 Actions, Programs and Enforcement

Despite the many calls for increased international cooperation, global law enforcement against illicit online pharmacies is well institutionalized and extensive.

The most comprehensive initiative is Operation Pangea, which started in 2008 and was the first inter-agency initiative targeting illicit online pharmacies through cooperation with pharmaceutical companies, health regulators, Internet Service Providers, Credit card companies and payment systems as well as wholesalers and delivery services. Performed almost annually, the number of participating countries and agencies varies from year to year but always mobilizes a high number of participating countries and achieves comprehensive results. Starting with only 10 participating countries, the operation has managed to mobilize more than 100 countries in most operations since 2010, except for 2020 (OECD 2020).

Operation Pangea VI in 2013 confiscated 9.8 million units of dangerous medicines, shut down over 9000 websites and arrested 58 individuals (Mackey & Liang 2013). Three years later in 2016, 103 countries cooperated and achieved the suspension of 4932 illicit online pharmacies (WHO 2017). One observation throughout the performance of the operation is that the activity of illicit online pharmacies continues to increase as well as the numbers of the associated enforcement efforts. The highest number of arrests was during Pangea XI in 2018, which resulted in 859 arrests worldwide and the seizure of 500 tons of pharmaceuticals and 110.000 medical devices worth over $14 million USD. However, this also reflects that seized volume and arrests made do not always correspond to the seized value, as the highest value ever seized by the operation was during Pangea VIII in 2015, confiscating counterfeit worth USD 81 million (OECD 2020).

The most recent Operation Pangea XIV was a cooperation of 92 countries and seized over 9 million units valued at 23 million dollars, arrested 277 individuals and took over 113.000 web links offline. The fact that antiviral medicines increased by 18% compared to the previous operation and the seizure of chloroquine by 104% can be associated with the Covid-19 pandemic (Weerth 2020). Thus, whereas the number of participating countries fell under the mark of 100 for the first time in 10 years, the amount of links deleted still increased more than 11-fold.

Other INTERPOL-led initiatives are Operation Rainfall which is covering pharmaceutical crime in Southeast Asia, Operation Quanoon which investigates illicit pharmaceutical trade and builds capacity and cooperation in Middle East and North Africa, as well as Operation Heera which tackles pharmaceutical counterfeit in West Africa. In a coordinated effort of about 1150 law enforcement officials in 2017, Operation Heera led to the confiscation of over 420 tons of illicit pharmaceuticals and medical products worth approximately USD 21.8 million, and the arrest of over 150 individuals (Interpol 2017). Similar to Pangea, the most recent operation Quanoon took place in 2020, seized illicit medical products worth over USD 14 million and confirmed the trend that criminals are exploiting the increased market demand due to Covid-19 through seizure of 61.000 respiratory masks in Morocco, 63.418 face masks and 360 sanitizing products in Jordan, and 85.000 medical products in Qatar (Border Security Report 2020). Another mentionable initiative is Operation Global Hoax, which seized

thousands of items in 2010 and Operation Global Hoax II in 2011-2012 seized over 30.000 parcels containing 150.000 counterfeit items, including pharmaceuticals (OECD 2020). A further example for the cooperation between law enforcement and pharmaceutical companies at regional level is Operation Viribius. The Europol-led initiative partnered with law enforcement in 33 countries and multiple pharmaceutical companies and dismantled 17 criminal organizations in 2019, thereby seizing 3.8 million illicit medicine packs and arresting 234 individuals (Novartis 2019). In sum, many different initiatives are practiced, usually under the authority of a centralized intelligence and policing agency, at the center of a web of many national and private stakeholders.

Illustrating procedural approaches: the Case of ACIM

The following section is illustrative to detail possible engagement of global criminal justice institutions to provide capacity to execute law enforcement operations against falsified medicines in regions and countries.

Another big operation against counterfeit is the *Action against Counterfeit and Illicit Medicine in Africa (ACIM)* which investigates the trade of falsified and substandard medical products following the clue of intellectual property infringements rather than through the conventions against organized crime. Operation ACIM conducts simultaneous investigations of suspicious containers in sea and air vessels to combat counterfeit in Africa through a detailed collaborative effort of multiple actors by comprehensively screening and targeting port cities. The operation itself is coordinated by an Operational Coordination Unit (OCU) guided by the WCO Secretariat, in close collaboration with WCO Regional Intelligence Liaison Offices (RILOs) and by financial and expert assistance of the Institute of Research against Counterfeit Medicines (IRACM) . Furthermore, Interpol provides technical assistance, regional health authorities are informed upfront to cooperate with their customs offices, and the Joint Container Cargo Control Units (JCCCUs) from the WCO/UNODC Container Control Program (CCP), especially providing technical assistance on pre-arrival information and inspection techniques to customs unit. Further information sharing takes place between customs administration who in accordance with national legislation communicate with rights holders and other private entities, between countries utilizing

the CENcomm and IPM platforms of the WCO and through bilateral mutual assistance agreements. As the entire operation is centered around the notion of intellectual property enforcement, the legal framework upon which these actors collaborate is consisting out of the Agreement on Trade Related Aspects of Intellectual Property Rights (15/4/1994), Part III, Section 4: Role and Responsibilities of Custom Administrations, the International Convention on Mutual Administrative Assistance on the Prevention, Investigation and Repression of Customs Offences (Nairobi Convention), multilateral and bilateral mutual assistance arrangements, national and regional legislations and the RILO recommendation EC0134E.

