TOWARDS GLOBAL HARMONIZATION: A COMPARATIVE ANALYSIS OF TAIWAN'S PHARMACEUTICAL TRACK AND TRACE SYSTEM

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ABSTRACT

This article is a comparative study of the U.S. Drug Supply Chain Security Act, the EU Falsified Medicines Directive, and Taiwan's pharmaceutical track and trace system. This comparative approach will highlight the commonalities and differences in these various frameworks as they relate to pharmaceutical track and trace and assess how these systems can learn from each other. The article will provide a springboard for discussing an international framework for pharmaceutical track and trace, focusing on legal and operational interoperability. The core of the article will revolve around the need for national pharmaceutical track and trace systems to be interoperable with other national or regional systems. It will further emphasize how a collaborative international approach is necessary to ensure the full effectiveness of the pharmaceutical supply chain. This article will give special attention to Taiwan's pharmaceutical track and trace system, providing a description of Taiwan's pharmaceutical track and trace regime and the elements necessary for its success, its weaknesses, and opportunities for growth in a global track and trace system. By integrating the provisions of Taiwan's Pharmaceutical Affairs Act, associated regulations, and data from various sources, the Taiwanese government has successfully created a comprehensive track and trace system for pharmaceutical products. Integration among government systems in Taiwan further enhances the track and trace ecosystem's comprehensiveness, enabling data to undergo various verification and auditing processes. Finally, this article will argue that national track and trace systems should be interoperable with other national and regional systems to guarantee complete protection of the pharmaceutical supply chain. Therefore, this article will conclude with a proposal for a worldwide unified, interoperable, and digital platform for pharmaceutical track and trace.

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I. INTRODUCTION

There is currently no unified, comprehensive transnational pharmaceutical track and trace regime.[1] "Unified" for purposes of this article means unified across both legal jurisdictions and among business trading partners. "Comprehensive" in this sense means the integration of all potential sources of data intelligence and utilization of the latest technologies. The lack of a unified, comprehensive transnational pharmaceutical track and trace regime creates a multitude of challenges for the transnational movement of pharmaceutical goods. This article will explore these ideas of "unified" and "comprehensive" by first comparing three different regimes: the United States, European Union, and Taiwan. The article will discuss the challenges of operating in disparate systems and attempt to provide suggestions for harmonizing the transnational pharmaceutical supply chain regime.

Pharmaceutical supply chains, like any other supply chain, suffer from multiple challenges.[2] However, the consequences for a disrupted pharmaceutical supply chain are arguably more serious due to the fact that pharmaceuticals are so intimately tied to our health.[3] The journey of a prescription drug from manufacture to consumption is incredibly complex.[4] The impact of a flawed supply chain resonates across various facets of business operations, emphasizing the critical importance of maintaining its integrity and efficiency.[5] On the human side, flaws in the pharmaceutical supply chain can result in harms to the health of citizens, resulting in possible economic and other social impacts due to the health of a nation's citizens.[6] Therefore, a harmonized system is crucial for the health and economic wellbeing of all citizens.

The following discussion will explore how three different regions are taking steps to secure the pharmaceutical supply chain, ensuring the safety of their populations. These three jurisdictions, each with their unique challenges and approaches, illustrate efforts to secure pharmaceutical supply chains. But the

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1. This would include a regime that goes beyond the 1994 WTO Agreement on Trade in Pharmaceutical Products and would include all aspects of the movement of pharmaceuticals, described in more detail in the various regimes described in this article. *See generally General Agreement on Tariffs and Trade: Trade in Pharmaceutical Products*, L/7430 (Mar. 25, 1994), GATT at 1–3 (1994) [hereinafter Pharma Agreement].

2. Edward Sweeney, *The Big Challenges for Supply Chains in 2022*, WORLD ECON. F. (Jan. 19, 2022), https://www.weforum.org/agenda/2022/01/challenges-supply-chains-covid19-2022 [https://perma.cc/2CQY-FJA8].

3. Beth Weinman et al., *The American Medical Product Supply Chain: Will Covid-19 Drive Manufacturing Back Home?*, 76 FOOD & DRUG L.J. 235, 236 (2021).

4. Robin Feldman, *Designing Disruption in Pharmaceuticals*, 28 BOS. UNIV. J. SCI. & TECH. L. 1, 5–6 (2021) (describing the journey of a pharmaceutical).

5. *See* Scott J. Shackelford et. al., *Securing the Internet of Healthcare*, 19 MINN. J.L. SCI. & TECH. 405, 411 (2018) (noting how medical devices are susceptible to malware attacks through the supply chain).

6. *See* Mariana P. Socal et al., *The Pandemic and the Supply Chain: Gaps in Pharmaceutical Production and Distribution*, 111 AM. J. PUB. HEALTH 635, 635–39 (2021).

article will also highlight the need for interoperability among pharmaceutical supply chains, arguing for a worldwide unified, interoperable, and digital platform for pharmaceutical track and trace.

II. UNITED STATES: THE DRUG SUPPLY CHAIN SECURITY ACT

Title II of the Drug Quality and Security Act ("DQSA"), commonly cited as the Drug Supply Chain Security Act ("DSCSA"), was enacted on November 27, 2013, and outlines requirements for the tracing of pharmaceuticals through the pharmaceutical supply chain, exchange of pertinent information between stakeholders in that pharmaceutical supply chain, and placing product identifiers on packages.[7] The DSCSA defines separate and unique requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers with respect to transactions involving prescription drugs.[8] The DSCSA calls for the United States Secretary of Health and Human Services to issue draft guidance documents establishing "standards for the interoperable exchange of transaction information, transaction history, and transaction statements" in order to comply with manufacturer requirements, wholesale distributor requirements, dispenser requirements, and repackager requirements under the DSCSA.[9] These standards should "comply with a form and format developed by a widely recognized international standards development organization."[10] There have been several milestones for the implementation of the DSCSA over the last 10 years, but the DSCSA becomes fully effective in November of 2023, when the rules for an interoperable, electronic system of tracing products will go into effect.[11]

The DSCSA calls for the drafting of guidance documents establishing "standards for the interoperable exchange of *transaction information*, *transaction history*, and *transaction statements*" in order to comply with stakeholder requirements under the DSCSA.[12] Reference to *transaction information* includes information such as the name of the product, its dosage, its National Drug Code ("NDC"), its lot number, the container size and number, the date of the transaction and shipment, transferor details, and transferee details.[13] Reference to *transaction history* includes a statement of the transaction

7. Drug Supply Chain Security Act, 21 U.S.C. §§ 360eee–360eee-4; The DSCSA specifically covers "product," meaning (subject to certain exceptions) "a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)." *Id.* § 360eee(13).

8. 21 U.S.C.A. § 360eee-1(a)(1) (West 2013) ("If an entity meets the definition of more than one of the entities listed [then] such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.").

9. *Id.* § 360eee-1(a)(2)(A).

10. *Id.*

11. *Id.* § 360eee-1(g)(1).

12. *Id.* § 360eee-1(a)(2)(A) (emphasis added).

13. 21 U.S.C. § 360eee(26).

information for every preceding transaction tracing back to the product's original manufacturer.[14] The transaction statement refers to a statement indicating that the entity transferring ownership

> (A) is authorized as required under the [DSCSA]; (B) received the product from a person that is authorized as required under the [DSCSA]; (C) received transaction information and a transaction statement from the prior owner of the product . . . ; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements . . . ; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.[15]

The term "transaction" under the DSCSA means "the transfer of product between persons in which a change of ownership occurs."[16] Therefore, a transaction, in theory, would not include moving a product from a warehouse to a pharmacy if these facilities are owned by the same entity and no change of ownership occurs.

