Available online on 15 Sep, 2026 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University
Copyright© 2013-26 IJDRA

Review Article

Open Access

Regulatory Frameworks for Strengthening Pharmaceutical Supply Chain Security: A Comparative Analysis of EU-FMD and US-DSCSA

Isha Makadia[a], Zuki Patel[a], Vinit Movaliya[a], Maitreyi Zaveri[a], Rahul Nayak[b], Niranjan Kanaki[a,*]

[a]*Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382024, Gujarat, India.*

[b]*Makcur Laboratories pvt. ltd, Near Sola Bridge, SG Highway, Thaltej, Ahmedabad – 380054. Gujarat. India.*

Abstract

False and counterfeit drugs are a significant worldwide medical danger especially in low and middle incomes where up to 1 out of 10 Medicines can be of inferior quality. Drug safety is also becoming hard to ensure through increased globalization and complexity of supply chains. Laws such as EU-FMD or US-DSCSA help to solve such problems by implementing the system of serialization, verifying, and tracing. At the same time, the centralized verification clarifies the concept of FMD, whereas DSCSA dwells upon end-to-end track-and-trace mechanisms. All these structures contribute to transparency and allow avoiding false medicines penetrating into the supply chain.

Conclusion: EU-FMD and US-DSCSA offer huge improvements in the supply chain security of the pharmaceutical; this is achieved by serialization, traceability, and verification systems. Even though their methods are not the same, both frameworks are successful in ensuring a decrease in the chances of falsified medicines. Ongoing technology innovation and harmonization of regulations across the globe are indispensable towards improvement in the future.

Keywords: Pharmaceutical supply chain; Falsified medicines; Drug Supply Chain Security Act; Falsified Medicines Directive; Track and trace; Serialization; Regulatory compliance.

Article Info: Received 20 Mar 2026; Review Completed 11 Jun 2026; Accepted 17 Jun 2026

Cite this article as:
Makadia I, Patel Z, Movaliya V, Zaveri M, Nayak R, Kanaki N. Regulatory Frameworks for Strengthening Pharmaceutical Supply Chain Security: A Comparative Analysis of EU-FMD and US-DSCSA. Int. J. Drug Reg. Affairs [Internet]. 2026 Jun 15 [cited 2026 Jun 15]; 14(2):40-45. Available from: http://ijdra.com/index.php/journal/article/view/887

DOI: https://doi.org/10.22270/ijdra.v14i3.887
*Corresponding author. E-mail address: niranjan.kanaki@kbiper.ac.in (N Kanaki)

1. Introduction

The pharmaceutical supply chain is crucial towards ensuring that safe, effective, and quality medicines are made available to the patients globally. It is an intricate system of manufacturers, wholesalers, distributors, pharmacies, healthcare providers, and regulators. As a result of globalization of pharmaceutical manufacture and expansion of world trade, the supply chain has increasingly been becoming more interdependent and integrated. Despite globalization enhancing access to medicines and reducing the cost, it has also brought about some vulnerabilities within the system that can be used by criminal gangs dealing with the production and supply of fake medicines. (1)

Falsified medicines are the pharmaceutical products which are aware or purposely misleading their identity, composition, or source. These are drugs that are of the incorrect substances, mistaken doses, or they could even have no active pharmaceutical component. In other cases, counterfeit drugs may comprise of harmful or polluted medicines which may cause extreme harm to the customers. According to the World Health Organization, the problem of bad and fake medicine is a significant health hazard in the globe particularly in the low and middle-income nations where the government measures may be inadequate. (2,3)

There are also significant risks of fake medicines in the economy as well as health of the population. The counterfeit drugs could lead to failure of drugs, reaction, and even death. Additionally, they are also the cause of the occurrence of antimicrobial resistance within the scenario when the patients receive ineffective drugs. Globally, it is estimated that the illicit trade of fake medicine makes those that engage in it billions of dollars yearly whereas pharmaceutical firms and health care systems incur heavy financial losses due to the vice. (4,5)

The causes as to why falsified medicines are becoming common are many. These are weak regulatory supervision, the growing complexity of the pharmaceutical supply chains, the rising popularity of online pharmacies, and the rising demand of high-value and life-saving drugs like oncology and diabetes drugs. It has also boosted the easy

distribution of fake medicines to final consumers who circumvent laws anticipated by black markets of online drug distribution. (4,6)

