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Tim K. Mackey*

Abstract

Objective. Counterfeit medicines are a global, multi-faceted, and complex public health problem. Global health diplomacy and cooperative efforts relying on governance systems have been limited in effectively addressing proliferation of this dangerous trade.

Methods. This review conducts a comprehensive mapping exercise of governance efforts by international organizations to address counterfeit medicines, including analysis of related international treaties and conventions that may be applicable to anti-counterfeit efforts. This work also reviews governance and global health diplomacy proposals from the literature that addresses counterfeit medicines.

Summary of Findings. A number of international organizations have become active in addressing the global trade of counterfeit medicines. However, governance approaches by international organizations, including the World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC), Interpol and the World Customs Organization (WCO), have varied in scope and effectiveness. Treaty instruments with applicability to counterfeit medicines have also not been fully leveraged to combat this issue. Results indicate that a formalized and multi-stakeholder governance mechanism is needed to address the issue. The UNODC is uniquely situated to act as a forum for such a proposal in partnership with other international organizations.

Implications of Findings. Global health diplomacy efforts to combat counterfeit medicines require multi-stakeholder and formalized governance structures that can leverage stakeholder participation and resources. Through cooperative arrangements leveraging the strengths of partners such as UNODC (combating transnational crime), Interpol (law enforcement purposes), the WCO (customs and border control), and the WHO (for public health science and analysis), the international community can mobilize a coordinated, inclusionary, health diplomacy response to the crisis of global counterfeit medicines.

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Background

The growing recognition and importance of global health issues in national and foreign policy has given rise to the practice and study of global health diplomacy (GHD). Because of the transnational and multidisciplinary characteristics of global health, unilateral state-based actions impact what happens at the multinational level and thus have far-reaching effects in areas of shared global health equity, social justice, and security (Novotny, 2007). Attention to GHD is driven by new challenges in global health, including the globalization of diseases, complex and interdependent global health delivery systems, and the changing roles of the public and private sector in contributing to global health problems, as well as developing solutions (Drager & Fidler, 2007; Feldbaum & Michaud, 2010; Kassalow, 2001; Kickbusch, Silberschmidt, & Buss, 2007). These challenges are apparent in the complex and multi-faceted debate regarding access to safe medicines and the public health dangers of counterfeit medicines.

The global multi-billion dollar illicit trade of counterfeit, fraudulent, substandard and otherwise dangerous medicines is a critical global health problem that has led to patient injury and death, and antimicrobial resistance, and can have an adverse impact on population-based health (Institute of Medicine [IOM], 2013) Yet, several challenges impede progress towards effective solutions addressing the entire scope of the problem. These challenges include failure to mobilize cooperation among stakeholders, lack of sufficient and/or quality data, and the complexity of the problem itself, which includes issues of intellectual property rights (IPR), drug supply and regulation, international trade, and the involvement of organized crime (Attaran, Barry, Basheer, Bate, Benton, Chauvin et al., 2012).

Policy and Governance Fragmentation

Specifically, a host of multinational state actors, international organizations, civil society and private-sector entities are actively involved in different facets of the problem (Mackey & Liang, 2011). Activities of these diverse actors range from manufacture, regulation, procurement, product registration, trade and commerce, customs, marketing, patient advocacy, criminal enforcement, and establishment of laws, policies, norms and guidance (IOM, 2013; Mackey & Liang, 2011). However, this complex system of diverse stakeholders has also given rise to competing interests and policy fragmentation which have impeded global collective action (Attaran et al., 2012; Mackey, Liang, & Kubic, 2012).

Indeed, conflicts have extended to the very definition of the problem, with no agreed-upon terminology for what constitutes a "counterfeit" medicine (Attaran et al., 2012). As an example, the World Health Organization (WHO) uses the term "substandard/spurious/falsely-labelled/falsified/counterfeit" (SSFFC) medical products; the United Nations Office on Drugs and Crime (UNODC) uses the term "fraudulent" medicines; and the European Commission uses the term "falsified" medical products to describe the problem. Without appropriate and agreed-upon definitions, it is difficult to quantify or develop harmonized solutions to address "counterfeits."

The complexity of the problem, which includes issues of drug quality (both intentional and unintentional activities), potential IPR violations by unauthorized manufacturers, incompatible member-state interests, and the need to provide equitable access to medicines, makes it difficult for global consensus building. Generally, "counterfeit medicines" describe medical products that are: (a) of substandard quality; (b) not manufactured to current good manufacturing practices; (c) are fraudulently mislabeled with respect to their identity/source; and (d) are otherwise tainted, adulterated, or made ineffective or harmful. However, agreement on establishing a standardized definition is elusive, further exacerbating current diplomatic and programmatic efforts.

Lack of Adequate Data

The scope of the counterfeit drug trade is immense, as counterfeits have been detected in high-income, middle-income, and resource-poor countries alike (IOM, 2013; Mackey & Liang, 2011). Yet reliable data on the exact prevalence of counterfeit medicines are difficult to ascertain due to inadequate surveillance and practical challenges of detection due to the criminality of the trade (Mackey & Liang, 2011; WHO, 2006b).

