



## Transnational Cooperation among ASEAN Member States to Fight Against Counterfeit Medicines

Nwe Si Win,<sup>1</sup> Aung Win Tun,<sup>2</sup> and Thammarat Marohabutr<sup>3\*</sup>

<sup>1,2</sup>ASEAN Studies for Sustainable Development Program, Faculty of Graduate Studies,  
Mahidol University, Nakhon Pathom, Thailand

<sup>3</sup>Faculty of Social Sciences and Humanities,  
Mahidol University, Nakhon Pathom, Thailand

\*Corresponding author, E-mail: thammarat.mar@mahidol.ac.th

### Abstract

This study examines the widespread distribution of counterfeit medicines smuggling across Southeast Asia and the policy responses of the Association of Southeast Asian Nations (ASEAN) to eliminate it. The ongoing and increasing counterfeit medicines trade is a transnational public health problem that is difficult to tackle by national governments alone due to the manufacturing of counterfeit medicines in China, India, and Pakistan, as well as within Southeast Asia by organized criminal groups and their international distribution through illicit channels. The problem identified by this research is that very few studies analyze ASEAN's policies on this matter or its capacity to lead and implement regional programs to eliminate counterfeit medicines. This study explores the extent of counterfeit medicines in the Southeast Asia region and analyzes existing regulatory, law enforcement, and healthcare policies of ASEAN to respond to counterfeit medicines issues.

A qualitative documentary methodology using the Qualitative Content Analysis (QCA) framework was employed to code and analyze documents collected from ASEAN, international organizations, and national news outlets. The findings add to the body of research by suggesting that ASEAN's policies are inadequate for fighting counterfeit medicines smuggling as they are largely regulatory in nature and ignore the healthcare and law enforcement actions needed to eliminate the transnational criminal networks that produce and distribute the counterfeit medicines. Additionally, ASEAN lacks the financial and human resources as well as the decision-making authority to enable sustainable transnational cooperation among member states on this issue.

**Keywords:** *Transnational Cooperation, ASEAN, Counterfeit Medicines Smuggling, Regional Policy.*

### 1. Introduction

Counterfeit medicines are well known in Southeast Asia for causing various health problems. Consumption of counterfeit medicines can lead to increased drug resistance, untreated diseases, and even death, all of which, in turn, create financial burdens for governments and reduce public trust in state health services. According to the World Health Organization (WHO), counterfeit medicines are medicines that have been “*deliberately and fraudulently mislabeled*” and produced with insufficient amounts of correct ingredients, wrong ingredients, or no active ingredients (World Health Organization, 2010). Some counterfeit medicines may contain dangerous ingredients such as mercury, arsenic, rat poison, or cement (International Criminal Police Organization (INTERPOL), n.d.). According to a 2019 study by the United Nations Office on Drugs and Crime (UNODC), Southeast Asian consumers, most of whom come from mostly low- and middle-income backgrounds, spend a worrying USD 520 million to 2.6 billion per year on counterfeit medicines (United Nations Office on Drugs and Crime (UNODC), 2019a).

[224]



For most member states of the Association of Southeast Asian Nations (ASEAN), Southeast Asia's leading regional institution, counterfeit medicines are a problem they do not have the capacity to eliminate on their own. Criminal syndicates operate transnational smuggling routes across national borders and control the manufacture and distribution of counterfeit medicines in many Southeast Asian countries (United Nations Office on Drugs and Crime (UNODC), 2013). They exploit weak regulations and poor law enforcement systems in almost all Southeast Asian countries to import counterfeit medicines from illicit pharmaceutical producers in China, India, and Pakistan or to manufacture the medicines inside Southeast Asia, which are then sold and distributed through a variety of channels (International Criminal Police Organization (INTERPOL), 2020). A combination of socioeconomic and political factors, namely poverty, poor drug safety surveillance and monitoring, low availability of affordable medicines, and weak international cooperation, contributes to the ongoing expansion of the counterfeit medicines trade in the region.

Despite the seriousness of this problem, there has not been much research into the effect of counterfeit medicines on ASEAN as well as ASEAN's policies on this matter. A review of the available literature found very few studies that provide a baseline understanding of the regional counterfeit medicines trade in Southeast Asia. There is also startling little scholarship on how ASEAN fosters collaboration among its member states to fight against the trade. Until the early 2010s, most research conducted on transnational smuggling in Southeast Asia was either on illicit drugs or human trafficking, most probably due to the global attention on combating narcotics production and human trafficking in the Golden Triangle between Myanmar, Laos, and Thailand. (Dupont, 1999; Emmers, 2003; Emmers, 2007; Sundram, 1999). The available baseline studies on counterfeit medicines smuggling in Southeast Asia were conducted largely by either United Nations (UN) bodies or affiliated international organizations, such as the Organization for Economic Cooperation and Development (Organization for Economic Cooperation and Development/ European Union Intellectual Property Office, 2020; United Nations Office on Drugs and Crime (UNODC), 2019a; United Nations Office on Drugs and Crime (UNODC), 2019b). These reports mainly provide an overview of counterfeit medicines' production and distribution networks, and seizures of counterfeit medicine stocks by National Medicines Regulatory Authorities (NMRAs), in Southeast Asia.