In an effort to address these hurdles, governments and regulatory bodies have come up with several policies and technology that aim at enhancing the security and integrity of pharmaceutical supply chains. The European Union Falsified Medicines Directive (EU-FMD) and the United States Drug Supply Chain Security Act (DSCSA) are two of the most sophisticated regulatory frameworks that have been developed to this end. The two regulations are also intended to increase transparency in the pharmaceutical supply chain and ensure unadulterated medicines do not find their way into legitimate distributors of pharmaceutical products through the use of digital authentication and track-and-trace executed through serialization. (7,8)

In this paper, regulatory structures and technological platforms, which relate to EU-FMD and DSCSA systems, will be put into focus. The purpose would be to evaluate how these structures help improve security of drug supply-chains and identify future technological advances to continue tracing medicine and improving patient safety.

2. Drug Supply Chain Security Act (DSCSA)

Drug Supply Chain Security Act (DSCSA) is an Act that was adopted in the United States in 2013 and is a section of Drug Quality and Security Act (DQSA). The overall intention of DSCSA is to ensure the pharmaceutical supply chain is safer such that the tracing, verification and identification of prescription drugs at a package level in the supply chain is enabled during its passage through the distribution chain. This law mandates that an interoperable electronic system be developed to foster the growth of prescription drugs in their entire supply chain safety to deliver the fake, stolen, pollute, or otherwise harmful drugs to the patients. (9,10)

Several players exist within the framework of the DSCSA model, and they include manufacturers, repackagers, wholesale distributors, dispensers (pharmacies), and third-party logistics providers (3PLs). All the stakeholders are highly significant to traceability, verification, and reporting of the suspicious or illegitimate products. (11)

2.1 Key Requirements of DSCSA

The DSCSA has various regulatory requirements to increase the integrity of pharmaceutical supply chains.

a) Product Identification

The DSCSA mandates that manufacturer of prescription drugs place unique product identifier on each package and it is coded as a 2D Data Matrix barcode. There are four large components of the product identification:

- National Drug Code (NDC)
- Serial number
- Lot number
- Expiration date

The advantage of this type of serialization is that it provides each drug package with a unique code and authenticity as it passes through the pharmaceutical supply chain. (12)

b) Product Tracing

The trading partners are obliged to submit T3 documentation such as transaction information, history of transaction as well as transaction statements when the ownership of a pharmaceutical product changes. Product name, dosage, the strength, the lot number, and transfer dates would be in the Information of the transaction. The transaction history was the record of ancient transactions. Transaction statement would assure that the product was being taken care of as per the requirements of DSCSA. (13)

Such electronic documentation will offer complete supply chain traceability of medicines.

c) Product Verification

The stakeholders in the supply chains should have a system that will be able to identify the identifiers of a product and conduct research when an item is considered to be of ill origin. They should quarantine the product and report it to the FDA within 24 hours in case of the product being found illegitimate. (14) The nature of its products can be classified as illegitimate discovered by counterfeits, maneuvered, robbed, and adulterated intentional or otherwise not worthy of distribution. (15)

d) Authorized Trading Partners

DSCSA only allows the authorized and licensed trading partners. The pharmaceutical firms and wholesalers must be registered by FDA. The pharmacies are required to source pharmaceutical products with its distributors that have been duly licensed and certified by the relevant state or federal authorities. (16)

The importance of such a measure is to limit the involvement in the pharmaceutical distribution systems to only verified and legitimate participants.

2.2 DSCSA Timeline of Implementation

Finally, with DSCSA, the implementation process took place in several stages in the period 2013-2023.

- 2013 - DSCSA enacted
- 2017 - Serialization requirements were added.
- 2019 - Checking of saleable returns adopted.
- 2020 - Authorized trading partner check.
- 2023 - Complete an interoperable electronic system and put it into practice.

In the last stage of DSCSA, pharmaceutical products are tracked through a comprehensive electronic system throughout the U.S. supply chain. (17**Error! Reference source not found.**)

2.3 Technologies in DSCSA Support.

a) Serialization Technology

Serialization is the key technology of the DSCSA compliance. The pharmaceutical boxes have 2D Data Matrix barcode serial numbers which can be used to authenticate and track a product. (18) Such fake products can be detected by serialization systems which would

enable the regulating bodies and other stakeholders in a supply chain to trace individual medicine packages.

b) Verification Router Service (VRS)