As an example, the Center for Medicine in the Public Interest previously estimated the counterfeit drug trade to be worth some $75 billion (Bulletin of the World Health Organization, 2010). The WHO has estimated counterfeit medicines make up less than one percent of medicines in developed country settings to over 10-30 percent in developing countries (WHO, 2006b). Publicly available data from law enforcement and manufacturer incident reports, and other data collated by the Pharmaceutical Security Institute (PSI), show an increase from 1,123 incidents of counterfeiting, illegal diversion and theft in 2005 to 1,986 in 2011, representing a 79 percent increase over this time period (PSI, n.d.). PSI data also implicate a total of 532 different pharmaceutical products in 2011 with this pharmaceutical crime largely concentrated in Asia and Latin America (PSI, n.d.).

However, WHO and PSI data are inherently insufficient and only provide a snapshot of the potential scope of the problem, and thus have limited generalizability. Currently, a comprehensive global counterfeit surveillance system collecting information from all relevant sources is not available. Exacerbating this situation has been sensitivity by both the industry and member states regarding the sharing of such data (Gibson, 2004). This lack of accurate and quality data makes it difficult to inform policy making and law enforcement activities.

System Complexities

Challenges to combating counterfeit medicines are also driven by the diversity and multi-faceted nature of the problem itself. Counterfeit medicines have been detected in a wide variety of delivery systems, including hospitals, pharmacies, the wholesale market, global health programs, unregulated informal economy settings (e.g., street markets, etc.), and on the Internet (Attaran et al., 2012; IOM, 2013; Mackey & Liang, 2011; Newton, Green, & Fernández, 2010; Siva, 2010). Though studies have identified weak drug regulatory regimes as a risk factor for counterfeit medicine infiltration, even highly controlled drug supply chains (such as the United States and the Europe Union) have been impacted (Cohen, Mrazek, & Hawkins, 2007; Mackey & Liang, 2011). The recent case of counterfeit Avastin detected in the United States demonstrates how even highly regulated markets have been compromised (Mackey & Liang, 2012a).

Further, a host of medical products have been implicated, including both branded and generic medications, lifestyle drugs, essential medicines (including antibiotics and those treating HIV/AIDS and malaria), life-saving drugs, and drugs that are not legally marketed (Cockburn, Newton, Agyarko, Akunyili, & White, 2005; IOM, 2013; Mackey & Liang, 2011; Newton et al., 2010). As an example, in 2012, researchers estimated that approximately one-third of the malaria drugs in Southeast Asia and Africa were counterfeit (Nayyar, Breman, Newton, & Herrington, 2012). The illegal trade of dangerous counterfeit products also extends outside of pharmaceuticals and has been detected in vaccines, medical devices, and food supplements that contain declared and undeclared active pharmaceutical ingredients (API) (IOM, 2013; Jackson, Arver, Banks, & Stecher, 2010; Mackey & Liang, 2011).

Driving this multi-billion-dollar criminal activity are high profits, difficulties in detection and surveillance, limited risk compared to other criminal activities, lack of drug regulatory and law enforcement harmonization, and the challenges of regulating any illicit global trade (Mackey & Liang, 2011). Given these challenges, the public health and patient safety risks of counterfeit medicines represent a quintessential GHD issue that needs to be urgently addressed. This paper conducts a mapping of a subset of governance mechanisms attempting to address counterfeit medicines. It concludes with a discussion of which governance principles can encourage an appropriate pathway forward.

Methods

This review utilizes a mapping exercise as an analytical framework to assess governance mechanisms utilized by international organizations (IOs) to address the global trade of counterfeit medicines. Inclusion criteria for IOs are: organizations with identifiable and established governance or programmatic activities specifically addressing counterfeit medicines; and organizations that are UN specialized agencies and/or international intergovernmental organizations recognized by the UN. These selection criteria specifically exclude states, national government agencies, foundations, civil society and other IOs that lack formalized programs. This assessment mapped IO governance efforts through document review relying primarily on IO official primary documents and peer-reviewed literature addressing IO counterfeit medicine activities.

In addition, the paper maps and conducts a legal analysis of international treaty instruments that address the global counterfeit medicines trade. Inclusion criteria are: treaty instruments that specifically address trade in pharmaceutical or medical-product-related commodities/materials; and global or regional treaty instruments that have member-state signatories (including those that have not fully come into force). In this assessment the paper reviews the text of the treaty instrument and peer-review literature addressing counterfeit medicines and international treaties.

Search methods for these criteria included database searches on MEDLINE; Google Scholar; and Google search engine (searched February 15-27, 2013) using key words associated with the topics described above. Finally, the paper reviews a selection of governance proposals from the literature as case studies to further inform results.

Results

The IOs identified included the WHO, the UNODC, the International Criminal Police Organization (Interpol), and the World Customs Organization (WCO). The World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) were not included, as they do not have active and dedicated programs to address counterfeit medicines, though may address counterfeit medicines in IO councils or dispute processes and may participate in international meetings/workshops/technical assistance/activities on the topic. Treaty instruments identified included the Council of Europe's (CoE) Medicrime Convention treaty, UNODC's United Nations Convention against Transnational Organized Crime (UNTOC), UNODC's Single Convention on Narcotic Drugs and its supplementary treaties, and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention). This paper did not review the Anti-Counterfeiting Trade Agreement. Governance proposals by Attaran et al. (2012) for a global counterfeit drug treaty, an Institute of Medicine proposal for codes of conduct, and a proposal by Mackey et al. (2012) for enhanced global health governance coordination were also provided as case studies.

This study was not a systematic review, though our initial findings indicate that there is a general lack of discussion of counterfeit medicines governance mechanisms in the peer-review literature. Based on these limitations, findings heavily relied upon primary document analysis. Results are summarized in Table 1.