Early research on ASEAN transnational cooperation on counterfeit medicines appeared in the late 2000s and was discussed within the context of ASEAN's regional mechanisms for combating transnational crime (Emmers, 2007; Lamy & Phua, 2012; Lamy & Liverani, 2015). These researchers argued that ASEAN institutions were the most effective platforms for encouraging dialogue and fostering cooperation between Southeast Asian countries on tackling counterfeit medicines smuggling. They argued that ASEAN member states have been taking collaborative regional action against transnational crime since the 1970s. However, despite this focus on transnational crime, the early literature showed that actual action by ASEAN on counterfeit medicines had been largely lacking. Research by Nwokike et al. (2013) found that ASEAN had only created a regulatory body, the Pharmaceutical Product Working Group (PPWG), to regulate medicines in the region, share information on detected counterfeit medicines through its post-marketing alert system, and reduce trade barriers to pharmaceutical production and trading.

While the available research suggests that ASEAN may be the most effective platform for transnational cooperation in Southeast Asia, scholars like Emmers (2003, 2007) argue that ASEAN lacks the ability to take concrete action on transnational crime issues because of the interference of ASEAN's

[225]



fundamental principles: non-interference in the domestic affairs of other states and consensus decision-making. Lamy and Phua (2012) add that ASEAN member states have more interests in national sovereignty than regional security.

The literature review revealed that there were gaps in ASEAN's leadership and its regulatory, healthcare and law enforcement policies on counterfeit medicines. This study aims to fill the gaps in the literature by investigating the scale of counterfeit medicines production and distribution in Southeast Asia and by exploring the role of ASEAN in eliminating the counterfeit medicines trade.

## 2. Objectives

1) To explore the transnational nature of counterfeit medicines smuggling in Southeast Asia, particularly how they are distributed in the region and what impacts they have on communities and national public health systems

2) To analyze the existing regulatory, law enforcement, and healthcare policy priorities of ASEAN in its response to the counterfeit medicines smuggling problem

3) To assess the ability and sustainability of ASEAN's regional cooperation mechanisms in eliminating the counterfeit medicines trade in Southeast Asia

## 3. Materials and Methods

This qualitative study was performed using documentary research methodology. A qualitative study was selected for this research because it allows the researcher to enquire and examine features of the social world. Relevant documents for this study were collected from a wide range of Southeast Asia-specific sources, including ASEAN's online content repository, the databases of Southeast Asian public health ministries and regulatory agencies, the content databases of the UN, ASEAN-focused newspapers and news websites, and academic journals. The search covered a ten-year period from 2013 to 2023, which was when ASEAN published its policies on counterfeit medicines smuggling and most of the relevant literature was written. An English language-only restriction was applied to the search results as the working language of ASEAN and its affiliated international organizations is English.

Online searches using combinations of key search terms related to ASEAN and counterfeit medicines were used to identify the relevant documents for this study. During the data collection phase, particular emphasis was given to the collection of regulatory, law enforcement, and healthcare policy documents produced by ASEAN, ASEAN member states, its institutions, and its partner organizations regarding action against counterfeit medicines. These included meeting minutes, reports, conference notes, ministerial statements, strategic plans, and action plans. A similar emphasis was placed on the collection of articles from academic and online media sources that critically analyze ASEAN's policies regarding the counterfeit medicines issue.

The coding and analysis of the collected data were conducted using the Qualitative Content Analysis (QCA) framework. A preliminary coding framework for each research objective was first developed using a sample of the five most relevant documents identified during the coding process. The sample codes identified by this open coding process were then used in a focused coding process to summarize and categorize the remaining documents to produce the final coding framework for analysis. The coding process aided the



discovery of themes and connections between different pieces of raw data and allowed for the holistic assessment of the codes to identify broad patterns in the transnational cooperation efforts of ASEAN in tackling counterfeit medicines smuggling.

