Review Article

Leveraging technology and partnerships to strengthen post-market surveillance of substandard medicines in Nigeria

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Abstract

The circulation of substandard and falsified (SF) medical products remains a persistent global health crisis, with a disproportionately severe impact on low- and middle-income countries (LMICs). Nigeria, as a major pharmaceutical market in Africa, is especially vulnerable due to a complex interplay of systemic challenges that weaken its regulatory framework. This review explores Nigeria's Post-Market Surveillance (PMS) landscape, highlighting key obstacles and leveraging recent advancements in technology and policy to propose an innovative, future-oriented strategy. Despite significant hurdles, the country has important opportunities to improve its PMS system through the strategic adoption of mobile authentication services, blockchain traceability, and artificial intelligence, along with targeted reforms. The paper concludes with specific, actionable policy recommendations, offering a roadmap for policymakers to develop a resilient, technology-driven PMS framework that safeguards public health and rebuilds trust in the nation's pharmaceutical supply chain.

Keywords: Substandard and falsified medicines, post-market surveillance, collaborative networks, pharmaceutical supply chain, public health

Introduction

The global health community recognizes substandard and falsified (SF) medicines as a critical threat, particularly in low- and middle-income countries (LMICs), where one in ten medical products fails quality standards [1]. Nigeria, with Africa's largest population and one of its fastest-growing pharmaceutical markets, carries a disproportionate burden [2]. A combination of regulatory, infrastructural, and market challenges has enabled SF medicines to circulate widely [3,4], leading to severe consequences ranging from treatment failures and preventable deaths to antimicrobial resistance and major economic losses [5,6].

Post Market Surveillance (PMS) is central to medicine quality assurance, ensuring that products on the market remain safe, effective, and of high quality [7]. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is the primary body responsible for Post Market Surveillance (PMS) [8]. Despite its mandate, the system remains underdeveloped, hindered by outdated infrastructure, limited access to modern detection technologies, inadequate laboratory capacity, and weak inter-agency coordination [9]. Yet, there are opportunities to develop PMS into a strong system capable of reducing SF medicines. Innovations such as mobile authentication services, artificial intelligence, blockchain, and rapid diagnostic tools are beginning to transform the quality assurance worldwide [10]. This review

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aims to examine Nigeria's PMS landscape, present evidence on the burden of SF medicines, evaluate the systemic challenges, highlight collaborative opportunities, and provide policy recommendations.

Burden of substandard and falsified medicines in Nigeria

Nigeria bears one of the heaviest burdens of SF medicines globally. NAFDAC estimates that counterfeit prevalence declined from 40% in 2001 to 16.7% in 2005, yet progress has plateaued, with the agency targeting <5% prevalence by 2025 [11,12]. Empirical evidence confirms the persistent nature of this threat: a 2021–2023 risk-based PMS report found quality failures across antibiotics, analgesics, and pediatric medicines [13]. A study in Enugu and Anambra revealed that 25.4% of 260 essential medicine samples failed USP-42 specifications [14], and in Lagos, nearly 20% of antibiotics sampled failed API content tests [15].

The consequences are devastating: poor-quality antimalarials alone are estimated to cause 12,300 deaths annually and cost Nigeria nearly US$892 million per year [16], also accelerating antimicrobial resistance and undermining national disease programs [17]. Tragic case studies, from the 2008 *My Pikin* incident [11] to the 2024–2025 recalls of contaminated cough syrups [18], underscore the human cost of regulatory gaps. Furthermore, the very existence of vast, unregulated open drug markets, through which NAFDAC seized falsified medicines valued at over ₦684 million (2022–2024), highlights the scale of the problem [12,19]. Together, these data show that despite notable progress, Nigeria continues to face a significant public health emergency due to SF medicines.