In the first phase of the operation, experts from the WCO share information and actively train customs officials in risk assessment techniques and the distinguishing counterfeit from genuine medicine in commonly organized workshops over 2-4 days. Subsequently, the operational phase of two weeks starts, in which custom officials in which selected containers and previously compiled reports over suspicious shipments are investigated and analyzed. Finally, the detailed reports are sent to the OCU for the finalization of the report, compiling of statistics and data as well as follow-up recommendations.

In ACIM1, a total of 15 countries participated and seized a total of 128.999.109 units, with 98% of these units being counterfeit medicine or pharmaceuticals. China and India together accounted for 96% of cases, with the report stating that “China is number one when it comes to counterfeit goods in general and India for illicit medicines" (WCO 2016, p.16). ACIM2 was performed in 2017 and grew in scope and seizure, with 18 participating African countries and total seizure of 258.933.104 units. Of these units, about 104million have been seized, almost 63million have been stopped and over 70 million have been released again. Those that got released were mainly antibiotics and antibacterial that have been intercepted due to improper labelling and transport conditions, and none of them had been tested for their continued suitability prior to the release (WCO 2017). Thus, whereas the cooperation works well in detection efforts, many regulatory problems persisted at the level of regional and national legislations as the main course of the investigation is to detect intellectual property infringements. Particularly during pandemic situations, this should not be the main focus, as the rapid and universal preservation and improvement of human life should be the supreme good,

indeed, public health should be upgraded to become a global public good (Gleckman 2021).

4.3 Sub-Conclusion on Capacity-Building

1. Capacity to assess a situation and define a vision

The global level has proven to act quickly and effectively in assessing the situation and what must be done to further cope with these dangers. Because of the international supply chains involved, the national level is arguably not particularly receptive towards the needs and urgency of the problem, as the country's interests and priorities can diverge depending upon their role as either production, consumption or transit country within the illicit pharmaceutical supply chains. African countries located at the lower end of the supply chain, who dispose of poor infrastructure and governance mechanisms are particularly vocal in the fight against illicit pharmaceutical trade as their market is easily flooded with fakes. Thus, they often seek cooperation with international organizations and partners. Countries with advanced economies have a high degree of per capita spending capacity and internet access and are thus more susceptible towards the dangers of illicit online pharmacies. Furthermore, the high attention given by the OECD in these regions arguably illustrates a higher importance of economic consequences towards domestic or regional industries. But while these perspectives are rather bottom-up and selective to particular interests, it is important to frame a position from a top-down perspective at the international level. The suitability of this trend can be observed following the establishment of legislative measures targeted at illicit pharmaceutical trade. Firstly, the conclusion of the MEDICRIME convention in 2016 can be interpreted as commitment to tackle the issue at the international level. And secondly, UNTOC Resolution 10/5 finally brought the matter precisely on the agenda of the global community and particularly accounted for the dangers arising out of the Covid-19 pandemic.

2. Capacity to engage stakeholders

Out of the necessity to investigate cross-border crimes within multiple jurisdictions, the global level is greatly able to connect the relevant actors to initiate joint-investigations, provide mutual legal assistance, process extradition requests, and facilitate the exchange

between law enforcement authorities. Indeed, it was due to the great capacity and experience of the UNODC in engaging different stakeholders together that it became the leading agency combating counterfeit medicines after the WHO faced increasing challenges and criticism (Mackey & Liang 2013). Whereas the WHO had difficulties to establish proper definitions to separate the public health focus from intellectual property infringements and to engage stakeholders accordingly, the UNODC filled that position in the global arena as it disposed of well-connected networks and partnerships. It furthermore administered the traditional drug treaties and was specifically empowered by resolution 20/6 of the Commission on Crime Prevention and Criminal Justice. Apart of the experience and network of the UNODC, the United Nations Office of Partnerships (UNOP) could further function as a gateway to increased stakeholder engagement since the public health threat of counterfeit directly and indirectly undermines multiple SDG's and would thus greatly fit into the programmatic outlook of the office.

A great example of how stakeholder engagement works is the increasing range and success of Operation Pangea, being able to regularly mobilize half of the international community. Indeed, it is not only the cooperation of the countries that determine the success of operations, but the cooperation between various law enforcement agencies internally, their cooperation with internet and financial providers externally and the provision of data at customs organizations. Given the sheer scale and complexity of the cooperation, the coordination at the global level is absolutely central.

3. Capacity to formulate strategies and implement

Whereas the global level is greatly able to provide international legislation and overall guidelines and objectives, it is up to the member states to translate these guidelines into action. However, UNODC and its network provide technical assistance and best practice. To support countries within this task and in order to preserve public health, the UNODC published a guide to good legislative practices for national policymakers in 2019. Such guidelines and legislations add real value to policymakers in order to make their governance frameworks more resilient against pandemic shocks, as they provide clear and structured information that can be easily implemented, and thus does not

divert additional resources and attention from the main task of containing the virus in itself.

4. Capacity to budget, manage and implement

The UNODC does not have any capacity to budget the processes it is involved with by itself but provides guidelines to and cooperates with national authorities to manage and implement the legislation and its enforcement. The current result is twofold. On one hand, arrests increased significantly before the pandemic started across all arrest categories (Point of Sale arrest, Transporting arrest, Distributor arrest, Manufacture arrest, Theft arrest) in 2017-2018, with particular emphasis on +73 in manufacture arrest and +163 in point-of-sale arrest (OECD 2020). On the other hand, arrests decreased across all categories between 2019 and 2020 except for transportation. Furthermore, while 39% of arrests were in the Asia Pacific Region, only 4% were arrested in Africa (PSI 2021b). Albeit this can possibly be attributed to economic lockdowns and border closures as well, it could also indicate institutional paralysis in times of crisis and inability to properly uphold the enforcement trend when attention and resources are diverted towards other challenges of the crisis. Furthermore, while the comparatively high number of arrests in the Asian region showcases efforts to suppress the origin of the supply chain, the low arrest rate in Africa is of concern as it is the region with the highest prevalence. Hence, the capacity to budget, manage and implement is limited by the way it is designed at the global level but arguably also within an outcome-based perspective through the results at national and regional level.