Verification Router Services Product Verification. These are online mechanisms through which the relevant parties can confirm the identifiers of their products through serialization. VRS systems allow wholesalers and manufacturers to communicate with each other when checking on returned medicines. (19)

c) Electronic Data Interoperability Systems

DSCSA needs a standardized electronic system that could exchange supply chain information between trading partners. Through these systems, verification and tracking of pharmaceutical products in the distribution system can be done in real time. (20)

d) Emerging Technologies

Some of the emerging higher order technologies, which are under development to improve the pharmaceutical traceability systems include:

By means of blockchain, it becomes possible to create secure and non-corrupt accountability of transactions between the supply chains. (21)

It means that AI technologies can detect anomalies and abnormal behavior in distribution data. (22)

One of the devices that will facilitate the storage and transportation of pharmaceutical products is the Internet of Things (IoT). (22)

To an enormous degree, such technologies are able to enhance the transparency of the supply chain and to intercept fake goods.

2.4 Responsibilities of the stakeholders under DSCSA.

a) Manufacturers

The task that manufacturers have is to introduce serialization and provide transaction information of the pharmaceutical products. They are also to ensure that there are identifiers of products on request and to look at suspicious products when reported by the downstream partners. (23)

b) Repackagers

Repackaged medicines are subject to the continuity of traceability of these items and this means that the item must be allocated new product identifiers and to ensure the continuity, there should be an appropriate documented account on what was transpired. (24)

c) Wholesale Distributors

The effect of the wholesaler is also critical in the factualization of fake drugstuffs. They are required to verify the saleable returns, hold records of the transactions and products have to be sourced by the approved trading partners. (11)

d) Pharmacies (Dispensers)

The drug stores must check the information of transactions and must have at least six years record and identify the suspect drugs before making the medicines available to patients. (25)

3. Falsified Medicines in the EU Directive (FMD)

In the legal sphere, the European Union came up with Falsified Medicines Directive (Directive 2011/62/EU) to ensure the chaining of falsified medicines is kept out of the supply chain of medicines. The guideline that contributed to the revision of Directive 2001/83/EC provided safety measures and positive checks that would help to protect the authenticity of the drug distributed in the countries that make up the EU. (26)

The primary concept of the FMD is that falsified medicines can be prevented to enter a legal supply chain as the security of the packaging can be enhanced, and the digital verification is used.

The packaging of the pharmaceutical should be safe in nature.

The FMD imposes an obligation on the manufacturers of the prescription drugs within the EU to include two obligatory safety features, which are compulsory.

a) Unique Identifier (UI)

Each package of medication must possess a distinct identifier which is coded into the barcode of Data Matrix. The following would be in two dimensions viz. product code, serial number, batch number, and expiry date. (27)

b) Anti-Tampering Device

The medical packages must be sealed with anti-tampering machine that ensures that the product has not been tampered with or even altered prior to its delivery to the patients.

Examples include tamper-evident seals, security labels and breakable elements of the packaging.

c) The European Medicines Verification System (EMVS) represents the principal instrument for assessing quality in relation to pharmaceuticals and other healthcare products in the European Union, including Great Britain. European Medicines Verification System (EMVS) The European Medicines Verification System (EMVS) is the key tool, which determines the quality in the context of pharmaceuticals and other healthcare products within the European Union, including Great Britain.

In order to make the FMD possible, the EU established the European Medicines Verification System (EMVS). The system is composed of two elements:

European Hub - a repository database run by the European Medicines Verification Organisation (EMVO).

National Medicines Verification Systems (NMVS) - databases on a country-level that are accessed by pharmacies and wholesalers.

The manufacturers submit serialization information in the European Hub that forwards such to national systems. Before dispensing the medicines, the pharmacists scan

them using barcodes to verify that they are the right medicine that the patient requires. (28)

Once verified, the unique identifier is decommissioned, such that the same serial number is not applicable again.

3.3 Technologies Used in FMD

Pharmaceutical packages can be uniquely identified by use of 2D Data Matrix barcodes through serialisation. With this technology, it is possible to scan and check medications in a pharmacy and hospital within brief durations.