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Governance Efforts by International Organizations (IOs)

World Health Organization (WHO). As the UN-specialized agency responsible for international public health, the WHO and the World Health Assembly (WHA), the decision-making body of the WHO, have long-standing interests in global medicines safety. In 1988, the WHA adopted resolution WHA41.16, directing the director-general (DG) to initiate programs for prevention and detection of the export, import and smuggling of falsely labeled, counterfeited, and/or substandard pharmaceuticals (WHO, 2011a). A similar resolution followed in 1994 (WHA47.13), directing the DG to assist member states' efforts to ensure a supply of good quality medicines and to combat counterfeit medicines (WHO, 2011a). In 1999 the WHO issued "best practices" and recommendations for addressing counterfeit medicines (WHO, 1999). However, growth of the counterfeit medicines trade continued and became increasingly complex due to a globalized drug supply chain and the emergence of the Internet, leading to subsequent resolutions in 1999 (WHA52.19) and 2004 (WHA57.14).

In 2004, the WHO launched the Good Governance for Medicines (GGM) programme, designed to formulate and implement policies for ethical management of pharmaceutical supply chains that has the potential to address counterfeit medicine manufacture and supply (Baghdadi-Sabeti & Serhan, 2010). Unfortunately, while GGM has engaged a number of countries in governance assessments, it has been limited by lack of political will and resource constraints (Baghdadi-Sabeti & Serhan, 2010).

A 2006 effort to coordinate global stakeholder activity led to the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) (WHO, 2006a). IMPACT was organized under the Declaration of Rome as a voluntary group of governments, organizations, institutions, agencies, and associations from developing and developed countries, in the public and private sectors, aimed at sharing expertise, identifying problems, seeking solutions, coordinating strategies and working towards the common goal of fighting counterfeit medicines, particularly in developing countries (WHO, n.d.). It received multisector endorsement by 160 participants (including 57 national drug regulatory authorities, seven IOs, and 12 international patient, provider and pharmaceutical associations) and is a collaboration of member states, IOs, regional and international economic organizations, and a number of non-governmental organizations (NGOs) (WHO, 2006a; 2011a).

Unfortunately, divergent member-state interests and lack of support significantly limited IMPACT's effectiveness (Shashikant, 2010). These differences were highlighted by a 2008 seizure of generic pharmaceutical products in the Netherlands en route from India to Brazil. The products in question were held up in customs in the transit country of the Netherlands for potential IPR infringement, though they were considered generic formulations according to the laws of India (country of origin) and Brazil (country of destination) (Mackey & Liang, 2011; Shashikant, 2009). This led to allegations at the 2009 WTO General Council meeting and dispute settlement body that the seizure violated the WTO's General Agreement on Tariffs and Trade (GATT) and the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health. India and Brazil, countries that are large-scale generic manufacturing sources, viewed the seizure as an inappropriate

exercise of IPR enforcement. This controversy led to criticism of the WHO's support for IMPACT and the negative perception that the WHO was actively involved in the enforcement of commercial interests (WHO, 2011b).

In response to this criticism, WHO member states created a working group of member states to assess the WHO's involvement with SSFFC, and its relationship with IMPACT (WHO, 2011a). This working group examined the WHO's role in ensuring access to safe and affordable medicines in the context of prevention and control of SSFFC from a public health perspective (expressly excluding trade and IPR considerations) (WHO, 2011a), and made recommendations to the 64th World Health Assembly. In 2012, the 65th WHA adopted resolution 65.19, effectively removing WHO support and replacing IMPACT with a new member state mechanism (MSM) (WHO, 2012a).

The MSM is a voluntary system open to WHO member-state participation only. Its objectives are broad:

- establishing global norms, standards and procedures
- strengthening national and regional capacity and quality control laboratories;
- exchanging information and promoting cooperation;
- identifying major challenges to access to safe medicines; and
- preventing SSFFC activities (WHO, 2012a).

It is governed by a member-state steering committee, including WHO regional blocks (WHO, 2012c). However, this pathway of global policy development under current WHO governance structures results in a state-centred process, similar to other member-state-directed activities and current WHO reform (Mackey & Liang, 2012b). Hence, diverse interests of non-member-state stakeholders may not be adequately addressed in these fora, and funding for intervention activities may be limited. Indeed, attempts to engage in broader stakeholder engagement within the general WHO governance structure through a proposed multi-stakeholder World Health Forum, have also been rejected by member states in the midst of WHO reforms and budget deficits (Mackey & Liang, 2012b).

The first meeting of the MSM, held in November 2012, has already been criticized for lack of transparency and progress (Hirschler, 2012). Further, disengagement of the WHO from broader stakeholder inclusion and relegation of non-state actors to invitation-only status for "specific topics" leaves critical (and powerful) stakeholders outside the discussion (WHO, 2012b). It should be noted that this exclusion not only applies to corporate entities but also other critical stakeholders such as the private foundations who fund global health efforts, and, most importantly, patient organizations. This limited participation may fail to resolve critical differences in ideologies of ensuring access to medicines advocated by civil society, industry concerns regarding unauthorized manufacturing and potential liability, and patient safety concerns about ensuring global safety of medicines.

The future effectiveness of the MSM is unknown. However, this governance structure may have limitations which preclude input and resource sharing of other stakeholders actively engaged in the fight against counterfeit medicines (WHO, 2012b). As in the case of the WHO's refusal to assist Taiwan during the SARS outbreak, individual state interests can adversely impact WHO attempts to address public health problems (Liang & Mackey, n.d.). Though constraints of its current governance structure and lack of resources are significant challenges, the WHO's established role as the international, public health, UN-specialized agency continues to necessitate participation and engagement.