5. Capacity to evaluate

Evaluation at the global level is highly suitable to assess the overall progress in the global fight against falsified medicines as it provides a broad range of indicators and serves as a focal point between national partners. Hence, much information flows together at the central level and can be analyzed in a context of cross-country comparison. Particularly, it can be measured against the progress towards achieving the SDG's. Apart from only retrieving data over national focal points, the high engagement and coordinative role of the UNODC allow for the compiling of own data rather than solely relying on secondary sources.

Chapter 5: Institutional capacity – Public Health and Safety

This chapter will elaborate upon possibilities to enhance capacities for further pandemic preparedness to ensure prevention of pharmaceutical crime and containment of damages from a health perspective by answering the sub-question:

RQ: To what extent can mechanisms at the global level increase capacity-building that fosters public health and safety in pharmaceutical regulation?

The most central institution providing guidelines for global medical supply chains is the World Health Organization (WHO). Functions performed at the global level are mainly concerned with setting international standards and guidelines as well as certification schemes. The *World Health Organization (WHO)* was the first actor being involved in regulating pharmaceutical products and many current regimes developed under its auspice. While it was initially tasked with development, production, quality assurance and monitoring, its focus shifted over time towards primary health needs of developing countries (Samson 2012). Programs and initiatives of the WHO are the International Pharmacopeia, the WHO Certification Scheme, the WHO Prequalification Program for Essential Medicines and the International Conference of Drug Regulatory Authorities (ICDRA). *The International Pharmacopeia* was originally adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 1948 and harmonizes national and regional quality specifications, excipients, and dosage forms. The *WHO Certification Scheme* is a guideline uniting over 140 regulatory authorities in facilitating information exchange between importers and exporters and respective information about drug producer compliance with the Good Manufacturing Practice (GMP). The *WHO Prequalification Program* is an international regime mainly used by UN agencies such as UNAIDS and UNICEF for approval of drugs and vaccines against HIV/AIDS, tuberculosis, and malaria. Apart from supranational and internal programs, the WHO also provides intergovernmental platforms. Such are the *International Conference of Drug Regulatory Authorities (ICDRA)* which was established in 1980 and enables all WHO members for horizontal cooperation by adopting recommendations in biennial meetings. Another effort of intergovernmental harmonization is the *Pharmaceutical Inspection Convention* in combination with the *Pharmaceutical Inspection Scheme*

(PIC/S), which unite 40 regulatory authorities in recognizing mutual inspection results. Also developed under the auspices of the WHO in 1949 is a private body pursuing harmonization efforts, the *Council for International Organizations of Medical Sciences (CIOMS)*, which is composed of 48 international scientific organizations and 18 national associations who are primarily focused on bioethics and pharmacovigilance. In order to mobilize the political will to strengthen the fight against fraudulent medicines, the WHO established a voluntary and self-governing oversight institution in 2012, the *Member State Mechanism (MSM)*, which leaves infringements of intellectual property out and solely focuses on health and well-being. The MSM is equipped with a secretariat, steering committee, chairs, and vice-chairs representing all regions and various working groups. Its aim is to identify the underlying factors that foster the trade in falsified and substandard products, agree on common definitions, to develop national action plans, create a network of global regulatory focal points, develop precise track and trace systems as well as reliable authentication technologies. The result is a program based on the three pillars 'Prevent, Detect, Respond', which established a network of communication channels between national focal points and particularly a Rapid Alert System to notify and advice international colleagues, created tools and systems that facilitate the reporting and the aggregation of results within a global database and sophisticated analysis of this database (OECD 2020). Accordingly, this research will elaborate upon the themes 'Prevention, Detection and Response' in order to explore ways on how to increase the technical capacities, improve access to quality medicines and medical products and strengthen the surrounding governance framework to achieve further pandemic preparedness.

5.1 Prevention

"There would be no need for detection and response if the production of substandard and falsified medical products or their access to the supply chain could be prevented in the first place" (WHO 2017, p. 47). Hence, the objectives of prevention are to secure a demand for quality products and to secure the supply thereof by establishing comprehensive legal frameworks, securing the integrity of supply chains, mobilizing multi-stakeholder engagement and raising education and awareness.