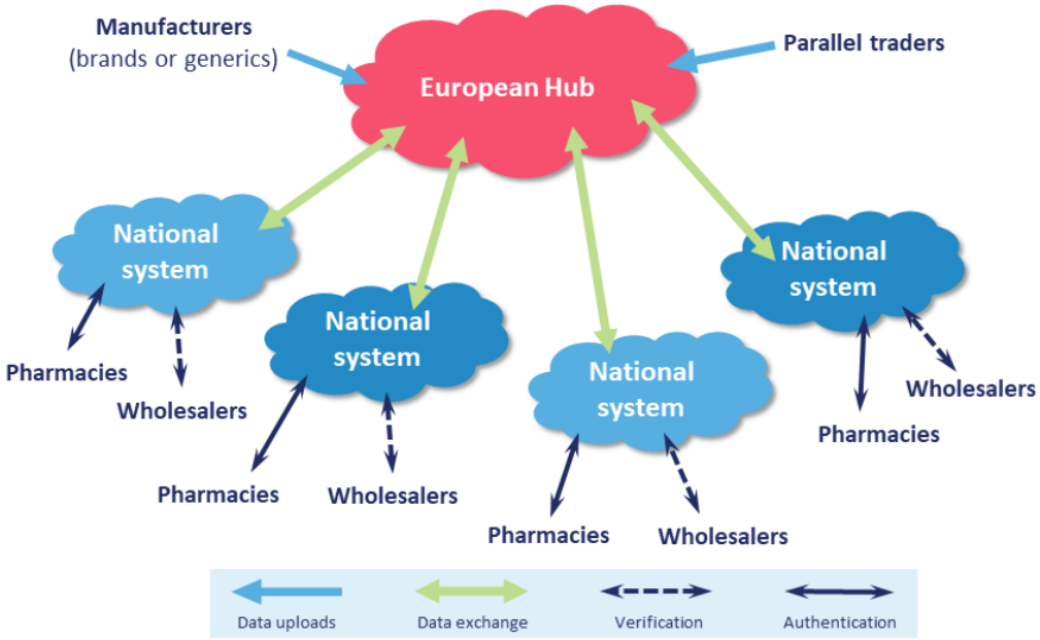


Figure 1. European Medicines Verification System (EMVS) Architecture: European Hub and National Systems

Verification Databases. This approach is centralized and it has different other names, such as black scorecards, green scorecards and others. Verification Databases. This practice is centralized and various other names are given to it, including black scorecards, green scorecards.

EMVS is a digital infrastructure that is centralized and connects manufacturers, wholesalers, pharmacies to regulators in the EU. (29**Error! Reference source not found.**)

Monitoring Systems of the Supply Chains.

The anomalies related to supply chains may be diagnosed, and suspicious medications tracked using the digital verification system, and this assists regulators to detect anomalies.

3.4 FMD Stakeholder Responsibilities

a) Manufacturers

- Manufacturers must use safety features on the packaging before submitting the serialization information to the European Hub before releasing products into the market.

b) Wholesalers

- The buyers of non-standard origin medicines should be checked by the wholesalers as well as the items being sold are produced by licensed manufacturers and individuals in this capacity to deliver goods.

c) Pharmacies and Healthcare Institutions

- The pharmacies must scan the barcode and issue the medicines to the patients in order to determine their authenticity.

d) Regulatory Authorities

- The FMD is applied to the regulatory bodies of the countries and the European Medicines Agency that conducts the investigation of falsified medicines. (9)

4. Implementation Challenges

Despite the effectiveness of DSCSA and FMD, a number of challenges can be still identified.

a) Implementation Costs

The pharmaceutical organization and supply chain network providers must pursue an expensive endeavor of executing serialisation systems, and IT infrastructure, and verification technologies.

b) Technological Complexity

The supply chain stakeholders should integrate complex e-structures in order to transfer the transaction information and confirm the product identifiers.

c) The threat of Data Insecurity and Cybersecurity

Cyber threats jeopardize the integrity of data as well as reliability of the pharmaceutical supply system due to the digitalization of its supply chain.

International of Spectacularism of Regulation

Interoperability in multinational pharma companies is an issue encountered since different countries have different laws and regulations governing them.