United Nations Office of Drugs and Crime (UNODC). The UNODC is a global leader in the fight against transnational organized crime, including "fraudulent" medicines. Established in 1997 by a merger between the UN Drug Control Program and Center for International Crime Prevention, the UNODC operates on a global scale through an extensive network of field offices. The UNODC relies on voluntary contributions, primarily from governments, for 90 percent of its budget (UNODC, n.d.).

The UNODC strategically employs international agreements to accomplish its goal of combating organized criminal networks, including the Russian mafiya, Mexican gangs, and Colombian drug cartels, which have been implicated in the counterfeit medicines trade (Mackey & Liang, 2011; Reynolds & McKee, 2010). Its activities arise from the UN Convention against Transnational Organized Crime (UNTOC), which has near universal ratification (UNODC, 2004).

In April 2011, the UN Commission on Crime Prevention and Criminal Justice (CCPCJ) Resolution 20/6 (CCPCJ, n.d.) requested and empowered UNODC to engage in the fight against the global, organized, criminal nature of the counterfeit medicines trade. It also empowered UNODC to promote evidence-based solutions for global and regional needs and raise awareness about the dangers of counterfeit medicines.

A relatively new participant in global counterfeit medicines efforts, UNODC has already forged collaborations with multiple stakeholders including Interpol, WCO, the International Narcotics Control Board, and other non-member-state actors, including the national regulatory agencies, the private sector, civil society, and professional associations (UNODC, n.d.). In February 2013, UNODC convened a high-level technical meeting of experts comprised of representatives from this diverse set of stakeholders. This meeting focused on global efforts to fight the transnational organized counterfeit medicines trade. It also sought creative solutions for how UNTOC could be relied upon to facilitate information exchange, investigation, and law enforcement activities (UNODC, 2013).

Recognizing the organized and transnational nature of the counterfeit medicines trade, UNODC has the potential to utilize existing international treaties, global programs on border control and money laundering, and coordination of relevant stakeholders. However, like the MSM system, the outcomes of the UNODC governance approach are relatively new, and its impact is unknown. Further, UNODC lacks a formal governance mechanism to operationalize its CCPCJ mandate. Though the recent high-level technical meeting is a start, future activities in the area are not well defined, nor has a specific funding mechanism been established. Hence, without the establishment of formal governance structures to support collaboration and cooperation, the impact of UNODC may be limited.

However, because of UNODC's emphasis on the criminal nature of the counterfeit medicines trade and its well-established body of international law to coordinate and provide technical assistance to member states on crime prevention, UNODC may prove an effective forum to address the issue. By focusing on crime, UNODC can avoid conflicting issues of access to medicines and IPRs. Further, UNODC's decision to engage all stakeholders at the outset, points to a more inclusive governance structure that can leverage respective competencies and resources of all actors to appropriately address counterfeit medicines.

Interpol. Created in 1923, Interpol, the world's largest international, intergovernmental, police organization with 190 member countries, targets the manufacture, trade and distribution of fake, stolen or illicit counterfeit medicines. In addition, it investigates the links between counterfeit medicines, other criminal activities, and organized crime, focusing on syndicate theft, fraud, illegal diversion, smuggling, trafficking, and money laundering (Interpol, n.d.).

Interpol is funded by its member countries, whose governments pay annual contributions based on their relative economic status and ability to pay (Interpol, n.d.). Law enforcement entities also pay search fees to access its information. It has no independent source of funding, and as such, like the WHO and UNODC, is heavily dependent on voluntary contributions for operations (Interpol, n.d.).

Like UNODC, Interpol focuses on organized crime's role in counterfeit medicines. However, Interpol differs in that it engages in more direct law enforcement interventions. It coordinates field operations to disrupt criminal networks; provides information and skills training, including police enforcement workshops; and establishes partnerships of police, customs officials, health regulators, public health entities, health care providers, the private sector, and researchers to develop methods to address counterfeit medicines (Interpol, n.d.). Interpol's strategy builds upon existing enforcement operational networks and multisector cooperative mechanisms to facilitate communication and information exchanges and disrupt organized crime networks (Interpol, n.d.). It also specifically focuses on illicit online pharmacies, a growing source of counterfeit medicines (Interpol, 2011).

Interpol partners with multiple stakeholders including the WHO, the Permanent Forum on International Pharmaceutical Crime, PSI, and the International Federation of Pharmaceutical Manufacturers and Associations in its operations (Interpol, n.d.). Interpol and its partners have employed successive multidisciplinary, multilateral, and multisector enforcement actions against dangerous physical and Internet counterfeit medicines networks. These include Operation Pangea I-V (aimed at illegal Internet sales), Operation Mamba I-III (enforcement against transnational organized crime in Eastern Africa), Operation Storm I-II (Southeast Asia), and Operation Cobra (Western Africa). Interpol also engages in consumer outreach, highlighting risks of online pharmacies (Interpol, n.d.).

However, Interpol is not a UN-specialized agency and does not have normative powers to erect treaty instruments. Further, it is heavily reliant upon voluntary contributions to fund operations, which may lack adequate transparency. Acting primarily as a global law enforcement entity, Interpol also lacks the necessary public health technical expertise to engage in the assessment of the health impacts of counterfeit medicines. Based on these limitations it is clear that Interpol will need to continue to partner with other organizations/institutions in order to inform its field-based operations.