Current state of post-market surveillance in Nigeria

NAFDAC oversees PMS through its Pharmacovigilance and Post-Marketing Directorate, with laboratories in Lagos, Kaduna, and Abuja serving as reference points [8]. Nigeria pioneered Mobile Authentication Service (MAS), enabling consumers to verify drug authenticity via SMS [20]. While innovative, uptake remains limited, studies report usage by only 20–40% of consumers, constrained by network challenges and low awareness [10,21]. Pharmacovigilance relies heavily on spontaneous adverse drug reaction (ADR) reporting through the Med Safety App and hospital-based systems [22]. However, under-reporting remains widespread, especially among nurses and pharmacists [23,24]. International partners such as the WHO has supported NAFDAC's post-marketing surveillance (PMS) in Nigeria through training, capacity building, and its Global Surveillance and Monitoring System (GSMS) for substandard and falsified medicines [25]. Complementing this, the U.S. Pharmacopeia's Promoting the Quality of Medicines Plus (PQM+) program has strengthened NAFDAC's laboratory systems and quality assurance capacity to improve medicine quality monitoring [26]. Despite these initiatives, Nigeria's PMS framework remains fragile, with significant room for strengthening infrastructure, coordination, and technology integration.

Challenges to post-market surveillance in Nigeria

Nigeria's PMS remains constrained by multiple, interconnected systemic barriers that limit its effectiveness. These challenges can be categorized into four key areas: (1) infrastructural and resource deficits: inadequate laboratory capacity, outdated analytical equipment, and a critical shortage of skilled personnel significantly delay the detection and response to poor-quality medicines [27,28]. A lack of sustained funding restricts the expansion of routine surveillance and investment in modern technologies. (2) Regulatory and enforcement weaknesses: despite reforms, enforcement is inconsistent, characterized by weak penalties for offenders, prolonged judicial processes, and critically poor inter-agency collaboration between NAFDAC, Customs, and security agencies [29,30]. This fragmentation creates significant loopholes that are easily exploited. (3) Unregulated markets and porous borders: the persistence of large, unregulated open drug markets (e.g., Idumota in Lagos, Sabon-Gari in Kano) provides a direct distribution channel for SF products [19,31]. This is compounded by porous borders, which facilitate the inflow of counterfeit medicines from abroad, especially given Nigeria's reliance on imported pharmaceuticals [32,33]. (4) Technological and awareness limitations: the uptake of technological solutions like the pioneering Mobile Authentication Service (MAS) remains low due

to poor telecom coverage, consumer fatigue, and limited public awareness [29]. More advanced tools (AI, blockchain) are underutilized due to cost and expertise gaps [34,35]. Furthermore, systemic under-reporting of adverse drug reactions by healthcare professionals cripples pharmacovigilance efforts [36,37].

Roles of technology in strengthening post-market surveillance

Blockchain technology is an advanced database that stores information in a transparent way that is resistant to tampering [38]. Blockchain technology was reviewed in the post-marketing surveillance of medical devices, and some of its advantages were easy documentation of activities, traceability of the devices, and detection of fraudulent activity [39]. It enhances drug safety by ensuring the integrity and transparency of the pharmaceutical supply chain [40]. Blockchain helps to track and verify the authenticity of drugs, thereby reducing the risks of counterfeit medications introduced to the market [41]. Artificial intelligence also plays a good role in drug surveillance [42]. After a product is put on the market, artificial intelligence (AI) greatly enhances post-market monitoring by improving the ability to track, evaluate, and react to data about its efficacy and safety [43]. Uses of AI in PMS are data collection, monitoring of activities, and predicting trends [44]. AI can be used to analyze trends from various sources, which include social media, patient registries, and research studies, which would give an insight into the efficacy of the drug or medical device, ultimately improving drug safety and outcomes of drug users [45]. A study suggests social media is an important tool for enhancing the post-marketing safety surveillance procedure as it provides information on safety issues from people raising concerns on social media or from debates about the drug [46].