(1) Education and awareness

Targeted media, education and awareness programs should educate the general public and civil society organizations and the issue of falsified medicines must be included in the core curriculum of medical, pharmacy, healthcare and regulatory academic training. Crucial is the promotion of responsible use of medicines, particularly with regard to the increased usage of online-pharmacies and the rise of a self-prescribing culture. With progressing digitalization and access to the internet, these trends are unlikely to reverse and should therefore be rather accompanied by close monitoring, regulatory control and education. Online pharmacies are in the unique position to bypass regulatory oversight through their direct interaction with the consumer and can use this position for their benefit. The trend towards self-diagnosis in online pharmacies is catered by the pharmacies themselves, through the usage of "Cyberdocs" who obtain medical information from consumers through questionnaires and then fill out prescriptions accordingly rather than getting them in consultation with a medical practitioner beforehand (Mackey & Gaurvika 2016). However, their licensing, efficacy review, business relationship and dispensing practices can go vastly unchecked depending upon the jurisdictions of consumer and pharmacy. As digital marketing campaigns of genuine and rogue pharmacies on the web exploit the information asymmetry between themselves and the consumers, it is the responsibility of regulators on all levels to not only tighten the control upon digital markets but also to actively correct for the imbalance in information through restrictive measures and education campaigns that are tailored towards demographic and geographical characteristics. For instance, about 80% of online pharmacy marketing is targeting English speaking countries and 10% Japan, often through the usage of consumer testimonials, images implying credibility, fake logos and seals and utilizing popular B2B-platforms like AliBaba (Mackey & Gaurvika 2016). Therefore, raising awareness about health information and products in the digital space is of high importance to curb the demand side of the trade. Indeed, many governmental web pages provide lists of warning signs to distinguish the genuine character of a pharmacy, eg. by recommending checking for spelling errors, watching for suspiciously low prices and not accepting bitcoin as the sole payment method. Apart from informational approaches, governments can attempt to regulate online pharmacies via verification schemes, seals, certifications and generic top-level domains. A good

example of this is the ‘Falsified Medicines Directive’ which introduced a common EU-wide logo in legal pharmacies that carries specific technical, electronic and cryptographic details leading to a register at the European Medicines Agency. The directive introduced further safety features such as unique identifiers and anti-tampering devices at the outer package, tougher rules on import of pharmaceutical ingredients and strict record-keeping requirements for wholesalers (Directive 2011/62/EU). However, as logos always carry the risk of misuse to suggest credibility, the usage of top-level domains like “.pharmacy” or the development of special search engines could improve the situation even more.

(2) Multi-Stakeholder Engagement

Clear and frequent communication channels between civil society groups, government departments and agencies as well as pharmacovigilant or toxicologic laboratories must be established and be based upon documented procedures. Especially the engagement of civil society has a crucial function to further spread awareness and bridge the divide between the private and public sector to increase accountability standards. A good example of an institution that emerged from the civil society is the non-profit multi-stakeholder campaign “Fight the Fakes" which originated from the King's University London and established a network which includes many pharmaceutical companies and association and now is a vocal proponent of the fight against falsified medicines, frequently participating in webinars and other formats and particularly engaging towards young people.

Whereas multi stakeholder engagement has a crucial role in education and regulatory and business scrutiny, it also became the governing paradigm for the global production and distribution of Covid-19 vaccines. An important institution coining the global vaccine market in the Covid-19 Pandemic is COVAX. Founded by ‘Gavi’ and ‘The Vaccine Initiative’ (associated to Bill and Melinda Gates Foundation and World Economic Forum), CEPI (associated to Norway, India, Bill and Melinda Gates Foundation, Wellcome Foundation) and the WHO, it is a prime example of multi-stakeholder engagement outside classical multilateral structures. The result is a global governance body that incorporated the intergovernmental UN system but shifted the power in the favor of corporates by appointing governmental representatives merely to

the advisory boards and thus marginalizes the role of the WHO by designing the initiative as stakeholder group operationally run by two other stakeholder groups (Gleckman 2021).

On one hand, the initiative is designed like a merchant bank with money from governments to prepare the vaccine industry and shape consumer markets in the global south, on the other hand, it is designed like an international trade association with the objective to reconcile public-private interests. Whereas its main function is to handle purchase and financing, it also provides diagnostics, therapeutics and national support. It operates over two distinct platforms: one that provides insurance and protection against unfair treatment for large purchasing countries that make contracts with individual manufacturers and provide pre-payments that constitute the initial capital, and another one framed under the term “Advanced Market Commitment" which provides doses for economically weak countries unable to finance themselves. The aim of COVAX is to fully cover 20% of the global population and to make 2 billion doses available by the end of 2021, half of which will go to the current 92 AMC-eligible developing countries (Berkeley 2020). Whereas this is a great achievement, it the COVAX initiative grants large power to business interests, as pharmaceutical companies have stakeholder status, whereas consumers are not represented and the WHO is marginalized, as the UN system is “weakened by decades of underfunding, public attacks and political marginalization, particularly by major OECD countries, media, and their leading policy institutions" (Gleckman 2021, p. 12). Considering that COVAX commitment is to vaccinate 20% of the global population, whereas herd immunity is achieved with a vaccination rate of 60-70% (Mandavilli 2021), it can be assumed that COVAX cannot effectively suppress the trade in falsified vaccinations by itself. Furthermore, the untransparent governance structure and isolation of democratic institutions arguably undermines citizens' trust into the initiative. Indicative is the vast range of conspiracy theories circulating that target Bill Gates (Friedman 2021), who is vastly involved into COVAX through his foundation. Thus, more transparent and democratic governance practices would not encounter conspiracy narratives and subsequently alleviate the ‘infodemic’ of fake news and the associated rising demand for falsified medicines.

(3) Comprehensive Legal Framework

The WHO plays a crucial role in the complex web of global pharmaceutical regulation and administers a range of guidelines, including the WHO Good Manufacturing Practice (GMP), the Good Distribution Practice (GDP), the Good Storage Practice (GSP) and the Good Pharmacy Practice (GPP), whose compliance is regulated within the WHO Certification Scheme.