Interpol differs from other IOs in its focus on law enforcement activities and prosecutions. Hence, Interpol is in many ways the implementation arm of coordinated efforts, although it also engages in capacity building and knowledge sharing. Hence, Interpol will play a crucial role in combating counterfeit medicines, but needs its operations to be supported and informed by other IOs that have normative functions with established formal global governance mechanisms.

World Customs Organization (WCO). The WCO is an independent intergovernmental organization established in 1952 to enhance customs' effectiveness and efficiency. The WCO represents 179 global customs administrations processing approximately 98 percent of all world trade (WCO, n.d.). Given the challenges of porous borders and the importance of customs processing and trade inspections in trafficking of counterfeit medicines, WCO has recently become a key partner for this issue.

WCO efforts against counterfeit medicines include the global Container Control Programme (CCP). Established in 2006, CCP is a joint WCO-UNODC initiative to monitor the movement of cargo shipped by sea. In 2011, the CCP resulted in the seizure of 195 containers of counterfeit medicines and precur-

sor chemicals (UNODC, 2012b). In the first half of 2012, CCP led to the seizure of 19 containers with over 100 tons of fake tramadol, a narcotic-like analgesic, all originating in India but seized in West Africa (UNODC, 2012b).

The WCO also engages in the training of specialized joint customs and police port control units to better detect and seize counterfeit medicines (UNODC, 2012b). Under a diplomatic cooperative agreement, CCP has 28 operational port control units across 14 countries and is receiving increased interest from the private sector (UNODC, 2012a). WCO also engages in a collaborative relationship with the Universal Postal Union (UPU) to prevent mailing of counterfeit medicines (UPU, 2010).

In 2010, WCO signed the Cotonou Declaration (a Chirac Foundation initiative calling for the development of anti-trafficking training and systems) to show its commitment to combating the increased trade in dangerous counterfeit medicines (Chirac Fondation, 2009). Consistent with this commitment, WCO customs enforcement activities have included Operation VICE GRIPS 2, which employed risk analysis, detection of fraud vectors, and utilization of technology solutions and partnerships, with support from the Institute of Research against Counterfeit Medicines as well as the private sector (WCO, 2012). This operation led to the seizure of more than 82 million doses of dangerous illicit medicines across 16 African countries in October 2012 (WCO, 2012). The seizures included some $40 million in counterfeit anti-malarial drugs, antibiotics, contraceptives and other medicines, all capable of exposing patients to harm through fake or ineffective ingredients (WCO, 2012).

However, WCO has limitations similar to Interpol in that its operations are generally isolated to customs and trade and it does not have normative functions or formalized governance structures. Its programs are also relatively new, and address all forms of counterfeit products, not only medical products, which may prove controversial in the debate regarding IPR enforcement.

Nevertheless, WCO, through its unique sentry role at political and trade borders, is another tool in the global counterfeit medicines strategic effort. Further, its risk and IT profile experience provide additional strategic advantages to combat counterfeit medicines.

Governance Instruments

Medicrime Convention. Diplomatic treaties provide an alternative and/or parallel GHD approach to combat counterfeit medicines. One key effort is the CoE's attempt to develop its own counterfeit medical products regulatory regime through the Medicrime Convention.

Because parallel trade in the European Union (EU) allows for the free flow of goods across borders, EU regulatory and public health agencies have additional challenges when combating trade of counterfeit medicines (Liang, 2006). Consequently, European bodies, including the CoE, European Parliament, European Commission, the European Medicines Agency, and Europol, have partnered to enact the first treaty criminalizing intentional manufacturing, supplying, and trafficking of counterfeit medicines, including the falsification of related documents, as well as unauthorized activities associated with manufacturing, trafficking, diversion/theft, or sale and intentionally bypassing regulatory requirements (i.e., "similar crimes") (Europe, 2011).

CoE's Medicrime is not limited to pharmaceuticals, but also includes medical devices, active pharmaceutical ingredients, and other illegal medicinal products. Perhaps most importantly, it contains specific language that it "does not seek to address issues concerning intellectual property rights," does

not criminalize generics that have been authorized for marketing by a competent authority, and does not criminalize non-intentional breaches of quality norms (Europe, 2011).

The Medicrime Convention was designed to provide health care agencies and law enforcement representatives with a common legal foundation to prevent and prosecute Medicrime-related offences (Europe, 2011). It is open to all EU member states but is attempting to gain wider adoption among non-EU member states. Medicrime requires a minimum of five countries, at least three of which must be CoE members, to ratify the treaty through domestic legislation. At present, although there are 21 signatories to the treaty, only one (Ukraine) has ratified it (Europe, n.d.).

Although any country may become a Medicrime signatory, current adoption appears to be European-focused, with only Guinea, Morocco and Israel as non-EU member-state signatories (Europe, n.d.). The Medicrime Convention has the potential to emerge as a broader international treaty instrument; however, current lack of ratification by existing signatories, failure to engage a larger number of non-EU member states, and the lack of input from non-member countries/entities during treaty negotiations may limit its global applicability. However, it may provide a roadmap for future, wider multilateral GHD efforts, particularly within the debate over safe access and IPR considerations.