#### 4. Results and Discussion

The data gathered was organized and presented under three overarching themes emerging from the documents. The first relates to the rapidly changing nature of counterfeit medicines production and distribution in Southeast Asia. The second relates to the inadequate scope and voluntary nature of ASEAN's policies to facilitate cooperation within ASEAN to tackle this public health emergency. The third theme explores the role of the ASEAN Secretariat and its anti-trafficking mechanisms in tackling counterfeit medicines.

##### 4.1 *The Multifaceted Problem of Counterfeit Medicines Smuggling in Southeast Asia*

The findings revealed that Southeast Asia's counterfeit medicines smuggling trade is multifaceted. At its core, it is an economic crime governed by the principles of supply and demand, where organized criminal syndicates and unethical pharmaceutical companies produce and distribute counterfeit medicines to exploit the demand for affordable medicinal alternatives from low- and middle-income customers in Southeast Asia (Boyd, 2017; International Criminal Police Organization, 2014; United Nations Office on Drugs and Crime (UNODC), 2019a). A recurring finding in the data is that people, especially those from low socio-economic backgrounds, do not seek out counterfeit medicines but often give in to the temptation of purchasing and consuming illegal drugs when they are exposed to them because of their extremely cheap prices (The Nation Thailand, 2021).

The counterfeit medicines smuggling trade transcends national jurisdictions and boundaries; counterfeit medicines flow into Southeast Asia from countries outside the region, namely China, India, and Pakistan and increasingly between neighboring countries since 2017 when organized criminal groups moved production of counterfeit medicines to Southeast Asia following crackdowns and stricter pharmaceutical regulations in China, India, and Pakistan (Redfearn, 2023; Boyd, 2017). Secret counterfeit medicine labs have appeared in Southeast Asian countries like Malaysia, Indonesia, and the Philippines, where counterfeit pharmaceutical products are manufactured. These counterfeit products are then exported to neighboring countries for packaging and distribution (United Nations Office on Drugs and Crime (UNODC), 2019b). Some mainstream pharmaceutical companies deliberately modify medicinal compounds or sell expired medicines to cut costs, thus contaminating legitimate pharmaceutical supply chains with counterfeit medicines (United Nations Office on Drugs and Crime (UNODC), 2013). This often happens with the collusion of corrupt and unethical pharmaceutical executives and government officials (Lam, 2022; Kuanpoth, 2017). The findings showed a worrying trend of counterfeit over-the-counter paracetamol in the Philippines and vaccines and cough syrup in Indonesia. Although no findings indicated that Singapore, the only high-income country in Southeast Asia, has domestic production of counterfeit medicines, there were findings showing that it is becoming a major transit and target country for counterfeit sexual enhancement, hormones, and beauty products (CNA News Asia, 2020).

Sales of counterfeit medicines are increasing rapidly as a result of the public's growing reliance on popular e-commerce platforms, social media platforms, and messaging sites for buying goods and essential items since the start of the COVID-19 pandemic (A Joint Effort Between EU-ABC & TRACIT, 2020). More

[227]



and more people are being exposed to listings and advertisements of cheaply priced counterfeit medicines, many of which are falsified prescription medicines (Boyd, 2017). Consumers unknowingly buy them, thinking they are genuine medicines offered at lower prices. When people become severely ill or die from taking counterfeit medicines, the public loses trust in national governments and healthcare systems to protect them (Syakriah, 2023).

During the course of the research, no full-scale Southeast Asia-focused study on the types of counterfeit medicines, their origins, their public health impacts, and the criminals running the trade were identified. It appears that both ASEAN authorities and officials from international organizations such as the UNODC, INTERPOL, and OECD do not have accurate and current data on the scale of the counterfeit medicines trade in Southeast Asia (United Nations Office on Drugs and Crime (UNODC), 2013; United Nations Office on Drugs and Crime (UNODC), 2019a; OECD and European Union Intellectual Property Office, 2020; The ASEAN Post Team 2019). Most of the available data is fragmented; each news article or official source provides insights on a specific aspect of the Southeast Asian counterfeit medicines trade only.

#### ***4.2 The Misalignment of ASEAN's Anti-Counterfeit Medicine Policies***

The lack of an official ASEAN baseline study on the transnational counterfeit medicines trade in Southeast Asia may explain why ASEAN's policy response to the issue seems to be misaligned with the reality on the ground. Despite public knowledge that the counterfeit medicines trade is operated by transnational criminal syndicates and drains healthcare resources, ASEAN has so far produced only one action plan to combat counterfeit medicines. The June 2021 ASEAN Action Plan on Substandard and Falsified Medicines provides a three-step approach to prevent, detect, and respond to the counterfeit medicines trade using a range of information-sharing, regulatory harmonization, and public advocacy initiatives (Association of Southeast Asian Nations (ASEAN), 2022).