A. DSCSA Stakeholder Requirements

The DSCSA defines separate and unique requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers with respect to transactions involving covered products.[17]

1. DSCSA Manufacturer[18] *Requirements*

a. Information exchange and retention

Currently under the DSCSA,[19] manufacturers are required to furnish a

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14. *Id.* § 360eee(25).
15. *Id*. § 360eee(27).
16. *Id*. § 360eee(24)(a).
17. 21 U.S.C.A. § 360eee-1(a)(1) (West 2013).
18. A manufacturer is:
> (A) a person that holds an application approved under section 355 of this title or a license issued under section 262 of Title 42 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

Id. § 360eee(10).
19. *See generally infra* Section II.D. This article was drafted before the DSCSA became fully effective in November of 2023.

subsequent owner with transaction history, transaction information, and a transaction statement.[20] Manufacturers must maintain this transaction history, transaction information, and a transaction statement for 6 years.[21] Manufacturers must have this information ready to provide to the U.S. government for a product recall or for investigating a suspect or illegitimate product.[22] With certain exceptions, manufacturers are expected to present the transaction information, transaction history, and transaction statement in an "electronic format."[23]

b. Product identifier

Under the DSCSA, a manufacturer must place a "product identifier"[24] on each package and homogenous case, and they must maintain the product identifier information for a period of 6 years.[25]

c. Trading partners

The DSCSA requires that trading partners be authorized trading partners.[26] For purposes of the DSCSA, trading partner means:

> (A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or (B) a third-party logistics provider[27] from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.[28]

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20. *Id.* § 360eee-1(b)(1)(A)(i)–(ii).

21. *Id.*

22. *Id.* § 360eee-1(b)(1)(B).

23. *Id.* § 360eee-1(b)(1)(C)(i).

24. "Product identifier" means "a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product." 21 U.S.C. § 360eee(14).

25. 21 U.S.C.A. § 360eee-1(b)(2)(A) (West 2013).

26. *Id.* § 360eee-1(b)(3).

27. *See id.* § 360eee(22) ("The term third-party logistics provider means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.").

28. *Id.* § 360eee(23).

d. System of verification

Manufacturers are obliged to establish systems for identifying and investigating products that are suspect or illegitimate.[29] When a verification request is received, manufacturers are required to inform the requester if the product identifier, which includes the standardized numerical identifier, matches the product identifier on the product.[30] Should the product identifier not match the manufacturer's, then the product is considered a "suspect product"[31] subject to further investigation.[32] In the event that the product is considered an illegitimate product,[33] the manufacturer must state this in response to the request for verification.[34] The manufacturer must use a "secure electronic database" of its own or a third-party.[35] The database may allow access to relevant stakeholders, "as appropriate."[36]

2. Wholesale Distributor[37] *Requirements*

a. Information exchange and retention

Currently under the DSCSA,[38] a wholesale distributor is permitted to take ownership of a product only if the preceding owner has supplied the transaction history, transaction information, and a transaction statement.[39] What

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29. *Id.* § 360eee-1(b)(4).

30.*Id.* § 360eee-1(b)(4)(C).

31. A "suspect product" is:

> a product for which there is reason to believe that such product — (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Id. § 360eee(21).

32. *Id.* § 360eee-1(b)(4)(C).

33. An "illegitimate product" is defined as

> a product for which credible evidence shows that the product — (A) is counterfeit, diverted, or stolen; (B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Id. § 360eee(8).

34. *Id.* § 360eee-1(b)(4)(C).

35. *Id.* § 360eee-1(b)(4)(D).

36. *Id.*

37. A wholesale distributor is "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 353(e)(4) of this title)." *Id.*§ 360eee(29).

38. *See infra* Section II.D.

39. 21 U.S.C. § 360eee-1(c)(1)(A)(i).

information the wholesale distributor must provide to a subsequent owner depends if the "wholesale distributor purchased a product directly from the manufacturer, [an] exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer."[40] If yes, the wholesale distributor must provide a transaction statement stating that the "wholesale distributor . . . purchased the product directly from the manufacturer, [an] exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer"[41] and the transaction history and transaction information.[42] If not, the wholesale distributor must provide a transaction statement, transaction history, and transaction information.[43] Similar to manufacturers, wholesale distributors must provide information to the U.S. government in cases of product recalls or for investigations into suspect or illegitimate product.[44]

b. Product identifier, trading partners, and system of verification

With certain exceptions, a wholesale distributor is allowed to conduct transactions only if the product is "encoded" with a product identifier.[45] The DSCSA requires that trading partners be authorized trading partners.[46] Wholesale distributors are required to have systems in place to identify and investigate suspect products and illegitimate products.[47] The wholesale distributor can use a "secure electronic database" developed and operated by itself or a third-party.[48] The database owner may, when suitable, grant access to the data to other participants in the pharmaceutical supply chain.[49]

c. Product returns

Should a wholesale distributor receive a returned product and wish to redistribute the returned product, it must verify the product identifier.[50]

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40. *Id.* § 360eee-1(c)(1)(A)(ii)(I)(aa).
41. *Id.* § 360eee-1(c)(1)(A)(ii)(I)(aa)(AA).
42. *Id.* § 360eee-1(c)(1)(A)(ii)(I)(aa)(BB).
43. *Id.* § 360eee-1(c)(1)(A)(iii). The difference here would be that the transaction statement does not need a statement that "the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer." *Id.*
44. *Id.* § 360eee-1(c)(1)(C).
45. *Id.* § 360eee-1(c)(2).
46. *Id.* § 360eee-1(c)(3).
47. *Id.* § 360eee-1(c)(4)(B).
48. *Id.* § 360eee-1(c)(4)(C).
49. *Id.*
50. *Id.* § 360eee-1(c)(4)(D).

3. DSCSA Dispenser[51] *Requirements*

a. Information exchange and retention

A dispenser is prohibited from taking ownership of a product unless it receives the transaction history, transaction information, and a transaction statement from the previous owner.[52] When transferring ownership, the dispenser must also provide transaction history, transaction information, and a transaction statement for the product.[53] The dispenser does not need to provide the transaction history, transaction information, and a transaction statement for the product when dispensing to a patient, when returning the product, or selling to another dispenser "to fulfill a specific patient need."[54] A dispenser should keep transaction information, transaction history, and transaction statements for at least 6 years[55] and must provide it to government officials in case of an investigation.[56]

b. Product identifier, trading partners, and system of verification

A dispenser is only permitted to handle products if they are "encoded" with a product identifier.[57] A dispenser may only deal with authorized trading partners.[58] A dispenser must also establish systems to effectively comply with regulations concerning suspect products and illegitimate products.[59]

4. DSCSA Repackager[60] *Requirements*

a. Information exchange and retention

A repackager can only accept a product when it includes a transaction

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51. A dispenser:

> means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

21 U.S.C. § 360eee(3)(A).

52. *Id.* § 360eee-1(d)(1)(A)(i).

53. *Id.* § 360eee-1(d)(1)(A)(ii).

54. *Id.* § 360eee-1(d)(1)(A)(ii).

55. *Id.* § 360eee-1(d)(1)(A)(iii).

56. *Id.* § 360eee-1(d)(1)(D).

57. *Id.* § 360eee-1(d)(2).

58. *Id.* § 360eee-1(d)(3).

59. *Id.* § 360eee-1(d)(4)(A)

60. A repackager is "a person who owns or operates an establishment that repacks and relabels a product or package for—(A) further sale; or (B) distribution without a further transaction." 21 U.S.C. § 360eee(16).

history, transaction information, and a transaction statement[61] and must provide such a transaction history, transaction information, and a transaction statement to any subsequent owner.[62] The transaction information, transaction history, and transaction statement must be captured and maintained for at least 6 years[63] and be provided to government officials in the course of investigations into suspect or illegitimate products.[64]

b. Product identifier, trading partners, and system of verification

A repackager must use a product identifier for the product[65] and must maintain this product identifier information for 6 years.[66] A repackager can only engage in transactions with a product identifier.[67] A repackager can only deal with authorized trading partners.[68] A repackager must establish systems to effectively comply with regulations concerning suspect products and illegitimate products.[69]

B. DSCSA Enhanced Drug Distribution Security

On November 27, 2023, the DSCSA called for an enhanced method of electronic tracing of pharmaceutical products.[70] This system requires the following:

- Transaction information and transaction statements are required to be "exchanged in a secure, interoperable, electronic manner."[71] The standards for the exchange are to be established through guidance documents issued by the FDA.[72]
- The transaction information shall contain the product identifier "at the package level for each package included in the transaction." [73]
- Systems must be in place to confirm the product's authenticity "at the package level" pursuant to guidance documents issued by the FDA.[74]
- Systems must be in place to respond to requests by appropriate government agencies for recall purposes or for investigating suspect or