Table 1. Comparison of DSCSA and Falsified Medicines Directive (FMD)

Parameter	DSCSA (USA)	FMD (European Union)
Primary Goal	All prescription drugs are to be monitored all throughout the supply chain of the drug.	Prevent, falsified medicines from entering the legal supply chain.
Type of System	Track-and-Trace System	Verification System
Important Technology	Serialization by using electronic transaction data exchange	Serialization by using a central verification database
Unique Identifier	Product identifier with NDC, serial number, lot number, expiry date	'Unique Identifier' with product code, serial number, batch number, expiry date
Safety Features	2D Data Matrix barcode on packaging	2D Data Matrix barcode + Anti-Tampering Device.
Database	The structure of the sharing of decentralized data among partners in trading activities is decentralized.	It is a centralized system (European Hub + NMVS)
Verification Stage	Throughout the supply chain	Mainly at the dispensing stage
Requirements at Data Exchange	Transaction Information, Transaction History, transaction statement (T3 data)	None, transaction data exchange; repository verification.
Stakeholders	Manufacturers, wholesalers, distributors, repackagers, pharmacies	Manufacturers, wholesalers, pharmacies, hospitals
End Goal	Complete electronic traceability of medicines	Authentication of medicines before use by a patient.

5. Conclusion

DSCSA and EU FMD are two of the most progressive laws, which aim to enhance the security of the pharmaceutical supply chain. These frameworks can help to minimize the risk of the appearance of falsified medicine on legitimate markets by applying the automation of serialization, digital verification, and traceability.

Though being used in different ways, both frameworks have one common objective: to enhance the supply chain transparency and to safeguard patient safety. The future improvement of the pharmaceutical supply chain security will require additional technological advancement and collaboration of governments all over the world.

Acknowledgements

We would like to express our gratitude to our guide, who help us in writing & reviewing in this article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

Reference

1. Melia E, English A, Naughton BD. The effects of global falsified drugs regulation on the stakeholders of legitimate pharmaceutical supply chain in healthcare: a systematic review. Front Med (Lausanne) [Internet]. 2024 [cited 2026 Mar 22];11:1429872. Available from: https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2024.1429872/full/
2. World Health Organization. Poor and counterfeited medical products [Internet]. Geneva: WHO; 2017 [cited 2026 Mar 22]. Available from: https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified/
3. World Health Organization. Substandard and falsified medical products [Internet]. Geneva: WHO; 2018 [cited 2026 Mar 22]. Available from: https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products/
4. Ozawa S, Evans DR, Bessias S, Haynie DG, Yemeke TT, Laing SK, et al. The prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries. JAMA Netw Open [Internet]. 2018 [cited 2026 Jan 28];1(4):e181662. Available from: https://jamanetwork.com/
5. Salami RK, Valente de Almeida S, Gheorghe A, Njenga S, Silva W, Hauck K. Health, economic, and social impact of substandard and falsified medicines in low- and middle-income countries: a systematic review of methodological approaches. Am J Trop Med Hyg [Internet]. 2023 [cited 2026 Jan 28];108(1):1–17. Available from: https://doi.org/10.4269/ajtmh.22-0525
6. Mackey TK, Nayyar G. Digital menace: a survey of international health, patient safety, and computer security risks of rogue online pharmacies. Br Med Bull [Internet]. 2016 [cited 2026 Jan 28];118(1):110–126. Available from: https://doi.org/10.1093/bmb/ldw016
7. European Medicines Agency. Falsified Medicines Directive (FMD) [Internet]. Amsterdam: EMA; 2011 [cited 2026 Jan 28]. Available from: https://www.ema.europa.eu/
8. U.S. Food and Drug Administration. Drug Supply Chain Security Act (DSCSA) [Internet]. US: FDA; 2013 [cited 2026 Jan 28]. Available from: https://www.fda.gov/