A close analysis of the plan, which has not yet been implemented because of a lack of funding and human resources, revealed that it lacks law enforcement-related objectives or initiatives to investigate and prosecute the organized transnational criminal groups that are responsible for the counterfeit medicines trade in the region. All of the counterfeit medicine-related ASEAN documents collected for this research do not contain any acknowledgement that the transnational counterfeit medicines smuggling problem is, by nature, an economic crime. Instead, it is portrayed as a regulatory problem that is caused by poor regulation of national and regional pharmaceutical supply chains and inequitable access to healthcare.

ASEAN's strategy to prevent counterfeit medicines from entering pharmaceutical supply chains relies mainly on information sharing (Association of Southeast Asian Nations (ASEAN), 2022). ASEAN seeks to increase real-time knowledge sharing and reporting on counterfeit medicine threats between national medicines regulatory and law enforcement agencies with an increase in regional counterfeit medicine awareness campaigns. However, ASEAN's strategy appears inadequate because there is no focus on engaging with issues on the supply side of the counterfeit medicines problem, particularly the import of counterfeit medicines from China, India, and Pakistan or the development of law enforcement strategies to prosecute organized criminal groups who manufacture and distribute the counterfeit medicines. Mitigating the flow of counterfeit medicines into Southeast Asia's pharmaceutical supply chains will likely require deterrence measures in the form of strict customs regulations and, strong penalties, and dedicated staff to implement them.



Similar to its prevention strategy, ASEAN's strategy to detect counterfeit medicines relies primarily on information sharing. The AHC 3 Action Plan for Combating Substandard and Falsified Medicines outlines steps to foster greater collaboration on the sharing of rapid alerts of suspected counterfeit medicines within ASEAN and with the WHO (Association of Southeast Asian Nations (ASEAN), 2022). This includes assigning focal persons in each ASEAN member state to report counterfeit medicines to ASEAN's Post-Market Alert System and the WHO Global Surveillance and Monitoring System to allow National Medicines Regulatory Authorities to rapidly recall counterfeit medicines that have been detected in another country. It also includes strengthening regional collaboration on pharmaceutical testing through the ASEAN Pharmaceutical Testing Laboratory Committee to conduct regular inspections and post-market surveillance of medicinal products in legitimate supply chains.

While these are seemingly beneficial initiatives, they do not provide specific details on how different types of counterfeit medicines available in Southeast Asia, of which there are many, would be detected in various channels. The findings show that many middle- and low-income ASEAN member states already struggle to monitor and inspect their country's drug outlets and pharmaceutical supply chains for counterfeit medicines (Megget, 2016; Gooch & Bormann, 2015). Regulating the online sale of medicines would be an even more overwhelming task, given how fast online transactions move. A comprehensive approach, perhaps even a separate action plan, for monitoring and preventing online sales of counterfeit medicines through collaborations between law enforcement and regulatory authorities will likely be needed to tackle this growing problem.

ASEAN's strategy to respond to counterfeit medicines smuggling focuses more on helping member states develop their solutions to the problem than setting the foundations for cooperative and cohesive healthcare, law enforcement, and regulatory strategy for combating counterfeit medicines (Association of Southeast Asian Nations (ASEAN), 2022). It outlines three key areas for action: capacity building for National Medicines Regulatory Authorities, training for addressing the distribution or supply of counterfeit medicines via the Internet, and the application of national regulatory or criminal law sanctions to address the problem. Each policy initiative is intended to be implemented by individual member states, with guidance from ASEAN and its sectoral bodies. AHC 3 also plans to help National Medicines Regulatory Authorities standardize their laboratory testing, post-market inspection and surveillance, and pharmacovigilance capacities using the WHO Global Benchmarking Tool (Association of Southeast Asian Nations (ASEAN), 2022).

These initiatives suggest that ASEAN is helping to facilitate transnational cooperation among its member states, but only in a supporting role. There are no indications in ASEAN's policy documents that ASEAN plays an independent, lead role in formulating binding regulatory and legal frameworks for deterring the illegal production and distribution of counterfeit medicines, and combating the individuals and syndicates behind the trade. The responsibility of combating counterfeit medicines rests mainly with member states.

Notably, the AHC 3 Action Plan for Combating Substandard and Falsified Medicines contains almost no healthcare- or law enforcement-related policies. However, under its universal health coverage strategy, ASEAN does have plans to improve the supply of safe and affordable medicines in the region, which are included in the 2016 ASEAN Drug Security and Self-Reliance and 2021 ASEAN Vaccine Security and



Self-Reliance policy documents (Association of Southeast Asian Nations (ASEAN), 2022; Association of Southeast Asian Nations (ASEAN), 2019; Association of Southeast Asian Nations (ASEAN), 2020). Its goal to create a harmonized regional pooled pharmaceutical procurement mechanism among its member states, if successfully achieved, would indirectly disrupt the business model of organized criminal groups who want to flood the market with counterfeit medicinal products from China, India, Pakistan, and elsewhere.