61. *Id.* § 360eee-1(e)(1)(A)(i).
62. *Id.* § 360eee-1(e)(1)(A)(ii).
63. *Id.* § 360eee-1(e)(1)(A)(iii).
64. *Id.* § 360eee-1(e)(1)(C).
65. *Id.* § 360eee–1(e)(2)(A)(i).
66. *Id.* § 360eee–1(e)(2)(A)(ii).
67. *Id.* § 360eee–1(e)(2)(A)(iii).
68. *Id.* § 360eee–1(e)(3).
69. *Id.* § 360eee–1(e)(4).
70. *Id.* § 360eee–1(g).
71. *Id.* § 360eee–1(g)(1)(A).
72. *Id.*
73. *Id.* § 360eee–1(g)(1)(B).
74. *Id.* § 360eee–1(g)(1)(C).

illegitimate products.[75]

- Systems must be in place "to produce the transaction information for each transaction going back to the manufacturer" if requested by the government or trading partner for investigating suspect or illegitimate product.[76]
- Systems must be in place to "associate" a returned product with the transaction information and transaction statement that is associated with that specific returned product.[77]

The FDA announced a one-year "stabilization period" to "allow trading partners to implement, troubleshoot and mature their electronic interoperable systems."[78] In addition, FDA is issuing exemptions to small dispensers, "and where applicable their trading partners" beyond this initial stabilization period until November 27, 2026.[79] These extensions recognize that certain stakeholders need more time to make such a big change to their systems.

C. DSCSA Guidance Documents and Pilot Projects

The FDA has been busy issuing guidance documents[80] and has established pilot projects to realize the enhanced drug distribution system explained above.[81] There is a host of guidance from the FDA.[82] Consequently, the FDA's guidance and pilot programs have played a crucial role in developing this system.

D. DSCSA Sunset

On November 27, 2023, the provision and receipt of transaction history will no longer be necessary.[83] This presumably is because this is the date that the Enhanced Drug Distribution Security system begins and such information will

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75. *Id.* § 360eee–1(g)(1)(D).

76. *Id.* § 360eee–1(g)(1)(E)(i)–(ii).

77. *Id.* § 360eee–1(g)(1)(F).

78. *DSCSA Compliance Policies Establish 1-Year Stabilization Period for Implementing Electronic Systems*, U.S. FOOD & DRUG ADMIN. (Aug. 30, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems.

79. *Waivers and Exemptions Beyond the Stabilization Period*, U.S. FOOD & DRUG ADMIN. (Oct. 9, 2024), https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/waivers-and-exemptions-beyond-stabilization-period.

80. *Id.* § 360eee–1(h).

81. *Id.* § 360eee–1(j).

82. *See generally* U.S. FOOD & DRUG ADMIN., DSCSA STANDARDS FOR THE INTEROPERABLE EXCHANGE OF INFORMATION FOR TRACING OF CERTAIN HUMAN, FINISHED, PRESCRIPTION DRUGS GUIDANCE FOR INDUSTRY (Sept. 2023), https://www.fda.gov/media/171796/download [https://perma.cc/7LT7-NVF3].

83. 21 U.S.C. § 360eee–1(k)(1).

be captured by the system.

E. DSCSA Conclusion

The DSCSA represents a significant step in securing the pharmaceutical supply chain in the United States, outlining clear and detailed requirements for all stakeholders. The DSCSA is one example of a regulatory frameworks that aims to protect consumers and ensure the integrity of pharmaceutical supply chains. But is this largely national regime enough in a globalized world? The article will continue to look at EU and Taiwanese regulations, highlighting that interoperability between jurisdictions is necessary for full realization of the goals of a pharmaceutical track and trace regime.

III. THE EU FALSIFIED MEDICINES DIRECTIVE

The EU's Falsified Medicines Directive aims to combat "falsified" medicines in the supply chain.[84] While both the Falsified Medicines Directive and DSCSA aim to secure the pharmaceutical supply chain, the language and provisions of the EU's Falsified Medicines Directive are more explicitly oriented towards the elimination of falsified medicines.[85] Commission Delegated Regulation (EU) 2016/161 explains the safety features necessary on pharmaceutical packaging and how to verify packages.[86] These features are designed to ensure the authenticity of the medicines and to prevent counterfeit (or "falsified") products from entering the legal supply chain.[87]

A. Authorization, Good Practices, Trading Partners

Similar to the idea of authorized trading partners under the DSCSA,[88] EU regulations require that the manufacture of medicinal products be authorized.[89] An entity holding such a manufacturing authorization must comply with good manufacturing practices and good distribution practices.[90] An entity holding such a manufacturing authorization must conduct audits (either by themselves

84. Directive 2001/83/EC of Nov. 6, 2001, on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J (L 311) 67, 67 (*amended by* Directive 2011/62/EU, of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC, 2011 O.J. (L 174) 74).

85. *See* Directive 2011/62/EU, of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products, 2011 O.J. (L 174) 74, 76. The DSCSA does refer to "suspect product" and "illegitimate product" but generally focuses on tightening the supply chain of legitimate product.

86. Commission Delegated Regulation (EU) 2016/161, art. 3, 2016 O.J. (L 32) 1, 7.

87. *Id.*

88. 21 U.S.C.A. § 360eee–1(b)(3) (West 2013).

89. Council Directive 2001/83, art. 40(1) 2001 O.J. (L 311) 67, 82 (EC).

90. *Id.* at art. 46(f).

or through third-parties) to ensure the proper manufacture and distribution of active substances.[91] An entity holding such a manufacturing authorization must inform competent authorities and the holders of marketing authorizations if products are, or are suspected to be, falsified.[92] An entity holding such a manufacturing authorization must verify that entities they are obtaining active substances from (trading partners, under the DSCSA) are properly registered.[93]

1. Import

Member States are responsible for ensuring that the manufacturing, importation, and distribution of products adhere to good manufacturing practices and good distribution practices.[94] To import products, the products must be manufactured in accordance with good manufacturing practices and must be accompanied by written confirmation from the exporting country's government.[95] This confirmation should verify that the manufacturing standards adhered to by the plant producing the exported active substance meet or exceed those established by the EU, among other requirements.[96]

2. Serialization

Similar to ideas in the DSCSA, the outer or immediate packaging of medicinal products must have a method to confirm the genuineness of the pharmaceutical product and distinguish individual packages.[97] The outer or immediate packaging must also include a method for determining whether the packaging has been tampered.[98]

3. Distribution Authorization

Distributors must obtain a distribution authorization.[99] An entity holding such a distribution authorization must maintain records for transactions in medicinal products received, sent, or brokered that includes things like date, name, quantity, supplier or consignee details, and batch number.[100]

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91. *Id.*
92. *Id.* at art. 46(g).
93. *Id.* at art. 46(h).
94. *Id.* at art. 46b(1).
95. *Id.* at art. 46b(2).
96. *Id.*
97. *Id.* at art. 54(o).
98. *Id.*
99. *Id.* at art. 79.
100. *Id.* at art. 80(e).

4. Safety Features Under Regulation 2016/161

The Commission Delegated Regulation (EU) 2016/161 (the "Safety Features Regulations") supplements Directive 2001/83/EC by establishing rules for safety features on packaging.[101] The Safety Features Regulations reiterate that manufacturers must affix a unique identifier to the packaging of medicinal products,[102] of which should be encoded in a two-dimensional barcode.[103] Manufacturers, wholesalers, and others supplying medicinal products should verify "the authenticity of the unique identifier" while simultaneously checking "the integrity of the anti-tampering device."[104]

The manufacturer needs to keep records:

> of every operation he performs with or on the unique identifier on a pack of medicinal product for at least one year after the expiry date of the pack or five years after the pack has been released for sale or distribution . . . and shall provide those records to competent authorities on request.[105]

A repositories system should be set up and maintained by a non-profit entity or group of non-profit entities established in the European Union by pharmaceutical supply chain stakeholders that contains data on the safety characteristics of products.[106] The repository system must function in union with the other repositories in the system, ensuring seamless communication regardless of the service provider.[107] The repository must be equipped with APIs that can facilitate communication "with the software used by wholesalers, persons authorised or entitled to supply medicinal products to the public and, where applicable, national competent authorities."[108] The repository should also preserve an "audit trail of all operations concerning a unique identifier, of the users performing those operations and the nature of the operations."[109]

5. Conclusion of the EU's Regime

The EU's Falsified Medicines Directive and the Commission Delegated

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101. Commission Delegated Regulation (EU) 2016/161, art. 5, 2016 O.J. (L 32) 1, 8.
102. *Id.* at art. 4.
103. *Id.* at art. 5.
104. *Id.* at art. 35.
105. *Id.*
106. *Id.* at art. 31; *see EMVO Mission*, EURO. MED. VERIFICATION ORG. (last visited Oct. 21, 2024), https://emvo-medicines.eu/ [https://perma.cc/W7AG-7XTE] ("The European Medicines Verification Organisation (EMVO) is a Belgian non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines.").
107. Commission Delegated Regulation (EU) 2016/161, art. 35, 2016 O.J. (L 32) 1, 17–18.
108. *Id.* at 18.
109. *Id.*

Regulation provide a robust system to combat falsified medicines. The regulations require stringent authorization, adherence to good manufacturing and distribution practices, and the implementation of safety features on pharmaceutical packaging. These measures reflect a concerted effort by the EU to safeguard public health by ensuring the authenticity and safety of medicinal products. Together with the DSCSA, these regimes cover a significant part of the pharmaceutical supply chain.