United Nations Convention against Transnational Organized Crime (UNTOC) and related conventions. Adopted in November 2000, UNTOC is the primary international instrument combating transnational organized crime. It empowers UNODC to address serious crimes, such as human trafficking, smuggling, and illicit manufacture and trafficking of dangerous materials. The convention includes 174 member states, giving it near universal adoption. Through UNTOC, UN member states commit themselves to enact robust domestic laws against organized crime and collaborate in the fight against criminal networks (UNODC, 2012b).

Given its global adoption, UNTOC has a broad legal framework to facilitate investigation, law enforcement and multi-stakeholder cooperation to combat the global counterfeit medicines trade. The language of the instrument is sufficiently broad to cover the crime of manufacturing and trafficking counterfeit medicines. These activities represent "serious crimes" perpetuated by transnational organized crime groups and involve money laundering, corruption, and other illegal activities (UNODC, 2004). With its multidisciplinary and multisector governance systems using uncontroversial, existing, internationally binding law, UNODC is uniquely poised to facilitate information sharing and collection, law enforcement cooperation, training and technical assistance. Indeed, Resolution 20/6 underscores its central role in creating a foundation for future law enforcement and judicial capacity against counterfeit medicines.

Further, international agreements, such as the Medicrime Convention if appropriately ratified, could legally complement UNTOC. Moreover, UNODC, through UNTOC, could also provide needed expertise for law enforcement efforts against global counterfeit medicines using existing mechanisms. Other creative applications of UNTOC (e.g., the marking and tracking of firearms) may also be considered in the battle against the trade and transport of counterfeit medicines.

In addition to its power under UNTOC, UNODC has oversight responsibility for controlled substances. For example, the UNODC operates the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, and the UN Convention against Illicit Traffic in Narcotic Drugs and Psycho-

tropic Substances (collectively Single Convention and Protocols). While, these international treaty instruments address illicit controlled substance drugs with abuse potential, rather than counterfeit medicines generally (UNODC, n.d.), they could be used in conjunction with UNTOC to address counterfeit controlled substances.

Though representing existing treaties, the Single Convention and Protocols are limited in applicability to narcotic and psychotropic substances contained in treaty schedules. Hence, non-scheduled drugs that are subject to counterfeiting would not be subject to its requirements. Further, these instruments provide certain exemptions for medical and scientific use that may be exploited by criminal actors.

Basel Convention. Adopted in 1992, the Basel Convention was signed by 178 parties to address international hazardous waste management and movement under the UN Environment Programme (UNEP). Though not specifically targeted at counterfeit medicines, Annex I of the treaty specifically includes "wastes from the production and preparation of pharmaceutical products" and "waste pharmaceuticals, drugs and medicines" (UNEP, n.d.). Hence, precursor chemicals, active pharmaceutical ingredients, and finished pharmaceutical products themselves are all subject to the treaty.

Criminal organizations engaging in the illicit manufacturing and trans-boundary trade of dangerous counterfeit medicines may not appropriately generate, store, transport or dispose of counterfeit medicine products in an environmentally sound manner as the convention requires, and are, consequently, guilty of illegal traffic and dumping of hazardous wastes under the Basel Convention. Given that the convention and requirements for environmentally sound management have direct relevance to the prevention and control of counterfeit medicines, UN member states and other IOs should actively pursue inclusion of programs combating counterfeit medicines into the Basel Convention.

In addition, the Basel Convention, although driven by UN member states, has emphasized broader stakeholder engagement in its technical working groups to strengthen implementation and cooperation of the Basel Convention (UNEP, 2013). However, the Basel Convention has certain limitations, most importantly a lack of adequate enforcement mechanisms. It also does not specifically ban the illicit trade of hazardous waste exports. It also utilizes requirements for notice, consent and tracking that may have limited applicability to criminal activities. Given these limitations, application of the Basel Convention may only be beneficial when other laws and enforcement mechanisms have been exhausted.

Other Governance Policy Proposals

Existing governance proposals vary widely in scope and operation. Proposed governance mechanisms to combat counterfeit medicines vary from internationally binding hard law, enhanced governance of existing IO efforts, and development of international soft law guidance.

A proposal that has been widely considered in the international community is the establishment of an internationally binding instrument on poor quality and unsafe medicines that endanger public health (Attaran et al., 2012). The treaty would create an international legal regime that would provide agreed-upon definitions of illegitimate medicines, mandate cooperation among states to investigate and enforce against this criminal trade, set global standards for prevention and control, provide financial and technical assistance for drug regulatory systems in poorer countries, and specifically

create a new public health law that would make it illegal to trade in illegitimate medicines (Attaran et al., 2012). This proposal could also potentially address the "counterfeit" definition problem by attempting to legally define different types of illegitimate medicines by treating falsified (e.g., deliberate, intentional fraud of a criminal nature) and substandard (e.g., unintentional or negligence errors or regulatory nature) differently to avoid controversy (Attaran et al., 2012). Most importantly, it would establish clear international binding rules and norms and if pursued and would be only the second public health treaty after the WHO Framework Convention on Tobacco Control.

Although laudable, creation of a new treaty is not without difficulties. The definitional, governance, and existing member-state differences provide barriers to a treaty's ability to garner consensus, support and implementation in domestic law. Given the WHO IMPACT experience, it may prove difficult for a public health treaty addressing counterfeit medicines to be administered by the WHO. Further, treaty negotiations are expensive, and states may fail to appropriately ratify or implement treaty-based obligations.