#### ***4.3 The Nature of ASEAN's Approach to Transnational Cooperation in the Fight against Counterfeit Medicines***

A close look at the policy initiatives in AHC 3's action plan and work program on combating counterfeit medicines shows evidence that ASEAN designed the anti-counterfeit medicine policies to be achievable by all member states. All of the policy initiatives have a strong focus on information sharing between NMRAs and customs authorities. Information sharing is an important but simple goal that can be achieved by every member state, no matter their socioeconomic status or political situation, as it may require only existing personnel and very little funding.

The intense focus on information sharing suggests that during negotiations to develop the policies for combating counterfeit medicines smuggling, ASEAN used the institution's established consensus-based decision-making process to ensure that the policies did not challenge its member states' sovereignty. This observation is consistent with Acharya and Johnston's (2007) work, which found that regional institutions in the developing world are more likely to possess design features that preserve sovereignty than challenge it. ASEAN's strong focus on information sharing to combat counterfeit medicines is a safe, lowest common denominator goal that does not threaten any member state.

From one perspective, the simplicity of ASEAN's policies is a promising start for efforts to combat counterfeit medicines smuggling in Southeast Asia. ASEAN's cooperation on this issue will help member states establish communication channels among their NMRAs to discuss and collaborate on advocacy projects, information sharing on detected and suspected counterfeit medicines, and training programs on monitoring, surveillance, and inspection.

In the case of ASEAN, continuous dialogue and cooperation could gradually help make relations between ASEAN member states more cohesive and reliant on each other for technical assistance and much-needed information on counterfeit medicine producers and distribution channels. However, there is a limitation in advocating for this type of transnational cooperation. As discussed above, ASEAN may have agreed to focus on information sharing because it does not want to risk interference in the domestic politics of its member states. This finding relates to Leifer's (1998) argument that consensus and non-interference in the ASEAN way of decision-making is a conflict avoidance and management tool that allows member states to build cordial relationships with their neighbors while allowing them to preserve what matters most to them: sovereignty over their domestic politics. In their efforts to prioritize peace and friendliness in transnational cooperation, ASEAN may have avoided discussions on bolder action on counterfeit medicines smuggling, such as the establishment of an ASEAN task force that investigates and prosecutes criminal groups and corrupt government officials involved in counterfeit medicines smuggling. The emphasis on consensus risks keeping the scope of transnational cooperation on this issue was minimal and focused on the sovereignty concerns of national governments. At the same time, criminal groups exploit ASEAN's inaction to expand their counterfeit medicine businesses and profit off their citizens.



If the discussion above has confirmed anything, it is that ASEAN member states are the primary actors in anarchy. They maintain authority over ASEAN and utilize it to fulfill their interests, namely the interests of the governments leading the ASEAN nations. On transnational cooperation on counterfeit medicines, the findings illustrate that ASEAN members are the implementers of the policies, and ASEAN sectoral bodies such as AHC 3 and the PPWG have only minor monitoring, coordination, and information-sharing responsibilities.

The result is an international order where the region's sole centralized regime, the ASEAN Secretariat, is prevented from becoming a decision-making body that has the authority to establish and implement policies in the interest of all Southeast Asian citizens. This creates a concerning paradox for transnational cooperation within ASEAN because while ASEAN member states have control over regional policies, there is no oversight body that ensures that the commitments and goals made by member states are achieved. Moreover, in the AHC 3 Action Plan for Combating Substandard and Falsified Medicines, there is a note saying, "*this collaborative action plan is dependent on sufficient human and financial resources in order to deliver these activities. Governments, regional and international organisations should combine efforts to mobilize the necessary resources*" (Association of Southeast Asian Nations (ASEAN), 2022).