IV. TAIWAN'S PHARMACEUTICAL TRACK AND TRACE REGIME

A. Background of the Pharmaceutical Affairs Act and the Establishment of a Track and Trace Framework under Article 6-1

The management of pharmaceutical affairs (*yàoshì*) is outlined in the Pharmaceutical Affairs Act (the "Act") of Taiwan.[110] The term pharmaceutical affairs includes matters relating to medicaments (*yàowù*), pharmaceutical firms (*yàoshāng*), pharmacies (*yàojú*), and related matters (*yǒuguānshìxiàng*).[111] The competent authorities for purposes of the Act are the Ministry of Health and Welfare of Taiwan and various local governments.[112] The term medicaments includes both drugs[113] (*yàopǐn*) and medical devices[114] (*yīliáoqìcái*)[115] A pharmaceutical firm includes dealers (*fànmàiyèzhě*) and manufacturers (*zhìzàoyèzhě*) of drugs or medical devices.[116] A pharmacy for purposes of the Act refers to a premises "managed by a pharmacist or an assistant pharmacist" and where "drugs are legally prepared and dispensed."[117] Pharmacies may dispense drugs and sell medical devices.[118] Beyond the introductory General Provisions in Chapter I, the Act delves into various aspects of pharmaceutical management. These include the administration of pharmaceutical firms (Chapter II), oversight of pharmacies and drug dispensation (Chapter III), drug registration and market approval (Chapter IV), intellectual property related matters (Chapter 4-1), regulation of medicament sales and manufacturing (Chapter V), management of specific controlled and poisonous drugs (Chapter VI), investigative procedures (Chapter VIII), imposition of fines (Chapter IX), and additional supplementary provisions (Chapter X). This comprehensive

110. 藥事法 [Pharmaceutical Affairs Act], art. 1 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2018), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001 [https://perma.cc/7T7R-QA83].

111. *Id*.

112. *Id*. art. 2.

113. *See id.* art. 6 (containing the definition of drugs).

114. *See id.* art. 13 (containing the definition of medical devices).

115. *Id.* art. 4.

116. *Id.* art. 14. *See also* arts. 15–18 (for definitions of drug dealer, drug manufacturer, medical device dealer, and medical device manufacturer).

117. *Id.* art. 19.

118. *Id.*

approach addresses multiple facets of and acts as the foundation to the pharmaceutical industry in Taiwan.

Article 6-1 of the Act establishes the framework for a track and trace system for products covered under the Act, and states:

> Distributors and manufacturers of drugs categorized and announced by the central competent health authority, shall establish their own traceability system for tracing the source and tracking the flow of the drugs according to their industry modes.
>
> The central competent health authority shall establish the traceability report system in the preceding Paragraph; the business in the preceding Paragraph shall use electronic methods to declare the information of the traceability system. The electronic declaration method shall be prescribed by the central competent health authority.
>
> The regulations governing the establishment, matters to be recorded, examination and other matters to be complied with for the traceability system mentioned in the preceding Paragraph shall be prescribed by the central competent health authority.[119]

The United States calls for a similar track and trace framework under the DSCSA.[120] The European Union also calls for a similar regime under its Falsified Medicines Directive.[121] There are also numerous other countries throughout the world with similar track and trace systems, and in addition to Taiwan, a number of countries in Asia have country level track and trace

119. *Id.* art. 6-1. Article 6–1 was introduced by Presidential Order (104) Hua-Zong-Yi-Yi-Zi no. 10400140921 on December 2, 2015; violators of this article could be fined between NT$30,000 and NT$2,000,000. *Id*. art. 92.

120. Drug Quality and Security Act, H.R. 3204, 113th Cong. (2013).

121. *See generally* Directive 2011/62/EU, of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products, 2011 O.J. (L 174) 74, 75.

regimes.[122] For example, South Korea,[123] China,[124] India,[125] and Malaysia[126] all have some sort of track and trace regime.

B. Good Distribution Practice ("GDP") and Good Manufacturing Practice ("GMP") Framework

The Act provides the framework for the use of GDP and GMP standards. Article 49 of the Act stipulates that pharmaceutical dealers must exclusively buy and sell drugs or medical devices from verified sources or dealers possessing valid pharmaceutical dealer licenses.[127] Article 53-1 of the Act calls for certain business undertakings engaging in the distribution of pharmaceuticals to meet standards outlined in the Western Pharmaceuticals Good Distribution Practice Regulations and obtain a license from the authorities.[128] The Western Pharmaceuticals Good Distribution Practice Regulations and western pharmaceuticals distribution licenses are prescribed by the central competent health authority and discussed below.[129] Article 57 of the Act calls for medicament manufacturing factories to comply with the Standards for

122. *See Digital Law Asia*, NAT'L YANG MING CHIAO TUNG U. SCH. L. https://digital.law.nycu.edu.tw/pharma/ [https://perma.cc/W98J-Y4S2] (last visited Oct. 26, 2024) (mapping of these various track and trace systems).

123. *Guideline for Pharmaceutical Serialization System [The first edition]*, HIRA, https://www.hira.or.kr/bbsDummy.do?pgmid=HIRAJ030000001000&brdScnBltNo=4&brdBltNo=46912#none [https://perma.cc/6RAN-E8KS] (last visited Oct. 26, 2024).

124. *China NMPA Rolls Out Drug Information Traceability System for Key Drug Products*, PHARMA TO MARKET (Nov. 13, 2020), https://www.pharmatomarket.com/china-nmpa-rolls-out-drug-information-traceability-system-for-key-drug-products/ [https://perma.cc/9SXP-6CC2].

125. Anil K. Sinha, *Indian government implements track and trace system for pharmaceuticals*, *in* GS1 HEALTHCARE REFERENCE BOOK 2016–2017 66, 66 (GS1 ed., 8th ed. n.d.).

126. *Pelaksanaan Projek Rintis Pharmaceutical Track & Trace*, NAT'L PHARM. REGUL. AGENCY (NRPA) MINISTRY OF HEALTH MALAY. (July 2022), https://www.npra.gov.my/index.php/en/component/content/article/225-english/1527375-pelaksanaan-projek-rintis-pharmaceutical-track-trace.html?Itemid=1391 [https://perma.cc/EH8A-98D2]. *See also Asia: Malaysia's NPRA Details Pilot Project for Track and Trace System*, TRPMA (July 28, 2022), https://trpma.org.tw/eng/news/news_5039 [https://perma.cc/EMT6-Y94W].

127.**藥事法** [Pharmaceutical Affairs Act], art. 49 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2018), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001 [https://perma.cc/7T7R-QA83].

128. *Id.* art. 53–1 ("Business undertakings engaged in wholesaling, importing and exporting pharmaceuticals, their product procuring, holding, supplying related to the quality management, organization and personnel, premises and equipment, documentation, operation procedures, customer complaints, returns and recalls, outsourced activities, self-inspections, transportation and other pharmaceuticals distribution practice, shall meet the standard of Western Pharmaceuticals Good Distribution Practice Regulations, and shall obtain the western pharmaceuticals distribution license upon the inspection and approval from the central competent health authority.").