Another proposal advocates for enhanced governance mechanisms between IO programmatic activities of the WHO, UNODC and Interpol (Mackey et al., 2012). The proposal recommends that these IOs should concentrate on their respective domains of expertise. This would include WHO focusing on public health aspects of improving access to safe medicines, strengthening health systems and surveillance systems, and conducting needed research on the epidemiology of counterfeit medicines (Mackey et al., 2012). In conjunction, UNODC would handle policy and enforcement aspects of the organized crime element of the trade, and Interpol would directly engage in law enforcement actions and capacity-building exercises on the ground.

This particular proposal emphasizes greater coordination between existing stakeholders and proposes establishing a new governance mechanism between the IOs to facilitate this cooperation. However, challenges associated with mobilizing coordination and cooperation of different IOs remains difficult. International organizations, such as the WHO, may not actively participate in newly proposed governance structures given existing mechanisms/mandates in place such as the MSM. Further, a funding mechanism to support such governance and rules to ensure transparency and appropriate stakeholder participation would need to be developed.

Finally, a recent US IOM report on falsified and substandard drugs contained a number of recommendations primarily focused on national drug regulatory strengthening, better surveillance and data collection, application of existing rules and norms on procurement and access to safe medicines, harmonization, and detection technology development (IOM, 2013). Also contained in this report was a proposal for a governance mechanism of voluntary soft law described as an international code of practice to encourage international action against falsified and substandard drugs (IOM, 2013). Specifically, the recommendation suggests partnership between the WHA, UNODC, and WCO to develop and institute a code of practice for surveillance, regulation, and law enforcement to prevent and respond to medicine-quality issues (IOM, 2013). As soft law, a code of practice could potentially be implemented quicker and at lower cost than other proposals.

This set of recommendations, although involving UNODC and WCO with their multi-stakeholder activities, also relies on the WHA—subject to the same potential barriers faced by the WHO. As discussed previously, current governance structure limitations of the WHO/WHA may limit non-member-state participation and may not adequately mobilize necessary resources. Furthermore, as a substantive

matter, soft law, such as a code of practice, is non-binding and lacks enforcement mechanisms. Moreover, crucial stakeholders, such as industry and patient groups, are excluded from the process, and could refuse to participate in these non-binding mechanisms.

The variety of policy proposals attempting to address the dangerous counterfeit medicine trade highlights the diversity of views and opinions on the subject. Each would have its own strengths, weaknesses and associated costs if pursued diplomatically.

Discussion

This study indicates that the problem of counterfeit medicines is a multi-faceted and complex problem that needs to engage multidisciplinary and multi-stakeholder groups in public health, patient safety, criminal prevention, law enforcement, manufacturing, trade and customs, and the environmental community. Hence, governance structures attempting to address counterfeit medicines that lack adequate representation, participation and active engagement from these diversely situated groups may limit needed global consensus building, collaboration, cooperation and leveraging of resources to effectively address the complex issues surrounding the global counterfeit medicines trade.

The IMPACT case study is an important one. Though IMPACT was successful in engaging a coalition of stakeholders who could provide the necessary technical expertise, information sharing mechanisms, capacity building and law enforcement activities, its success was severely limited by the WHO's governance limitations, in particular, its inability to overcome member-state differences. Yet, given the complexity of the global drug supply chain, the need for better data collection from all sources, and the need for formalized multi-stakeholder governance structures as advocated in fundamental principles of global health governance, it appears that alternative governance solutions need to be assessed.

While all of the IOs reviewed have competencies to contribute, UNODC is uniquely poised to lead the fight against counterfeit medicines given its status as a specialized agency of the UN with existing normative powers and a mandate to fight counterfeits. These advantages can enable it to avoid contentious disagreement between member states by focusing on the criminality of the trade. By focusing on the criminal activities and enforcement, UNODC can align differences in interests that have previously focused on more contentious issues such as medicines access and IPRs. Consequently, UNODC should actively engage in the development of a multilateral, multi-stakeholder governance mechanism in the global fight against counterfeit medicines. Moreover, UNODC support under Resolution 20/6, applicability of UNTOC, and other well-accepted, ratified treaties uniquely situates it to immediately engage and actively promote GHD on the counterfeit medicines issue.

UNODC's existing pathways of coordination and partnership with IOs such as the WHO, Interpol and WCO would allow efficient allocation of resources to avoid overlapping efforts, improve areas such as education, consumer outreach, and capacity building, and potentially improve data collection. This would also allow the WHO to maintain its crucial role as the premier international public health organization, and focus its efforts on analysis of the public health implications of counterfeit medicines in the drug supply chain, methods to change behaviour to avoid exposure/consumption, activities to promote access and reduce reliance upon pharmaceuticals, and approaches to strengthening public health and drug regulatory infrastructures. Similarly, Interpol and WCO could continue to focus efforts on field-based operations and technical capacity building, informed by UNODC leadership and public health data from the WHO.

Conclusion

Dangerous counterfeit medicines have been identified as a global concern as early as the first century, yet more than a millennia later limited progress has been made (WHO, 1999). Current diplomatic and governance efforts are fragmented across a multitude of different stakeholders. Though cooperation between international organizations has commenced, lack of a formalized multi-stakeholder governance mechanism to leverage resources and technical expertise persists. Instead, shared values and goals embodied in global health diplomacy should be applied by the global community towards solutions to ensure equitable access to safe medicines, while at the same time combating this form of transnational organized crime. Only through shared diplomatic efforts and sound governance can progress on combating counterfeit medicines be achieved.