9. Le P, Grund L, Marwa J, Ojo W, Otts J Jr, Arab F. Fighting substandard and counterfeit pharmaceuticals through pharmaceutical supply chain security: Drug Supply Chain Security Act (DSCSA) of 2013. Innov Pharm [Internet]. 2018 [cited 2026 Jan 28];9(2):1–11. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6438546/
10. United States Congress. Drug Quality and Security Act (H.R. 3204) [Internet]. US: congress.gov 2013 [cited 2026 Jan 28]. Available from: https://www.congress.gov/
11. United States Pharmacopeia (USP). Drug Supply Chain Security Act (DSCSA): summary [Internet].US; USP; 2014 [cited 2026 Jan 28]. Available from: https://www.usp.org/sites/default/files/usp/document/supply-chain/apec-toolkit/country-regional-guidelines/United%20States%20of%20AmericaDrug%20Supply%20Chain%20Security%20Act%20SummaryFood%20and%20Drug%20Administration.pdf
12. U.S. Food and Drug Administration. Product identifiers under DSCSA: questions and answers [Internet]. US: US FDA; 2021 [cited 2026 Jan 28]. Available from: https://www.fda.gov/media/116304/download
13. EMMA International. The Drug Supply Chain Security Act T3 data and DSCSA [Internet]. US:EMMA International 2024 Nov 6 [cited 2026 Jan 29]. Available from: https://emmainternational.com/t3-data-and-the-drug-supply-chain-security-act-dscsa/
14. U.S. Food and Drug Administration. Enhanced drug distribution security under DSCSA: industry guidance [Internet]. US: FDA; 2023 [cited 2026 Jan 29]. Available from: https://www.fda.gov/media/117950/download
15. U.S. Food and Drug Administration. Suspect and illegitimate product definitions under DSCSA [Internet].US: FDA; 2021 [cited 2026 Jan 29]. Available from: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FDA/DSCSA-Definition-of-Suspect-and-Illegitmate-Product-guidance-%281%29.pdf
16. TrackTraceRx. OCI and authorized trading partners: a DSCSA requirement [Internet]. TrackTraceRx; 2021 [cited 2026 Jan 29]. Available from: https://blog.tracktracerx.com/oci-and-authorised-trading-partners-a-dscsa-requirement
17. TraceLink. DSCSA timeline: what you need to know [Internet]. TraceLink; 2024 [cited 2026 Jan 30]. Available from: https://www.tracelink.com/dscsa-timeline-what-you-need-know
18. Sarkar S. Digital traceability of pharmaceutical drugs in supply chain. [Internet]. ResearchGate;2022 [cited 2026 Jan 30];10(2):39–44. Available from: https://www.researchgate.net/
19. Sundavadra R. Verification router services (VRS) in DSCSA compliance [Internet]. Jekson Vision 2024 Jun 25 [cited 2026 Jan 31]. Available from: https://jeksonvision.com/the-role-of-verification-router-services-vrs-in-the-compliance-of-dscsa/
20. U.S. Food and Drug Administration. Interoperable exchange of information for drug tracing [Internet].US FDA; 2023 [cited 2026 Jan 30]. Available from: https://www.fda.gov/media/171796/download
21. Enhance pharmaceutical supply chain through blockchain in internet of things. Internet Things J [Internet]. 2024 [cited 2026 Jan 30];26:101215.
22. Roy A, Mohapatra A, Sharwan C, Kumar A, Kumar S, Maholay A, et al. Pharmaceutical supply chain management artificial intelligence: a systematic review. World J Biol Pharm Health Sci [Internet]. 2025 [cited 2026 Jan 29];21(1):204–213. Available from: https://doi.org/10.30574/wjbphs.2025.21.1.1088
23. Le P, Grund L, Marwa J, Ojo W, Otts J Jr, Arab F. Counterfeiting or low-quality medicines: combating with DSCSA. Innov Pharm [Internet]. 2018 [cited 2026 Jan 29];9(2):1–11. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6438546/
24. Brechtelsbacher ED, Pennell B, Durham M, Hertig JB, Weber RJ. Analysis of Drug Supply Chain Security Act. Hosp Pharm [Internet]. 2016 [cited 2026 Jan 29];51(6):493–500. Available from: https://pubmed.ncbi.nlm.nih.gov/27354753/
25. National Community Pharmacists Association. Drug Supply Chain Security Act: what pharmacists should know [Internet]. US:NCPA; 2020 Sep [cited 2026 Jan 29]. Available from: https://ncpa.org/sites/default/files/2020-09/hamacher-dscsa-slides.pdf
26. Smith G, Smith JA, Brindley DA. The falsified medicines directive: the way to secure supply chain. J Generic Med [Internet]. 2014 [cited 2026 Jan 29];11(3-4):169–172. Available from: https://doi.org/10.1177/1741134315588986
27. Krähenbühl C. Delegated regulation EU-FMD safety features. Eur Ind Pharm [Internet]. 2016 [cited 2026 Jan 30]; (28):4. Available from: https://farmaceitubiedriba.lv/uploads/files/eipg28complete.pdf
28. European Medicines Verification Organisation. European Medicines Verification System explained [Internet]. EU: EMVO; 2023 Jun 16 [cited 2026 Jan 30]. Available from: https://emvo-medicines.eu/wp-content/uploads/The-European-Medicines-Verification-System-Explained.pdf
29. Systech. EU Falsified Medicines Directive infographic [Internet].; 2018 Mar [cited 2026 Feb 15]. Available from: https://health.ec.europa.eu/medicinal-products/falsified-medicines_en/