129. *Id.*

Medicament Factory Establishment[130] and register pursuant to the Factory Management Act.[131] Furthermore, medicament manufacturing activities (including overseas manufacturing factories) must comply with GMP.[132] Of note, the Act states that government authorities can "send personnel overseas to inspect such foreign manufacturing factories on a periodical basis or as necessary."[133]

1. Western Pharmaceuticals Good Distribution Practice Regulations

The Western Pharmaceuticals Good Distribution Practice Regulations are promulgated pursuant to Article 53-1 of the Pharmaceutical Affairs Act ("GDP Regulations").[134] The GDP Regulations contain ten tables covering certain aspects of the pharmaceutical distribution process.[135] The various standards for implementing a quality management system and conducting system reviews are presented in Table 1.[136] Table 2 delineates the criteria for organizational structure and personnel.[137] The standards concerning premises and equipment are detailed in Table 3,[138] while those related to documentation are enumerated in Table 4.[139] Operational procedures standards can be found in Table 5,[140] and the criteria for handling complaints, returns, and recalls are outlined in Table 6.[141] Table 7 addresses the standards for outsourced activities,[142] and Table 8 elaborates on the self-inspection requirements.[143] Finally, transportation standards are illustrated in Table 9.[144]

130. 藥物製造工廠設廠標準 [Standards for Medicament Factory Establishments], art. 57 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2013), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030008 [https://perma.cc/X8RR-ZU6Y].

131. **藥事法** [Pharmaceutical Affairs Act], art. 57 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2018), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001 [https://perma.cc/7T7R-QA83].

132. *Id*.

133. *Id*.

134. 西藥優良運銷準則 [Western Pharmaceuticals Good Distribution Practice Regulations] art. 1 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2017), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030086 [https://perma.cc/5DBF-KS9C].

135. *Id*.

136. *Id*. art. 2.

137. *Id*. art. 3.

138. *Id*. art. 4.

139. *Id*. art. 5.

140. *Id*. art. 6.

141. *Id*. art. 7.

142. *Id*. art. 8.

143. *Id*. art. 9.

144. *Id*. art. 10.

2. Pharmaceutical Good Manufacturing Practice Regulations

The Pharmaceutical Good Manufacturing Practice Regulations are promulgated under Paragraph 5 of Article 57 of the Act.[145] The Pharmaceutical Good Manufacturing Practice Regulations are basically organized into sections covering Western pharmaceuticals, Chinese pharmaceuticals, and medical devices.

a. Western pharmaceuticals

There is only one article covering western pharmaceuticals. It states:

> The manufacturing, processing, re-packaging, packaging, storage, and distribution of Western medicinal products, including those only for export, shall comply with the good manufacturing practices for Western medicinal products adopted by the competent central health authority with reference to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Implementation of the aforesaid good manufacturing practices may be phased in; the items to which the phased-in implementation applies and the related schedules shall be announced by the competent central health authority.[146]

PIC/S publishes a *Guide to Good Manufacturing Practice for Medicinal Products* including its detailed Annexes.[147] Part I covers medicinal products.[148] Part II covers starting materials.[149] The annexes cover other specific areas of activity (21 annexes).[150] Taiwan acceded to the PIC Scheme in January of 2013.[151] Taiwan was the 43rd member admitted to the PIC Scheme, ahead of some neighboring countries, demonstrating its government's commitment to

145. *Id.* art. 1.

146. *Id*. art. 3.

147. PHARMACEUTICAL INSPECTION CONVENTIONAL–PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME [PIC/S], *Guide to Good Manufacturing Practice for Medicinal Products*, (Aug. 25, 2023), https://picscheme.org/docview/6605 [https://perma.cc/6SGB-BNSQ].

148. PHARMACEUTICAL INSPECTION CONVENTIONAL–PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME [PIC/S], *Guide to Good Manufacturing Practice for Medicinal Products Part I*, (Aug. 25, 2023), https://picscheme.org/docview/6606 [https://perma.cc/YX4K-2ZVR].

149. PHARMACEUTICAL INSPECTION CONVENTIONAL–PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME [PIC/S], *Guide to Good Manufacturing Practice for Medicinal Products Part II*, (Aug. 25, 2023), https://picscheme.org/docview/6607 [https://perma.cc/Q33W-DPAB].

150. PHARMACEUTICAL INSPECTION CONVENTIONAL–PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME [PIC/S], *Guide to Good Manufacturing Practice for Medicinal Products, Annexes*, (Aug. 25, 2023), https://picscheme.org/docview/6608 [https://perma.cc/2QC5-EZ4E].

151. PHARMACEUTICAL INSPECTION CONVENTIONAL–PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME [PIC/S], *List of PIC/S Participating Authorities*, https://picscheme.org/en/members?paysselect=TW [https://perma.cc/J6NS-6EFR] (last visited Sept. 22, 2024).

quality standards in pharmaceutical manufacturing.[152]

b. Chinese pharmaceuticals

Articles 4-59 in Chapter 2 of the *Pharmaceutical Good Manufacturing Practice Regulations* deal with the "manufacturing, processing, re-packaging and packaging of raw materials of Chinese herbal medicine."[153] These articles cover most areas of the manufacturing environment from sanitation to reporting.[154] The government body overseeing Chinese Medicine is the Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare.[155] Information regarding quality control of traditional Chinese medicines is also published on the Taiwan Ministry of Health and Welfare website.[156]

c. Medical devices

Articles 60-145 in Part 3 of the *Pharmaceutical Good Manufacturing Practice Regulations* deal with medical devices.[157] In this Part, "standards related to the design, development, production, installation, and servicing of medical devices are prescribed in accordance with the contents of medical device quality management system of [ISO 13485:2016]."[158] This ISO standard "specifies requirements for a quality management system where an organization

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152. TAIWAN MINISTRY OF HEALTH AND WELFARE, *PIC/S入會五大效益持續發酵, 台灣製藥大"藥"進* [Five benefits of joining PIC/S for Taiwan's pharmaceutical industry], https://www.mohw.gov.tw/cp-3214-23150-1.html **[**https://perma.cc/Z6DJ-4BRZ] (last visited Sept. 22, 2024).

153. 西藥優良運銷準則 [Western Pharmaceuticals Good Distribution Practice Regulations] art. 4–59 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2017), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030086 [https://perma.cc/5DBF-KS9C]. These sections include General Provisions, Environmental Sanitation, Factory Buildings and Facilities, Facilities, Organization and Personnel, Management of Raw Materials and Product Containers and Caps, Manufacturing Process Control, Management of Packaging and Labeling, Storage, Shipping and Sales, Quality Control, Records and Reports, Handling of Complaints and Returned Products, and Pharmaceuticals for Use in Clinical Trials.

154. *Id*.

155. *See Department of Chinese Medicine and Pharmacy*, MINISTRY OF HEALTH AND WELFARE, (Oct. 19, 2018), https://www.mohw.gov.tw/cp-3779-39358-2.html **[**https://perma.cc/8DW6-ZH7Q**]**.

156. *Quality Control of TCM*, MINISTRY OF HEALTH & WELFARE (Nov. 23, 2023), https://www.mohw.gov.tw/cp-3701-58121-2.html **[**https://perma.cc/6C4F-9U54**]**.

157.西藥優良運銷準則 [Western Pharmaceuticals Good Distribution Practice Regulations] art. 60–145 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2017), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030086 [https://perma.cc/5DBF-KS9C]. The sections encompass General Provisions, Quality Management System, Management Responsibility, Resource Management, Product Realization, Measurement, Analysis and Improvement, Essential Mode, and Medical Devices for Use in Clinical Trials.

158. *Id*. art. 60.

needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements."[159]

C. The Regulations Governing the Trace and Track System for Medicinal Products and the Taiwanese Pharmaceutical Track and Trace Ecosystem

Article 6-1 of the Act sets the framework for a track and trace system, mandating that both distributors and manufacturers create a system for traceability.[160] The Act requires the competent health authority to develop a report system to declare required information.[161] The method of electronic declaration is to be determined by the central competent health authority.[162] Importantly, this central authority is responsible for creating regulations,[163] which includes the Regulations Governing the Trace and Track System for Medicinal Products.[164] Recall that the Taiwan regulatory regime also calls for GDP and GMP standards.[165]

The Taiwan Government has created tools available to the public to help assist industry in complying with this regulatory framework. For example, the Taiwan Food and Drug Administration ("TFDA") maintains a dedicated section on its website for track and trace information.[166] This website features news and announcements,[167] access to the declaration system,[168] audio-visual training

159. INT'L STANS. ORG., ISO 13485:2016, *Medical devices — Quality Management Systems — Requirements for Regulatory Purposes*, (2016) https://www.iso.org/standard/59752.html [https://perma.cc/6MQT-ET28].