Table 1

INSTITUTION	NAME	MECHANISM	ADVANTAGES	WEAKNESSES
World Health Organization (WHO)	*International Medical Products Anti-Counterfeiting Taskforce (IMPACT)*	Multi-sectorial collection of a voluntary group of stakeholders comprised of some 40 public and private sector actors including member states, organizations, institutions, law enforcement agencies, other agencies and associations, and manufacturers. Activities organized into five subject-based working groups.	Includes broad participation from both public and private sector members and can act as a forum for collaboration and coordination on specific subject areas targeted at combating the counterfeit drug trade.	Viewed by certain member states as inappropriately engaged in IPR enforcement and effectively no longer has WHO support/participation.
	WHO New Member State Mechanism (MSM)	Voluntary mechanism open to all member states. Governed by steering committee including representation from WHO regional blocks.	Has WHO and member-state support with objective of establishing global norms, standards, and procedures for addressing SSFFC.	New mechanism that has received criticism for lack of transparency and inclusion. Does not actively engage non-member stakeholders.
UN Office of Drugs and Crime (UNODC)	*Commission on Crime Prevention and Criminal Justice (CCPCJ) Resolution 20/6*	Resolution by CCPCJ establishing member-state support for UNODC engagement in combating transnational organized crime of fraudulent medicine trade.	Allows for collaboration with other organizations and provides member-state support for UNODC technical assistance, capacity building, and research on fraudulent medicines not previously formalized.	Recent resolution. Not a formal governance mechanism with enduring operation capabilities and limited in scope of requests/implementation.

	United Nations Convention against Transnational Organized Crime (Palermo Convention)	International treaty adopted by 174 member states to combat transnational organized crime.	Near universal adoption by member states. Broad enough to be applied to transnational organized crime of fraudulent medicines. Contains important enforcement and cooperation mechanisms for law enforcement and other stakeholders. Can also complement other counterfeit drug treaty instruments.	Structurally limited in applicability to transnational organized crime. Though fraudulent medicines trade is largely a transnational, not domestic-only, crime.
	Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, and the UN Convention Against Illicit Traffic in Narcotic Drugs	Set of international treaty instruments to address illicit controlled substance drugs with abuse potential informed by recommendations by the WHO.	Well-established international treaties that contain strong enforcement provisions against illicit traffic and trade of controlled substances.	Limited in applicability to narcotic and psychotropic substances contained in schedules. Non-scheduled drugs that are counterfeited would not be subject to treaties. Also has exemptions for medical and scientific use that may be exploited by criminal actors.
Interpol	*Interpol Operations: Pangea, Mamba, Storm and Cobra*	Multi-agency global field operations coordinated by Interpol.	Direct multidisciplinary enforcement actions targeted against physical and Internet counterfeit drug networks.	Primarily an enforcement mechanism with limited validated data collection. Unclear effectiveness.

World Customs Organization (WCO)	*Operation VICE GRIPS 2 and Global Container Control Program* (CCP)	In partnership with IRACM and UNODC, provides border and customs monitoring and seizure of counterfeit medicines.	In partnership with IRACM (VICE GRIPS2) and UNODC (CCP), provides mechanisms for field operations and capacity building in customs enforcement against counterfeit drugs. Multisectorial in operation.	Operations are isolated and have not been instituted as formalized programs. CCP program is new and addresses all forms of counterfeit products, not only medical products.
Council of Europe (CoE)	*Medicrime Convention*	First international treaty that criminalizes activities associated with supply/trafficking of counterfeit medicines.	Regional treaty with 21 signatories but open globally to other countries. Not limited to pharmaceuticals applies to other medical products. Specifically does not address issues concerning IPRs.	Lacks sufficient state participation for ratification. Has already been negotiated, which may limit future participation from larger non-member states.
United Nations Environmental Programme (UNEP)	*Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal*	International treaty that addresses issue of international hazardous waste management and movement.	International binding treaty with wide adoption by 178 parties. Annex specifically includes pharmaceutical products and waste as categories to be controlled. Can apply also to API and precursor chemicals.	Lack of adequate enforcement mechanisms. The United States is not a participating country. Limited in enforcement applicability to wastes and disposal where criminal laws may be more effective.

Current Policy Proposals	*International Treaty on Counterfeit Medicines*	Policy proposal for international treaty criminalizing the illegitimate medicines.	Would act as an internationally binding instrument. As proposed would establish agreed-upon definitions, establish public health law powers, establish global standards/norms, and provide financial and technical assistance for drug regulatory systems.	Challenges and costs of negotiating and implementing a global treaty. State-based political barriers of global consensus on "counterfeit" medicines. Would be only the second public health treaty erected by the WHO after FCTC.
	WHO-UNODC-Interpol Governance Mechanism	Policy proposal to establish a governance mechanism between WHO, UNODC and Interpol.	Would allow respective organizations to focus on subject area expertise of public health (WHO), policy and law capacity building (UNODC) and field enforcement (Interpol) for dangerous counterfeit medicines.	Requires coordination and cooperation of different international organizations where no formalized mechanism currently exists. International organizations (IOs) may not actively participate given their own current initiatives.
	Institute of Medicines Code of Practice	Technical report proposal for partnership between the WHA, UNODC and WCO to establish non-binding code of practice to encourage international action against falsified and substandard drugs.	Soft law mechanisms are relatively low cost and can be implemented more quickly than binding instruments.	Soft law governance mechanisms are non-binding on participants and would lack enforcement mechanisms. Crucial stakeholders, if excluded, may not adhere to code.

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