It is unclear whether ASEAN officials or member state representatives included this note, but it confirms the non-binding and voluntary nature of ASEAN's transnational cooperation on this issue. Without the appropriate resources to even begin with, ASEAN's commitment to tackling counterfeit medicines smuggling risks has become an empty promise, especially as the AHC 3 action plan was endorsed in June 2021. However, the findings between then and late 2023, when this research was conducted, did not reveal any progress on the securing of these resources. Additionally, as the findings highlight, ASEAN's influence on regional cooperation between member states is limited because, despite being Southeast Asia's leading regional institution, it has neither legal powers nor a significant budget (Russell, 2020). It is not an actual regional intergovernmental organization that represents the region's interests as a whole, including its citizens and governments. Rather, it is designated as a coordinator of information, tasked with collecting data on the implementation of ASEAN projects, producing progress reports for projects, and organizing meetings for officials from member states (Lin, 2022). This limited mandate influences the capacities of all ASEAN sectoral bodies, as evidenced by the largely administrative duties that AHC 3 and PPWG have been assigned in the efforts to combat counterfeit medicines. As Lin (2022) explains, since ASEAN's inception, member states have been careful to maintain a '*political master*' relationship with ASEAN's '*servant*' bureaucrats. This institutional design makes ASEAN weak as it does not have the capacity to implement more decisive action to dismantle the counterfeit medicine smuggling networks or independently conduct deeper research into the transnational crime behind counterfeit medicines to identify the full scale of the problem so effective policies and actions can be designed.

ASEAN's limited capacities are further weakened by its limited human resource and financial capabilities. The available data is inadequate, but the findings suggest that the ASEAN Secretariat has 300 staff members and an overall annual budget of around USD 20 million (Russell, 2020). The findings suggest that with this budget, ASEAN can only pay the salaries of its staff, manage ongoing operations, and organize the more than 1,500 meetings held each year. These figures are concerning as they show that the ASEAN Secretariat is understaffed and underfinanced. Therefore, efforts to combat counterfeit medicines in Southeast





Asia will rely on the voluntary financial and human resource contributions of ASEAN member states, which they have not yet committed to date. Unless ASEAN member states expand ASEAN's capabilities, the regional organization will only be able to serve a secretarial role on this issue.

## 5. Conclusion

The study results show that ASEAN cannot maintain sustainable cooperation among its member states in its fight against counterfeit medicines smuggling in Southeast Asia because of a misalignment between ASEAN's policies and the criminal nature of the trade. Counterfeit medicines are being imported to and produced in Southeast Asia by a wide variety of criminal actors, from organized criminal syndicates to unethical pharmaceutical companies, and unknowingly bought by the public through legitimate and illegal channels. ASEAN's policies to combat these counterfeit medicines entirely overlook the criminal nature of the problem and instead focus on the regulatory weaknesses of the region's pharmaceutical supply chains through increased information sharing between the national regulatory, customs, and law enforcement authorities of member states.

This limited cooperative approach, likely created through consensus to make it achievable by all member states, maintains the status quo of non-interference in domestic affairs while allowing ASEAN to take some action to investigate and limit the distribution of counterfeit medicines. Additionally, the findings demonstrate that ASEAN is mandated by member states to conduct only administrative duties. In the years since the issuing of the anti-counterfeit medicine policies, there is no data suggesting that the policies have been implemented or that member states have committed financial and human resources to enable transnational cooperation to combat counterfeit medicines.

There are several gaps in the findings that would benefit from further research. One is the need for a deeper understanding of the decisions and intentions of ASEAN in developing the policies of the June 2021 ASEAN Action Plan on Substandard and Falsified Medicines. Further research using open-ended questionnaire interviews with ASEAN policymakers and AHC 3 personnel about the agreements and discussions that led to the creation of the June 2021 action plan would help reveal how the decisions were made and why the action plan is very focused on regulatory action. Additionally, further exploration of the financial and human resources of the ASEAN Socio-Cultural Community and AHC 3 would be very useful for quantifying ASEAN's role in assisting with implementing the June 2021 ASEAN Action Plan on Substandard and Falsified Medicines. Such a study could help shed light on how ASEAN utilizes its resources and how this influences policy formulation.

## 6. Acknowledgements

Words cannot express my gratitude to my advisor, Assistant Professor Dr. Thammarat Marohabutr's supervision throughout the process. Also, I would like to express my most profound appreciation to my program director, Lecturer Dr. Aung Win Tun and my faculty, Faculty of Graduate Studies. I also could not have undertaken this journey without my defence committee and the contribution of Assistant Professor Dr Niyada Kiatying-Angsulee, who generously provided knowledge and expertise. I would like to extend my sincere thanks to the librarians and classmates from Mahidol University. I would not have completed this study without the support of the people around me.