Electronic health records are the digital versions of the medical histories of patients kept by health professionals, which usually contain a complete medical history of the patient which including allergies, side effects, and adverse effects of drugs [47]. They provide real-time access to the patient, making it easier to track patients' health progress and response to medications [48]. To conduct research that benefits society, public health experts are actively leveraging electronic health data [49]. Clinical data is now scarce, but as more providers use EHRs, the amount of data will increase [50]. This way, drug manufacturers, researchers, and public health organizations will be able to better monitor illness outbreaks and possible threats from drugs in the market during post-marketing surveillance. A summary of these technology strategies, their key functions, and associated challenges is presented in **Table 1**.

Roles of collaborative networks

The key stakeholders involved in collaborative networks for post-market surveillance of medicines are illustrated in **Figure 1**. Effective PMS depends on multi-stakeholder collaboration [51]. In Nigeria, key actors include NAFDAC, Customs, the Pharmacists Council of Nigeria, healthcare facilities, pharmaceutical companies, academia, and patients [52].

Figure 1. Collaborative networks in post-market surveillance

Table 1. Technological and collaborative strategies for strengthening post-market surveillance in Nigeria

Strategy	Key Functions	Challenges	Examples with cited references	Policy recommendations
Mobile Authentication Services (MAS)	Allows consumers to verify drug authenticity via text messages	Limited uptake due to poor network coverage, low public awareness, and consumer fatigue	Nigeria's existing MAS system [29]	Expand awareness campaigns, improve telecom coverage, and incentivize consumer use
Blockchain	Ensures transparency and integrity of supply chains, enabling drug tracking and authenticity verification	High cost, complexity, and need for infrastructure	Applied in supply chain surveillance projects globally [55]	Pilot blockchain systems for Nigeria's drug supply chain, and establish a centralized database for real-time monitoring
Artificial Intelligence (AI)	Improves surveillance through big data analytics, signal detection, and predictive modeling of ADRs	Limited local expertise and insufficient digitized data	Used for pharmacovigilance trend analysis in other LMICs [35]	Invest in AI capacity, integrate with NAFDAC's Med Safety App for ADR reporting
Electronic Health Records (EHRs)	Provide longitudinal patient data on medication outcomes, allergies, and ADRs	Clinical data scarcity due to low EHR adoption rates	Leveraged in research for population-level drug safety [57]	Scale up EHR adoption and link with PMS systems for real-time pharmacovigilance
Electronic Health Records (EHRs)	Facilitate data sharing among regulators, providers, and international partners to detect and respond to SF medicines	Under-reporting of ADRs, fragmentation of agencies (e.g., NAFDAC, Customs, Police)	ADVANCE project in Europe for multi-stakeholder drug safety collaboration [58]	Establish multi-agency taskforces and public-private partnerships to strengthen PMS coordination in Nigeria
Collaborative networks	Integrate regulators, healthcare providers, industry, academia, NGOs, and patients for shared PMS activities	Fragmented coordination, under-reporting by frontline staff, unclear roles, limited data sharing	NAFDAC-Customs joint operations, ADVANCE and ENCePP consortia [51-55]	Formalize data-sharing platforms, define stakeholder roles, provide incentives, and strengthen multi-stakeholder engagement

ADVANCE: Accelerated Development of Vaccine benefit-risk Collaboration in Europe; ADR: Adverse Drug Reaction; AI: Artificial Intelligence; EHRs: Electronic Health Records; ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance; LMICs: Low- and Middle-Income Countries; MAS: Mobile Authentication Services; NAFDAC: National Agency for Food and Drug Administration and Control (Nigeria); NGOs: Non-Governmental Organizations; PMS: Post-Market Surveillance; MAS: Mobile Authentication Services; ADR: Adverse Drug Reaction; LMICs: Low- and Middle-Income Countries; AI: Artificial Intelligence; EHRs: Electronic Health Records; NAFDAC: National Agency for Food and Drug Administration and Control (Nigeria); PMS: Post-Market Surveillance; NGOs: Non-Governmental Organizations; ADVANCE: Accelerated Development of Vaccine benefit-risk Collaboration in Europe; ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

NAFDAC's joint operations with Customs and security agencies have enhanced seizures, yet coordination remains fragmented [53]. Lessons can be drawn from global consortia such as ADVANCE in Europe and ENCePP, which successfully integrate regulators, academia, and industry into shared PMS systems [54,55].