160. **藥事法** [Pharmaceutical Affairs Act], art. 1–6 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2018), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001 [https://perma.cc/7T7R-QA83].

161. *Id*.

162. *Id*.

163. *Id*.

164. 藥品追溯或追蹤系統申報及管理辦法 [Regulations Governing the Trace and Track System for Medicinal Products] art. 1 FAWUBU FAGUI ZILIAOKU [TAIWAN Ministry of Justice Laws and Regulations Database] (2016), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030083 [https://perma.cc/U3MX-6QW6].

165. *See supra* Part B.

166. TAIWAN FOOD & DRUG ADMIN., *Pharmaceutical Track and Trace Area*, https://www.fda.gov.tw/TC/site.aspx?sid=9405&r=968484419 [https://perma.cc/2JUT-QDG4] (last visited Oct. 31, 2024).

167. TAIWAN FOOD & DRUG ADMIN., *Drug Track and Trace Notice and Announcement Area*, https://www.fda.gov.tw/TC/siteList.aspx?sid=9445 [https://perma.cc/4Q44-CJYF] (last visited Oct. 31, 2024).

168. TAIWAN FOOD & DRUG ADMIN., *Drug Track and Trace Declaration System*, https://dtracebook.fda.gov.tw/ [https://perma.cc/3E5B-U9MS] (last visited Oct. 31, 2024).

information,[169] and briefings.[170] Furthermore, the TFDA conducts 2-3 annual training sessions for both industry professionals and government representatives to enhance understanding and compliance with the track and trace system.[171]

The TFDA Track and Trace system utilizes data and statistical analysis to create reports.[172] The TFDA also utilizes data from the National Health Insurance Administration to regularly update information on counterfeit drugs, monitor shortages, and manage stockpiles.[173] The TFDA Track and Trace system also shares information with various government entities and platforms to assist in the overall security of the pharmaceutical supply chain.[174] The Taiwan Government built system infrastructures to utilize statistical analysis to help the TFDA and health bureaus.[175] This includes transaction information and inventory information and can be early indicators of negative anomalies.[176]

The Regulations Governing the Trace and Track System for Medicinal Products were formulated under Article 6.1.3 of the Act ("Track and Trace Regulations").[177] The Track and Trace Regulations require distributors and manufacturers to "establish their own information system for tracing the source and tracking the flow of the medicinal products according to manufacturing, import, sale or export process and establish the information system and management measures."[178] Moreover, the central competent health authorities

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169. TAIWAN FOOD & DRUG ADMIN., *Login Platform for Audio-visual Learning*, https://www.fda.gov.tw/TC/siteList.aspx?sid=9988 [https://perma.cc/7JEQ-YSM3] (last visited Oct. 31, 2024).

170. TAIWAN FOOD & DRUG ADMIN., *Drug Track and Trace Declaration System Information related to Industry Briefing Sessions*, https://www.fda.gov.tw/TC/siteList.aspx?sid=10060 [https://perma.cc/KJ73-L34B] (last visited Oct. 31, 2024).

171. Yang Po-Wen, Section Chief Div. Medicinal Prod., Taiwan Food & Drug Admin., Pharmaceutical Track and Trace System Introduction and Experience Sharing (October 20, 2022) (on file with the author).

172. Hsin-mei Huang, *Pharmaceutical Track and Trace Lecture Series – An Introduction to the Taiwanese Medicinal Products Traceability System*, DIGITAL L. ASIA (Feb. 10, 2023), https://digital.law.nycu.edu.tw/blog-post/zlfmfk/ [https://perma.cc/MBW8-9SJ9] (citing Yang Po-Wen, Section Chief Div. Medicinal Prod., Taiwan Food & Drug Admin., Pharmaceutical Track and Trace System Introduction and Experience Sharing (October 20, 2022) (on file with the author)). The speech was part of the "Pharmaceutical Track and Trace Lecture Series" co-hosted by National Yang Ming Chiao Tung University School of Law and the Center for Digital Governance and Legal Innovation.

173. *Id.*

174. *Id.* ("The track and trace system is interfaced with district public health bureaus, hospitals, the Controlled Drugs Management Information System, and the Medical Resource Dispatch and Support System for Emergency Response (MRDSS).").

175. *Id*. (noting that "the system has established a cross-reference and statistical analysis function, which is able to provide statistics, inquiries, and output of reports").

176. *Id.*

177. 藥品追溯或追蹤系統申報及管理辦法 [Regulations Governing the Trace and Track System for Medicinal Products] art. 1 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2016), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030083 [https://perma.cc/LMN5-L3LU].

178. *Id.* art. 2.

have developed a system to oversee the traceability systems implemented by distributors and manufacturers.[179]

The Track and Trace Regulations apply to medicinal products license holders ("License Holders") and distributors engaged in wholesaling ("Distributors").[180] License Holders must report the following information:

1. Pharmaceutical manufacturing or importing information;[181]
2. Active ingredient information;[182] and
3. Transactional information.[183]

License Holders must submit information electronically by the 10th of the month following the month of reporting.[184]

Distributors must report the following information:[185]

1. Information regarding product supplier;[186] and
2. Information regarding flow of medicinal product.[187]

Distributors must submit information electronically by the 10th of the month following the month of reporting.[188]

License Holders and Distributors must keep relevant information in their records "for at least five years from the date of manufacturing, import, export or supply."[189] Companies must comply with requests for data initiated by relevant authorities.[190]

Of note, Mr. Yang Po-Wen, a Taiwanese expert in this area, mentioned that drug packages in Taiwan employ barcodes, and while the GS1-128 is widely used in Taiwan, its use is not mandated.[191] The hesitance to require GS1-128 standards stems from concerns that adopting these standards may lead to higher costs and potentially deter pharmaceutical companies from entering Taiwan's

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179. *Id.*

180. *Id.* art. 3.

181. *Id.* art. 4 ("(1) Name of the medicinal product, approved number, indication, dosage form, ingredients, company name, name and address of manufacturer recorded on the medicinal product license. (2) Bar code or other symbol for identification purpose. (3) Batch number. (4) Quantity. (5) Manufacture date. (6) Expiry date or shelf life. (7) Declared import date of medicinal product.").

182. *Id.* ("(1) The source of active ingredient. (2) Manufacturer's name, address and nationality.").

183. *Id.* art. 4. ("(1) Receptor's name, address, contact person and telephone number. (2) Name of medicinal product. (3) Batch number. (4) Quantity. (5) Manufacture date. (6) Expiry date or shelf life. (7) Delivery date.").

184. *Id*. art. 4.

185. *Id*. art. 5.

186. *Id*. ("(1) Name, address, contact person and telephone number of supplier. (2) Name of the medicinal product and approved number on the medicinal product license. (3) Batch number. (4) Quantity. (5) Manufacture date. (6) Expiry date or shelf life. (7) Delivery date.").

187. *Id*. ("(1) Name, address, contact person and telephone number of receptor. (2) Name of the medicinal product and product license number. (3) Batch number. (4) Quantity. (5) Manufacture date. (6) Expiry date or shelf life. (7) Delivery date.").

188. *Id*.

189. *Id*. art. 6.

190. *Id*. art. 7.

191. Huang, *supra* note 172.

market.[192]

D. Penalties

Under the Act, relevant authorities have the authority to confiscate or destroy counterfeit items.[193] In cases where counterfeit or substandard drugs, or faulty medical devices are sold, relevant government agencies will publish "the name, address, and the responsible person of the firm or the business, the name of the drugs involved, and the details of violation."[194] Government agencies can also suspend business operations and revoke licenses.[195] Seized counterfeit or illegal drugs are subject to confiscation and destruction.[196] Misbranded drugs or defective medical devices that are still useable can be modified to conform to specifications.[197] In specified circumstances relating to medicaments, "its manufacturer or importer shall immediately notify medical care institutions, pharmacies, and pharmaceutical firms, and within a prescribed time limit, shall recall the medicament in question from the market and dispose of it together with its stock of the medicament."[198] Finally, there are stiff criminal consequences for manufactures who import counterfeit drugs or prohibited drugs.[199]

E. Conclusion of Taiwan's Regime

Overall, the primary objective of Taiwan's pharmaceutical track and trace system, much like the DSCSA and EU regime, is to safeguard the pharmaceutical supply chain's security and reliability while preserving public health. The Act provides the foundation for the management of pharmaceutical affairs, and with its regulatory base, participation of government, and participation of industry, the system is relatively successful in protecting public health. The Taiwan Government has built robust system infrastructures for statistical analysis, enabling the TFDA and health bureaus to identify and address potential issues proactively. This comprehensive approach to pharmaceutical supply chain management ultimately protects public health and promotes confidence in the quality and safety of medications available to consumers.