[232]



## 7. References

- Acharya, A., & Johnston, A. I. (Eds.). (2007). *Crafting Cooperation: Regional International Institutions in Comparative Perspective*. Cambridge: Cambridge University Press.
- The ASEAN Post Team. (2019). Fake medicine giving ASEAN a headache. Retrieved December 10, 2023, from <https://theaseanpost.com/article/fake-medicine-giving-asean-headache>
- Association of Southeast Asian Nations (ASEAN). (2019). *ASEAN Leaders' Declaration on ASEAN Vaccine Security and Self-Reliance (AVSSR)*. Retrieved October 9, 2023, from <https://asean.org/wp-content/uploads/2019/11/7-ASEAN-Leaders-Declaration-on-ASEAN-Vaccine-Security-and-Self-Reliance-AVSSR.pdf>
- Association of Southeast Asian Nations (ASEAN). (2020). *Regional Strategic and Action Plan for ASEAN Vaccine Security and Self-Reliance (AVSSR) 2021-2025*. Retrieved October 9, 2023, from [https://asean.org/wp-content/uploads/2021/10/AHMM-ADOPTED\\_AVSSR-Strategic-and-Action-Plans-2021-2025-cleaned-version\\_FINAL.pdf](https://asean.org/wp-content/uploads/2021/10/AHMM-ADOPTED_AVSSR-Strategic-and-Action-Plans-2021-2025-cleaned-version_FINAL.pdf)
- Association of Southeast Asian Nations (ASEAN). (2022). *ASEAN Action Plan for Combating Substandard and Falsified Medicines (SFM)*. Retrieved October 9, 2023 from [https://asean.org/wp-content/uploads/2022/07/AHMM-adopted ASEAN Action Plan on SFM SOMHD-endorsed\\_21062021\\_-14-May-2022.pdf](https://asean.org/wp-content/uploads/2022/07/AHMM-adopted ASEAN Action Plan on SFM SOMHD-endorsed_21062021_-14-May-2022.pdf)
- Boyd, A. (2017). Fake Pharma thrives on the Mekong. Retrieved December 10, 2023, from <https://asiatimes.com/2017/11/fake-pharma-thrives-mekong/>
- CNA News Asia. (2020). *Undercover Asia - S7: Fake medicine sold in Malaysia could kill you* [TV series]. Retrieved November 15, 2023, from <https://www.channelnewsasia.com/watch/undercover-asia/fake-medicine-sold-malaysia-could-kill-you-1466616>
- Dupont, A. (1999). Transnational crime, drugs, and security in East Asia. *Asian Survey*, 39(3), 433–455. <https://doi.org/10.2307/3021207>
- Emmers, R. (2003). *The threat from Transnational Crime in Southeast Asia: Drug Trafficking, Human Smuggling and Trafficking and sea piracy*. *Revista UNISCI*, 2, 5–11. [https://doi.org/10.5209/rev\\_unis.2003.n2.29458](https://doi.org/10.5209/rev_unis.2003.n2.29458)
- Emmers, R. (2007). International regime-building in ASEAN: Cooperation against the illicit trafficking and abuse of drugs. *Contemporary Southeast Asia: A Journal of International and Strategic Affairs*, 29(3), 506–525. <https://doi.org/10.1355/cs29-3g>
- Gooch, L., & Bormann, T. (2015). Trade in harmful counterfeit pills going global. Retrieved December 10, 2023, from <https://www.aljazeera.com/features/2015/4/9/trade-in-harmful-counterfeit-pills-going-global>
- International Criminal Police Organization (INTERPOL). (n.d.). *Fake medicines*. Retrieved November 15, 2023 from <https://www.interpol.int/en/Crimes/Illicit-goods/Shop-safely/Fake-medicines>
- International Criminal Police Organization (INTERPOL). (2014). *Pharmaceutical Crime and Organized Criminal Groups An analysis of the involvement of organized criminal groups in pharmaceutical crime since 2008*. Retrieved September 7, 2023, from <https://www.republicoftogo.com/content/download/88014/2193589/1>
- International Criminal Police Organization (INTERPOL). (2020). *COVID-19: The Global Threat of Fake Medicines*. Retrieved September 17, 2023, from [https://www.interpol.int/content/download/15305/file/20COM0356%20-%20IGGH\\_COVID-19%20threats%20to%20medicines\\_2020-05\\_EN.pdf](https://www.interpol.int/content/download/15305/file/20COM0356%20-%20IGGH_COVID-19%20threats%20to%20medicines_2020-05_EN.pdf)