The Certification Scheme is an administrative instrument developed by the WHO to facilitate international trade in pharmaceuticals by requiring a participating country upon request of a commercially interested company to certify or attest to the competent authority of another interested party that a specific pharmaceutical product is authorized within the country and that its production is compliant with the WHO GMP standard. The WHO GMP originated in 1968 and is an assurance that medicines are of high quality, appropriate for their intended use and meet the requirements of the marketing authorization and clinical trial authorization. Up to today, over 100 countries adopted the WHO GMP and many more adopted their provisions into their own national GMP requirements (WHO 2018). The GMP sets out precise details for production, labelling, documentation, quality control, personnel, premises and equipment, quality risk management and importantly, on-side inspections of the production facilities. However, due to the Covid-19 pandemic, some authorities like the European Medicines Agency conducted inspections remotely and gave waivers upon the inspection fees when confirmation of compliance with GMP could not have been handed out following the inspection (EMA 2021). Although stating that on-site inspection will resume as soon as feasible, such temporal limitations to independent quality assurance can be determined a supply chain vulnerability arising out of the Covid-19 pandemic.

Furthermore, the GSP lays down specific provisions for product recalls, dispatch and transport, returned goods, storage requirements, premises and facilities as well as personnel. However, in most countries, central medical storage facilities are among the best regulated places nationally, with the problems arising when medicines are in transport, eg. waiting in docs with too high temperature or low security for weeks while awaiting customs clearance (WHO 2017). Thus, the rise in bureaucratic barriers as caused by the pandemic response created great vulnerabilities for diversion and deterioration of medicines in transit.

The most specific WHO guideline to prevent the distribution of counterfeit pharmaceuticals is the WHO Good Distribution Practice (GDP) which explicitly states that the "the guidelines can also be used as a tool in the prevention of the distribution of counterfeit pharmaceutical products" (WHO 2010, p. 237) although only containing general provisions which must be extended by provisions in national legislation to suit the situations in individual countries. However, these general provisions lay a foundational basis to combat pharmaceutical counterfeit from a regulatory point of view. Decisively, Article 19 'Counterfeit Pharmaceutical Products' states that counterfeit products must be kept apart from other products, be clearly labelled as not for sale and national regulatory authorities and the holder of the market authorization of the original product must be notified immediately (Article 19.1). Furthermore, a formal and recorded decision upon the disposal must be taken immediately once the counterfeit is confirmed (Article 19.3). Many aspects of these provisions are reflected throughout the other provisions laid down under the GDP.

For instance, Article 4.6 of the General Provisions urges the need for collaboration of all parties, including governments, custom agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors, and entities responsible for the supply of pharmaceutical products to patients to ensure quality and safety of pharmaceuticals and prevention of exposure to counterfeit products. Furthermore, Article 8.12 'Traceability of Pharmaceutical Products' mentions that provisions must be made for visual and analytical identification of possible counterfeit and subsequent notification of license holders and national or international authorities. Article 9.10 'Storage Areas' obliges that special storage spaces in warehouses must be assigned for the temporal storage of suspected counterfeit to prevent unintended or unauthorized usage. Article 12.6 'Dispatch and Receipt' mandates that the information written on the receipt must be sufficient to recall and investigate a batch of counterfeit or potential counterfeit. Article 16.2 'Complaints' states that all complaints and information must be reviewed carefully and according to written procedures and the appropriate action, including recall of products, must be taken. Furthermore, Article 16.6 lays down that documentation of complaints and information on counterfeit must be documented carefully and shared with responsible national and international authorities. In the case of product returns, the distributor and recipient are accountable for administering the

process and ensuring that no counterfeit can enter the supply chain (Article 18.1). To prevent the importation of counterfeit, Article 20.8 ‘Importation’ urges customs, law enforcement agencies and regulatory agencies responsible for the supervision of counterfeit pharmaceuticals to establish means of cooperation and information sharing. Lastly, Article 21.2 that each contract should define the responsibilities of the engaged parties and that responsibilities of the contractors should be included to avoid the possibility of counterfeit entering the distribution chain, such as suitable training programs.

(4) Supply Chain Integrity

A key element to achieve better surveillance and subsequent inspections and analysis are the installation of track and trace systems and sophisticated authentication technologies.

Track and Trace Systems are based on the “traceability” of products, which can be defined as the ability to identify the origin and various stages of consumption goods in the production and distribution process (WHO 2015). Due to the globalized supply chains, the adoption of global standards that provide for specific local or regional provisions can be highly recommended.

Furthermore, the scope of the tracing, in terms of which units are tracked, increases in cost and complexity the more individual the tracking is targeted. Tracking the batch level contains a large number of units which probably cannot be individually differentiated but thus keeps supply chains flowing quite easily. Similarly, tracking the tertiary level (pallet) within the batch follows a similar cluster. Tracking the secondary level (unit of sale) and the primary level (unit of dispensing) displays greater complexity in implementation and requires more human resources but enables the reconstruction of the entire supply chain and better monitoring for adverse effects (WHO 2015).

Further attempts to modernize track and trace systems have been based upon the usage of blockchain technology; however, experiments to implement such in Nigeria failed, noting that “problems associated with tackling counterfeits in Nigeria include a high level of illiteracy, unemployment, over-dependence on medicines importation, deficient regulatory activities, open drug markets, lack of political will, cumbersome regulatory

processes of new drugs registration, corruption amongst regulators and border control personnel, lack of domestic production of drugs, lack of infrastructure, lack of government incentives to encourage domestic manufacturing, chaotic distribution system, absence of a befitting technology to detect the originality of drugs after sales and lack of regulatory agencies' presence in remote locations" (Labaran & Hamma-Adama 2021, p.32).

Although technological applications evidently cannot work without a functioning political environment, they are an indispensable part of the solution.