This system, however, does have weaknesses. For example, standards for

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192. *Id*.

193. 藥事法 [Pharmaceutical Affairs Act], art. 77 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2018), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001 [https://perma.cc/7T7R-QA83].

194. *Id*. art. 78.

195. *Id*.

196. *Id*. art. 79.

197. *Id*.

198. *Id*. art. 80.

199. *Id.* art. 82.

barcodes and serialization are not consistent, which introduces inefficiencies and pain points for stakeholders.[200] Hesitance to use international standards such as GS1-128 could also prevent Taiwan businesses from full participation in international pharmaceutical trade. These inconsistencies, however, could be solved with a unified regional or international framework for track and trace of pharmaceuticals. More regional international participation and adherence to regional or international standards could encourage the government and industry in Taiwan to adopt a more consistent serialization and barcode standards.

Taiwan, like other countries, faces challenges related to counterfeit drugs.[201] A recent case involving rosuvastatin, which was mixed with another drug and introduced into the market, highlights this issue.[202] Despite the government's comprehensive response to the incident, the counterfeit drugs were still able to infiltrate the Taiwanese market. This underscores the importance of continued vigilance by the Taiwanese government to mitigate the risks of introducing counterfeit pharmaceuticals into its national market. One important step could be the participation in an international, cooperative system of tracking and tracing pharmaceuticals.

There are clear parallels with the DSCSA, the European Falsified Medicines Directive, and the pharmaceutical regulations in place in Taiwan. Each of these regulatory frameworks mandates stringent tracking and verification systems to ensure the authenticity and safety of medicinal products within their respective supply chains. Despite these similarities, there are missing elements, discussed below.

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200. TAIWAN CENTER FOR DRUG EVALUATION, *Expert Meeting Minutes Taiwan Pharmaceutical ePedigree System Specification and Application Plan*, (July 16, 2014), http://www.tpmma.org.tw/epaper/Upload_Files/%E5%8F%B0%E7%81%A3%E8%97%A5%E5%93%81%E5%B1%A5%E6%AD%B7%E5%B9%B3%E5%8F%B0%E7%B3%BB%E7%B5%B1%E8%A6%8F%E6%A0%BC%E8%88%87%E6%87%89%E7%94%A8%E8%A6%8F%E5%8A%83-%E6%9C%83%E8%AD%B0%E7%B4%80%E9%8C%84.pdf [https://perma.cc/5DZA-UZG5] (noting concerns about the feasibility of implementing serialization in Taiwan, discussing which country's serialization system Taiwan should adopt, and questioning whether it is possible to connect to those systems).

201. *See, e.g.*, Lee I-chia, *Batch of Lipid-Lowering Drug Faked: AstraZeneca*, TAIPEI TIMES (Mar. 06, 2017), https://www.taipeitimes.com/News/taiwan/archives/2017/03/06/2003666236 [https://perma.cc/PSB9-7ANE].

202. *Id.*

V. A WORLDWIDE UNIFIED, INTEROPERABLE, AND DIGITAL PLATFORM FOR PHARMACEUTICAL TRACK AND TRACE[203]

This article recommends that national track and trace systems should be interoperable with regional and global systems to ensure the full safety of the pharmaceutical supply chain. Therefore, this article advocates for a worldwide unified, interoperable, and digital platform for pharmaceutical track and trace. This digital platform would ideally be independent of national platforms, but national systems should be interoperable with the digital platform and be capable of interfacing with other member states. Such interoperability would entail the establishment of standardized data formats, communication protocols, and compliance requirements that facilitate information exchange between member states. By promoting interoperability, countries can efficiently share crucial information, while maintaining the independence of their own systems. The author has synthesized these three systems and created a proposed system, called the CAPTRACE system below.

A. Need for Transnational Cooperation

One government expert from the TFDA has expressed the need for transnational cooperation with regard to pharmaceutical track and trace.[204] In addition, CPhI's ASEAN Pharma 2020 Report revealed a key finding that, "the regional industry now favours introducing large scale counter measures, supply chain tracking and serialization. In fact, an overwhelming 93% of the industry experts surveyed believe that the Southeast Asian market would significantly benefit from a Track and Trace-style scheme to reduce the space for counterfeiting in the region."[205] These kinds of sentiments underscore the

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203. As noted in the author biographical section at the beginning of this article, the author has utilized ChatGPT to create or assist in the creation of content included throughout this article. For this section in particular, the author utilized significant assistance from ChatGPT to create or assist in the creation of content, especially with respect to synthesizing the elements of the CAPTRACE Agreement. Prompts included various stems that included the author's proposed language followed by significant copy editing, reversion, and further additions by the author. The author used the assistance of ChatGPT to synthesize elements of the DSCSA, the EU Directive, the Taiwan regulatory regime, and other ideas into a unique approach for the world under the CAPTRACE Agreement. This included the assistance of ChatGPT to add detail to text, expand on ideas, and create novel ways of expressing ideas. As such, ChatGPT assisted in drafting significant portions of this section under the guidance and editing of the author. This iterative process of interacting with ChatGPT (collaboration, synthesis, modification, reversion, augmenting, repeating) proved to be invaluable for the content in this section, providing a higher quality end product and superior content for the reader. For a discussion on best practices for disclosing the use of AI tools, *see generally* Mark L. Shope, *Best Practices for Disclosure and Citation When Using Artificial Intelligence Tools*, 112 GEO. L.J. ONLINE 1 (2023).

204. Huang, *supra* note 172.

205. CPHIINSIGHTS, ASEAN PHARMA REPORT: OPPORTUNITIES & THREATS 2020 AND BEYOND 7 (Mar. 2020) (available at https://www.medicpresents.com/medicfiles/9746_asean-report-rep-2020-vd-003.pdf [https://perma.cc/D9XS-HXHR]).

growing consensus within the industry for a unified track and trace regime.

ASEAN has one regional project that appears promising under the recently published ASEAN Pharmaceutical Regulatory Policy. The ASEAN Pharmaceutical Regulatory Policy states:

> It has been recognised, that in order to provide a structure and instruments to realise the free flow of safe, efficacious and quality pharmaceuticals in the region, to facilitate access to needed pharmaceuticals and eliminate substandard and falsified products, it is important to adopt first a common ASEAN Pharmaceutical Regulatory Policy (APRP). The APRP will include the principles and other key features serving as a common basis for coordination and development of the ASEAN Pharmaceutical Regulatory Framework (APRF) and will be followed by the development of legal instruments when required to implement such policy. The APRP will provide guidance for the development of comprehensive set of initiatives to support the integration of the market in the pharmaceutical sector.[206]

ASEAN, however, is limited in international scope. One vehicle to facilitate transnational track and trace cooperation on a world level would be a Cooperative Agreement on Pharmaceutical Track and Trace ("CAPTRACE Agreement").[207] The CAPTRACE Agreement would provide for a unified, comprehensive system for tracking and tracing pharmaceutical products. The CAPTRACE Agreement would be complementary to other trade and cooperative arrangements. A working group could be developed under the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to explore the CAPTRACE Agreement.[208]

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206. ASS'N OF SE. ASIAN NATIONS [ASEAN], *ASEAN Pharmaceutical Regulatory Policy*, at 2 (Mar. 15, 2022), https://asean.org/wp-content/uploads/2022/08/Final-Text-APRP-adopted-AEM-and-AHMM.pdf [https://perma.cc/BDM6-AECX].