- A Joint Effort Between EU-ABC & TRACIT. (2020). *Tackling Illicit Trade in ASEAN Advocacy Paper, 2020*. Retrieved September 17, 2023, from [https://www.tracit.org/uploads/1/0/2/2/102238034/illicit\\_trade\\_paper\\_final\\_final.pdf](https://www.tracit.org/uploads/1/0/2/2/102238034/illicit_trade_paper_final_final.pdf)
- Kuanpoth, J. (2017). Combating counterfeit drugs: Case studies of Cambodia, Vietnam and Thailand. *Journal of Generic Medicines*, 14(1), 4–15. <https://doi.org/10.1177/1741134317728403>
- Lam, T. (2022, May 19). Former deputy health minister jailed in fake cancer drug scandal. Retrieved September 17, 2023, from <https://e.vnexpress.net/news/news/former-deputy-health-minister-gets-jail-in-fake-cancer-drug-scandal-4465636.html>
- Lamy, M., & Liverani, M. (2015). Tackling substandard and falsified medicines in the Mekong: National responses and regional prospects. *Asia & the Pacific Policy Studies*, 2(2), 245–254. <https://doi.org/10.1002/app5.87>
- Lamy, M., & Phua, K. H. (2012). Southeast Asian Cooperation in health: A comparative perspective on regional health governance in ASEAN and the EU. *Asia Europe Journal*, 10(4), 233–250. <https://doi.org/10.1007/s10308-012-0335-1>
- Leifer, M. (1998). *The ASEAN Regional Forum: A model for cooperative security in the Middle East*. Australian National University, Department of International Relations, IR Working Paper No. 1998/1. Retrieved December 10, 2023, from <https://bellschool.anu.edu.au/experts-publications/publications/1733/asean-regional-forum-model-cooperative-security-middle-east>
- Lin, J. (2022). Is the ASEAN Secretariat Overdue for a Renewed Mandate? Retrieved October 27, 2023, from <https://fulcrum.sg/is-the-asean-secretariat-overdue-for-a-renewed-mandate/>
- Megget, K. (2016). \$2.2m in fake drugs seized in Myanmar. Retrieved October 27, 2023, from <https://www.securindustry.com/pharmaceuticals/-2-2m-in-fake-drugs-seized-in-myanmar/s40/a2964/>
- The Nation Thailand. (2021). EU-funded campaign urges consumers to beware of counterfeit cosmetics and beauty products. Retrieved November 15, 2023, from <https://www.nationthailand.com/lifestyle/30401110>
- Nwokike J., Ludeman E., & Thumm E. (2013). *Comparative Analysis of Pharmacovigilance Systems in Five Asian Countries*. Management Sciences for Health (MSH). Retrieved November 15, 2023, from <https://siapsprogram.org/wp-content/uploads/2014/02/Asia-PV-report.pdf>
- Organization for Economic Cooperation and Development/European Union Intellectual Property Office. (2020). *Trade in counterfeit pharmaceutical products*. OECD Publishing. <https://doi.org/10.1787/a7c7e054-en>
- Redfearn, N. (2023). Pharma and consumer health product counterfeiting across South East Asia. Retrieved September 17, 2023, from <https://rouse.com/insights/news/2023/pharma-and-consumer-health-product-counterfeiting-across-south-east-asia>
- Russell, M. (2020). *The Association of Southeast Asian Nations (ASEAN) The EU's partner in Asia?* Retrieved October 27, 2023, from [https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/659338/EPRS\\_BRI\(2020\)659338\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/659338/EPRS_BRI(2020)659338_EN.pdf)
- Sundram, P. (1999). *Combating Transnational Crime in ASEAN*. Retrieved October 9, 2023, from <https://asean.org/combating-transnational-crime-in-asean-by-s-pushpanathan/>
- Syakriah, A. (2023). 'This is my last responsibility': Indonesia's parents seek justice over child cough syrup deaths. Retrieved October 27, 2023, from <https://www.theguardian.com/world/2023/mar/02/this-is-my-last-responsibility-indonesias-parents-seek-justice-over-child-cough-syrup-deaths>



- United Nations Office on Drugs and Crime. (2013). *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment*. UNODC. Retrieved November 15, 2023, from [https://www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA\\_EAP\\_c12.pdf](https://www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA_EAP_c12.pdf)
- United Nations Office on Drugs and Crime. (2019a). *Transnational Organized Crime in Southeast Asia: Evolution, Growth and Impact 2019*. UNODC. Retrieved November 15, 2023, from [https://www.unodc.org/documents/southeastasiaandpacific/Publications/2019/SEA\\_TOCTA\\_2019\\_web.pdf](https://www.unodc.org/documents/southeastasiaandpacific/Publications/2019/SEA_TOCTA_2019_web.pdf)
- United Nations Office on Drugs and Crime. (2019b). *Organised crime syndicates are targeting Southeast Asia to expand operations*. Retrieved November 15, 2023 from <https://www.unodc.org/roseap/en/2019/07/transnational-organised-crime-southeast-asia-report-launch/story.html>
- World Health Organization. (2010). *Counterfeit medical products*. (Report No. A63/23). WHO. [https://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_23-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_23-en.pdf)