Authentication technologies of medicines should have a non-cloneable level of security, high product application and authentication speed, be based on proven standards, must be difficult to remove and reapply, be easy to check and enable automatic authentication, be consumer friendly and legally compliant with regulation by the industries. Such include overt/visible technologies (Tamper-evident measures, Holograms, Optically variable devices, color shifting security inks and films, fugitive inks, security graphics, scratch-off technologies, overt use of a covert technology), covert/hidden technologies (invisible printing, latent images and 3D intaglio printing, embedded images, digital watermarks, hidden marks, microtext or microprinting, anti-copy or anti-scan designs, safety fibrils or filaments, laser coding, marks in a die-cut profile, substrates, odor) and forensic/chemical markers (chemical taggants, biological taggants, DNA taggants, isotope ratios, micro-taggants (WHO 2017b).

5.2 Detection

The aim of detection is to improve the means of detection technologies and to make them more available and to report occurring incidents in a safe and standardized manner. Thus, improved border controls and reporting systems, risk-based inspections and surveillance as well access to laboratories and screening technologies are crucial.

'Detection' work is highly reliant on the previously described 'Prevention', as it requires strong awareness throughout the supply chain, great cooperation between actors to triangulate data and share information and builds up on the availability of detection and authentication technologies in the field and laboratories.

As counterfeit can enter at each part of the global supply chains, border controls and customs screenings must be strengthened. Designated ports should be established for

the import and export of pharmaceuticals, which are separated from other spaces and equipped with high technological capacities and specifically trained regulatory authorities and customs personnel. The separation of the pharmaceutical supply chain does not only reduce the risk of deterioration of the products while being in transit, it could also have greatly fostered the situation of overloaded customs checks following the pandemic response. Whereas pharmaceuticals and other medical goods disposed of special export licenses, the checking of their validity could have arguably been better accomplished in a separate lane receiving sole attention. Furthermore, as import/export documentation is often only available in paper form upon arrival and can be incorrect due to genuine errors or deliberate manipulation (OECD 2020), data should be made available via electronic channels prior to the arrival to assure more accurate and permanent information which facilitates the work at the border points. Particular scrutiny must thereby be paid in Free Trade Zones, as there are currently over 3500 FTZ's in over 130 countries which are often located in key ports, which can pose significant risks for illicit activity without additional transparency and oversight (OECD 2019b).

Whereas customs report the detection of falsified goods by the nature of their duty, a culture of non-reporting can persist among healthcare workers and companies, which are generally required to immediately report spotted counterfeit and notify the relevant authorities.

A culture of non-reporting among healthcare workers can be traced back to a lack of awareness, a lack or overcomplication of formalized reporting methods and systems, lacking feedback and responses from regulatory authorities or employer, fear against their manager or supplier, fear or knowledge of corruption and the possibility to be subject to prosecution or civil actions. Similarly, companies sometimes do not report incidents as they fear reputational damages, costs associated with product recalls and disproportionate responses from regulatory authorities (WHO 2017). Thus, to combat unethical practices in the public and private sector, it is necessary to establish more transparency in procurement processes to avoid that responsible managers attempt to conceal questionable purchases and whistle-blower protection mechanisms that protect personnel from fear of retaliation through criminal groups or employers. Good examples for procurement processes are for instance the electronic bidding system

implemented in Chile or the public posting of medical supplies in hospitals in Buenos Aires (Kohler et. al 2014). To facilitate the reporting process and avoid human error, a standardized reporting form should be provided that contains the point of detection in the supply chain, the quantity of suspected products found, a visual description of the packaging, the product name as marketed, the name of the active substance if known, the dosage units and batch number, photographs and descriptions of irregularities, details on the supply history of the product as well as the description of the circumstances leading to the discovery (WHO 2018b).

The more detailed data and information are collected, stored, and processed, the better risk-based inspections can be performed. All regulated and unregulated parts of the supply chain must be subject to regular targeted and random inspections based upon documented risk-based strategies. The inspection programs must be tailored specifically for all entities engaged in the manufacture (relabeling and repackaging), importation, distribution and wholesale as well as the sale and supply of the medicines at the end of the customer, and must review the administrative structure, the organizational structure, the personnel, documentation and records, as well as the quality of the medicines and suitability of the facility (WHO 2002). The reliability of inspections is particularly important due to mutual recognition agreements embodied in the WHO Certification Scheme and PIC/S programs. Therefore, as each joint in the system can potentially threaten the supply chain, sufficient laboratories and screening technologies must be present in each country.

National quality control laboratories must be external to the supply chain and easily accessible to seek testing and advice towards actors within the supply chain. Their work must be based upon documented procedures that are tailored towards the analysis of substandard and counterfeit pharmaceuticals. Furthermore, specifically trained staff must have access to field screening technology and any required reference materials and carefully document their usage. National control laboratories should be able to perform physical testing methods (Disintegration, Reflectance spectroscopy, refractive index) and chemical testing methods (colorimetry, dissolution, chromatography, spectroscopic techniques, mass spectrometry) (OECD 2020). Considering that not all countries dispose of the appropriate resources and knowledge, information must be shared, and technical assistance provided to the widest and most accessible extent possible.

5.3 Response

To protect public health and prevent the recurrence of falsified or substandard medical products after their initial surfacing, regulatory controls must be strengthened, legal processes must be designed more transparent, policies and procedures must be evidence-based and alerts and recalls handled effectively and efficiently.