207. Similar in spirit to the *Framework Agreement on Facilitation of Cross-border Paperless Trade in Asia and the Pacific*. Framework Agreement on Facilitation of Cross-border Paperless Trade in Asia and the Pacific, *opened for signature* Aug. 23, 2016 (entered into force Feb 20, 2021) https://repository.unescap.org/bitstream/handle/20.500.12870/1048/ESCAP-2019-PB-Framework-agreement-facilitation-cross-border-paperless-trade.pdf?sequence=1&isAllowed=y [https://perma.cc/SZ7B-3PFX]; *see also Status of the Framework Agreement on Facilitation of Cross-border Paperless Trade in Asia and the Pacific*, UN TREATY COLLECTION (Sept. 22, 2024 4:13 PM), https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=X-20&chapter=10&clang=_en [https://perma.cc/B5H9-NGVM].

208. PHARMACEUTICAL INSPECTION CONVENTIONAL–PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME [PIC/S], *Introduction*, https://picscheme.org/en/about [https://perma.cc/P9PN-DVPA] (last visited Oct. 31, 2024) ("The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S presently comprises 54 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia).").

The framework for the CAPTRACE Agreement should find inspiration from the various track and trace systems in the region and around the world, including the DSCSA, EU Falsified Medicines Directive, and the track and trace system in Taiwan. A worldwide system that is similar to the comprehensive DSCSA or EU Falsified Medicines Directive would facilitate integration into relevant pharmaceutical markets beyond Europe and North America.

VI. CAPTRACE PROPOSAL

A. Licensing Authorized Trading Partners

The proposed CAPTRACE Agreement should be designed to establish a robust framework for the licensing and regulation of authorized trading partners within member states. The activities of authorized trading partners relating to manufacture, export, import, distribution, and related movement of covered products should comply with GMP and GDP in order to uphold the highest quality and safety standards in the pharmaceutical supply chain. Ideally, a written confirmation or standard authorization from the member state would be exchanged or made available on a transparent platform for easy inspection, noting that a particular trading partner is an authorized trading partner and that member state standards have been met with regard to a covered product.

B. Auditing Authorized Trading Partners

Under the CAPTRACE Agreement, an entity seeking authorization to operate as a trading partner would be subject to a comprehensive member state led auditing process, which would evaluate its compliance with the established GMP and GDP guidelines and agreed-upon standards of member states. This process could be conducted by a national-level agency, intergovernmental body, or qualified third-party auditing organization, ensuring consistency in the evaluation. The authorized trading partner should be periodically subjected to audits in order to maintain its accreditation status. Noted above, Taiwanese law provides for government authorities to "send personnel overseas to inspect . . . foreign manufacturing factories on a periodical basis or as necessary."[209] Reciprocal agreements could be included in the CAPTRACE Agreement to allow for routine inspections by member states like the one provided for under Taiwanese law.

209. 藥事法 [Pharmaceutical Affairs Act], art. 57 FAWUBU FAGUI ZILIAOKU [TAIWAN MINISTRY OF JUSTICE LAWS AND REGULATIONS DATABASE] (2018), https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001 [https://perma.cc/7T7R-QA83].

C. Reporting Requirements

The CAPTRACE Agreement should mandate that authorized trading partners promptly report any suspicious or counterfeit pharmaceutical products to a designated competent oversight authority. This authority would be responsible for investigating the reported cases and informing other member states.

D. Trade Only Within Authorized Network

The CAPTRACE Agreement could stipulate that authorized trading partners can only engage in business transactions with other similarly authorized entities. This provision would be intended to create a closed network of authorized trading partners, thereby minimizing the chances of counterfeit products infiltrating the pharmaceutical supply chain. This authorized trading partner network would require an exchange of transaction information, transaction history, and transaction statements, like that under the DSCSA. The "exchange" of this information would be required to be recorded in "real-time." Implementing a "real-time" information exchange system would offer numerous advantages for the authorized trading partners and competent oversight authorities within member states, including enhanced traceability, rapid response to suspected counterfeit products, improved efficiency in product recalls, enhanced transparency and accountability, and simplified auditing and compliance monitoring.

E. Unique Identifiers

The proposed CAPTRACE Agreement envisions the implementation of a harmonized system of unique identifiers for pharmaceutical products among member states, aimed at enhancing the traceability and verification of product authenticity. This system would involve the assignment of a distinct identifier to each individual product at the smallest level possible, which would be registered in a centralized database accessible to all authorized trading partners. Unique identifiers for products should adhere to internationally recognized standards, ensuring consistency and interoperability across different systems.

F. Multiple Anti-tampering Mechanisms

In addition to the unique identifier, pharmaceutical packaging should be designed to incorporate multiple anti-tampering mechanisms that would enable the detection of any unauthorized access to or manipulation of the product. These anti-tampering mechanisms would serve as a necessary added layer of protection against potential counterfeit products entering the pharmaceutical supply chain. These anti-tampering mechanisms and unique identifiers would be unique to CAPTRACE Agreement member states but would also be

verifiable by other jurisdictions.

G. Verification Requirement

As part of their responsibilities under the CAPTRACE Agreement, authorized trading partners would be required to verify the authenticity of the unique identifiers assigned to the pharmaceutical products they handle. This process would involve cross-referencing the identifier with a centralized database (to be created by member states) to confirm that a covered product is genuine and has been sourced from an authorized trading partner. In the event of any discrepancies or concerns, the authorized trading partner would be obligated to report the issue to the relevant competent oversight authority for further investigation. This authority would be responsible for investigating the reported issue and, if necessary, take appropriate actions to inform other member states.

H. Routine Inspection of Pharmaceutical Products

Authorized trading partners would be expected to routinely inspect the pharmaceutical products in their possession or control for signs of irregularity. If any evidence of irregularity is discovered, the trading partner must immediately notify the competent oversight authority for further handling, including communicating with member states. Authorized trading partners would also be expected to keep inspection records for a defined period of time.

I. Track and Trace Platform

Drawing inspiration from the DSCSA, EU Directive, and Taiwan regulatory approaches, the proposed CAPTRACE Agreement advocates for the implementation of an advanced, interoperable electronic tracking and tracing system for pharmaceutical products. This system, which would be modeled after the requirements under various systems (but taking significant inspiration from the DSCSA, EU Directive, and Taiwan regulatory approaches), is intended to bolster the security and integrity of the pharmaceutical supply chain among member states, while also facilitating swift and efficient responses to irregularities. To achieve these objectives, the CAPTRACE Agreement would call for (at least) the following: secure and interoperable data exchange, inclusion of product identifiers, product verification systems, recall and investigation mechanisms, and transaction information retention protocols.[210] This platform would operate independently from national platforms; however, national systems should be compatible with this digital platform and capable of interacting with other member states through APIs or other electronic data

210. For the DSCSA approach, see 21 U.S.C. § 360eee–1(g) (Enhanced drug distribution security).

exchange protocols. Through fostering interoperability, countries can effectively share vital information while preserving the autonomy of their individual systems.

J. Driven by Data

Under this framework and taking inspiration from the Taiwan experience, oversight authorities could leverage data-driven and automated auditing and oversight processes, facilitating the development of more sophisticated and efficient auditing and oversight methods. Relevant authorities could identify patterns, trends, and anomalies that may signal potential risks or non-compliance issues. Relevant authorities could quickly analyse large volumes of data and flag potential issues for further investigation. This allows oversight authorities to allocate their resources more effectively and cover a broader scope of the pharmaceutical supply chain. Data-driven and automatic auditing and oversight methods can be continually refined and adapted based on new information, evolving regulations, or changes in the pharmaceutical supply chain landscape. The experience gained from Taiwan regarding its use of data from multiple sources could be instructive to this data driven model.

VII. CONCLUSIONS

By implementing the CAPTRACE Agreement, member states could enhance the integrity of their pharmaceutical supply chains, foster greater transparency, and ultimately, ensure the safety and efficacy of the pharmaceutical products being distributed to its citizens. Only addressing the issue of pharmaceutical supply chain safety at a national level is incomplete, as the complex and global nature of the pharmaceutical supply chain necessitates a more comprehensive, unified approach. Supply chains often span multiple countries, and involve numerous manufacturers, distributors, and trading partners, each subject to different regulatory frameworks, oversight mechanisms, and industry standards. By fostering collaboration and harmonizing robust tracking and tracing systems across borders, stakeholders can work together to effectively address the challenges posed by counterfeit and substandard products, as well as other supply chain disruptions. This cooperation ultimately protects public health and ensures the availability of safe pharmaceutical products for end consumers when those products are needed most.