Alerts and Recalls are a crucial element in containing the circulation and damages of falsified medicines and can only effectively be performed by a high degree of ordered, international cooperation. National Medical Regulatory Authorities (NMRA) in all countries must establish focal points that report substandard and falsified medicines and upload information concerning the incident into the WHO Global Surveillance and Monitoring System and which can subsequently trigger Rapid Alerts. Such Alerts in turn must be immediately served by other NMRA's through a documented procedure issuing, receipt and response towards the detection of substandard and falsified medical products.

Regulatory Strengthening is necessary as currently less than 30% of regulatory agencies in the world can ensure the adequacy of medicines and vaccines (Tesfaye et. al 2020). Thus, countries should develop specific legislations to empower NMRA's and criminalize the falsification of medicines and based on that draft detailed national and regional action plans that outline the framework of cooperation. Such action plans must be implemented and executed by specifically trained personnel. National action plans should contain detailed and documented allocations of resources, roles, activities and responsibilities, clearly establishing where one accountability ends, and another begins. Regional action plans need to be developed to coordinate strategies, particularly between countries that are geographically dependent and share the same economic area. The harmonization among NMRA's must be paralleled by a harmonization of transparent legal processes and penalties.

The sanction provisions and their specific use should be published by the relevant national or regulatory authorities and be applied in a just and consistent manner in line with the principle of proportionality. That is, they should be effective in combating the crime, should be efficient as providing the most optimal means to achieve the deterioration of the crime and appropriate as the degree of the punishment must reflect the severity of the crime. The ways in which the regulatory authorities are strengthened

must be founded on evidence-based policies. Therefore, all incidents have to be gathered in a centralized database and reviewed to identify weaknesses in the supply chain which have to be answered by respective changes in policy and regulation. The data that underpins the policymaking should hereby be retrieved from a wide range of sources and incorporated into Good Governance practices, that enable countries to take ownership of the initiatives, put the surrounding political context into perspective and enable the monitoring and evaluation of their impact (Kohler et. al 2014).

5.4 Sub-Conclusion on Capacity-Building

1. Capacity to assess a situation and define a vision

The global level, particularly with the WHO at its core, is greatly suitable to track the trends and challenges imposed by falsified medicines in the context of global medical supply chains during a global pandemic. That is, because it is the institution at the center of global health information, which had the capacity to declare Covid-19 to be a pandemic, is strongly engaged in the allocation of essential medicines and vaccinations and disposes over a wide network of experts and focal points.

Particularly by the means of the WHO Monitoring and surveillance system, it is immediately informed about detection of counterfeit and able to issue alerts to the national authorities. Thus, in collaboration with its various decentralized associates, the WHO possess great capacity to assess the impact of Covid-19 and its interplay with falsified medicines.

2. Capacity to engage stakeholders

The WHO is able to mobilize relevant stakeholders due to its comprehensive institutional entanglement and long history as a global regulatory body. The WHO is virtually omnipresent and arguably the only actor cooperating with such a high number of international partners.

For the purposes of detection and response, the WHO facilitates cooperation between NMRA's and pharmaceutical companies to quickly identify suspected counterfeit and take the appropriate action. It further diminishes incentives for falsification by connecting stakeholders and facilitating the process of medicine supply and vaccine procurement in times of crisis. Being a crucial element of legitimacy in the COVAX-

initiative, it can be argued that the capacity reached by the initiative is predominantly due to the WHO. However, the initiative is also a great example of how the role of the WHO has been diminished to a mere mediator bringing multiple partners to a table, as its reduction to an advisory function greatly undermines its capacity to shape decisions in the interest of public health excluding the high salience of economic interests.

3. Capacity to formulate strategies and implement

Considering that the WHO Certification Scheme is applied by over 140 countries, the global level greatly influenced the international standards for medical supply chain security. Furthermore, it is greatly involved by its multiple public and semi-public bodies and agencies involved in the harmonization processes of quality standards of medicines and their respective environments.

On an intergovernmental level, the almost universal participation in the Member State Mechanism equips the WHO with extensive capacities to foster and guide decision-making towards the conclusion of new strategies to prevent the circulation of falsified medicines in the supply chain and provides a certain degree of assurance that those will be implemented within national legislation. Similarly for the combating of falsification of medicines, the WHO is at the forefront of the fight by facilitating analysis, investigating patterns of adverse health effects, raising awareness and gathering data, and publishing and updating guidelines on supply chain resilience.

4. Capacity to budget, manage and implement

In the realm of global medical supply chain regulation, the global level is able to provide comprehensive technical assistance and guidelines for states to translate into their national legislations. However, the specific guidelines are merely general provisions which must be adopted and adjusted according to the national and regional context of the specific countries. Furthermore, the budgeting of the WHO itself is subject to budgeting considerations of their member states. Hence, budgeting and managing at the global level is rather constrained. Especially in times of Covid-19, budgeting and management practices of countries diverged significantly, reflecting different spending capacities and priorities of the countries.

5. Capacity to evaluate

Being the primary source of global intelligence on pharmacovigilant data and central stakeholder in coordinating the global response at a multilateral level, the WHO represents the major focal point for evidence-based policy advice at the international level. Through its great stakeholder engagement and regulatory infrastructure, the WHO represents the central linkage to store, transfer and evaluate data related to both, the pandemic and falsified medicines.

Accordingly, the WHO has great capacity to evaluate the development of illicit trade in falsified medicines with a specific focus on health related aspects.

Chapter 6: Conclusion

It can be concluded that the successful distribution of falsified medicines is fostered by a combination of product-, market- and governance characteristics which cause grave health-related, socio-economic- and governance-related damages to individuals and societies around the world. The Covid-19 pandemic has reinforced the demand and supply of falsified medicines due to the turbulence it has caused in the political and economic sphere, mutual reinforcement effects between pandemic and digitalization and due to its effects on the socio-economic situation of individuals. The high heterogeneity of policy responses within and between nations particularly revealed and distorted global supply chain dependencies and transnational regulatory cooperation. The "new normal" caused by the Coronavirus further reinforced the overall time people spent online and facilitated the trend towards provision and usage of e-services and e-commerce, which in turn increased the exposure to offers of potential counterfeit in the digital space. Thus, problem-solving efforts must be international and intersectional to tailor an encountering regime based on strong legislative grounds, resilient supply chains and common understanding and awareness.

Encountering the illicit trade in falsified medicines through criminal justice approaches, the global level provides the general framework of international law for criminalization within national legislations and cooperation in investigations. However, the high decentralization of actors and divergence of national frameworks and sometimes political interests can hinder effective enforcement efforts. Albeit enforcement and awareness are increasing, the proportionality of proper sanctioning does not yet mirror the severity of the crime in most of the courtrooms. Whereas aggravating circumstances can apply in relation to criminal organizations, the list of aggravating circumstances should be further amended to include trafficking in falsified medicines during pandemic situations to achieve further preparedness by making the crime more unattractive especially in pandemic situations. The global level should further engage stronger with civil society actors to increase the pressure of governments to criminalize the non-mandatory UNCAC offences in their national criminal codes, to cut through corruption entanglements in the private sector. Altogether, a global law enforcement effort targeted

at medical products related to the pandemic response should be initiated, which is carried out similar to the Pangea and ACIM initiatives but choosing a stronger framework to identify entanglements of public officials, and not being limited to online purchases or regional focus.

To increase the resilience of supply chains against falsified medicines to foster public health and safety, the WHO provides great capacity to establish resilient global regulatory structures protecting the pharmaceutical supply chains against infiltration of counterfeit. Albeit having a rather steering and advising nature, it's path dependent centrality enabled it to determine the current agenda, to conclude standards serving as basis for guidelines and decision-making and to provide technical assistance in their implementation. It furthermore oversees a vast network of a multitude of medical experts, national officials and other stakeholders, and is thus highly capable of monitoring pandemic and counterfeit incidents. Based on this knowledge, the WHO can identify vulnerabilities and corresponding recommendations to improve the prevention, detection and response mechanisms concerning falsified medicines.
Prevention must be achieved by increasing awareness among civil society and health care professionals, coupling epidemiological insights to the characteristics of falsified medicines and their forms of harm. Furthermore, legal frameworks and standards must be reassessed and strengthened by harmonizing implemented practices and guidelines. In order to carry out risk-based and random inspections in times of crisis, the medicinal supply chains should be separated and administered over special points accounting for their unique characteristics, to ensure quality control and transparency even in times of economic lockdown and bureaucratic turbulence. The network of stakeholders should be stronger institutionalized without giving up on clear oversight and democratic decision-making. E.g., the multitude of actors should be a tight web of satellites around the WHO acting as focal points of technical assistance and pharmacovigilant and epidemiologic data. Particularly regarding the COVAX initiative, more salience should be allocated to the public and multilateral sphere to distribute vaccines in a just and human-centric manner. One approach would be to determine Health as a public good accessible to everyone on equal terms. The detection of circulating counterfeit can be increasingly encountered through R&D of authentication and supply chain surveillance

technologies. As such technologies and the training on their usage become cheaper and available, supply chains grew more resistant. Promising is the application of blockchain technology to facilitate streamlined, anonymous and trustful data sources which are combined accessible over a single scanning device, although first tests in the field have shown that political problems must be solved prior to effective deployment of technological solutions. To increase the preparedness for further pandemics, clear procurement plans must be established that upon documented procedures and practices outline the sourcing and distribution of medical goods, and every step in the pandemic control must be publicly recorded on a freely accessible governmental webpage. Similarly, governments must act in a foreseeable and internationally coordinated manner to avoid confusion, high heterogeneity and supply chain distortions through policy actions. To achieve this, institutions at the global level can evaluate the experiences from the Covid-19 pandemic to conclude pandemic guidelines that enable evidence-based policies. The increasing data exchange and central storage thereof, as well as the training of national focal points, is the most promising development to design more resilient supply chains and effective responses.

Overall, this research has shown that the global level is capable of increasing the institutional capacity of national actors and their regional entities by providing guidelines and legal frameworks plus the technical assistance to implement and execute this guidance. However, lacking enforcement. The global level is suitable to conclude such guidelines, as the global level is the appropriate instance to conclude general best practices and perform stakeholder engagement for a global problem. This holds especially true for the interplay between medical supply chains and pandemic response, as both problems are global in nature but subject to regional specificities. Hence, as no one-size-fits-all approach can prevail, the institutional capacity can best be strengthened through provision of a uniform framework with comprehensive minimum security standards. To finally take the fight against fakes to the next level, a promising proposal of Mackey 2013 would be the establishment of a trilateral technical working group, in which the UNODC as chair exercises global stakeholder cooperation, strengthening of rule of law, regulation and capacity and refers IP and trade related issues WIPO/WTO. The WHO would be tasked with data surveillance, scientific research on health impacts, pharmaceutical governance and ensuring access to medicines. And thirdly, INTERPOL

could conduct field operations, stakeholder education, mobilize resources and test anti-counterfeiting technologies. Together, this trilateral group could effectively combat falsified medicines through drug surveillance, development of legal, policy and regulatory spaces and strong public outreach and education.

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