Healthcare providers are frontline contributors, but under-reporting by nurses and pharmacists weakens pharmacovigilance [56]. NGOs like USP and private startups like RxAll play complementary roles by providing technical innovations and consumer-facing tools [26]. Strengthening collaborative networks in Nigeria will require formalized data-sharing platforms, clear role definitions, and incentives for participation.

Policy recommendations and future directions

To strengthen PMS in Nigeria, reforms must be both practical and forward-looking. Legislative reform is a critical first step. Enacting a Medicines Quality and Safety Act would unify fragmented laws and create an enabling legal framework that mandates serialization across the supply chain. Such an act could also establish specialized fast-track courts for counterfeit medicine cases and introduce asset forfeiture provisions to deter offenders, ensuring that legal outcomes are both swift and impactful [57]. In parallel, decentralization of laboratory capacity is urgently needed. Establishing regional Centres of Excellence for PMS within universities and teaching hospitals would expand testing beyond the three national laboratories. Equipped with advanced technologies such as high-performance liquid chromatography (HPLC) and next-generation sequencing, these hubs could strengthen Nigeria's capacity to detect falsified medicines while fostering academic–regulatory partnerships [58].

Sustained engagement with the pharmaceutical industry is equally important. Fiscal incentives such as tax reliefs, subsidies, and preferential procurement policies could motivate manufacturers to adopt serialization and barcoding more rapidly, similar to India's experience in enforcing traceability for pharmaceutical exports [59,60]. Alongside economic tools, Nigeria should harness technology-driven surveillance. The deployment of geospatial and satellite monitoring, coupled with AI-powered analytics, could support border agencies and NAFDAC in mapping illicit trafficking routes and identifying cross-border hotspots of counterfeit drug inflows, adapting existing models applied in the monitoring of other transnational crimes [61].

On the international stage, Nigeria would benefit from deeper integration with global and regional frameworks. Active participation in the WHO Global Surveillance and Monitoring System (GSMS) and Africa CDC's medicine quality networks would enhance early warning mechanisms, improve access to real-time alerts, and strengthen Nigeria's positioning as a regional leader in quality assurance [62,63]. To sustain these reforms, human capital development is indispensable. Establishing a National School of Regulatory Science, modeled after the U.S. FDA's Centers of Excellence, could institutionalize advanced training programs for NAFDAC officers, customs personnel, and pharmacists, thereby professionalizing and modernizing Nigeria's regulatory workforce [64].

Equally important is empowering consumers, who remain the final defense against SF medicines. Expanding the Mobile Authentication Service (MAS), introducing nationwide awareness campaigns, and piloting innovations such as IoT-enabled smart packaging and handheld portable screening devices would engage patients more directly in medicine verification and strengthen community participation in surveillance [59,65]. Future research should provide the evidence base to guide policy. Priorities include cost-benefit analyses of serialization, rigorous evaluations of AI-driven pharmacovigilance systems in resource-limited contexts, and consumer behavior studies to better understand the drivers of counterfeit medicine purchases. Together, these reforms would move PMS beyond fragmented efforts and toward a resilient, data-driven system capable of safeguarding medicine quality for all Nigerians.

Conclusion

Combating substandard and falsified medicines in Nigeria demands a decisive and integrated strategy. Current efforts, while showing past progress, are hampered by systemic weaknesses in regulation, infrastructure, and enforcement. To build a resilient system, Nigeria must enact

robust legislation like a dedicated Medicines Quality and Safety Act and invest in regional Centers of Excellence for decentralized testing. Success hinges on strengthening multi-stakeholder collaboration and fully leveraging innovative technologies such as AI and blockchain for supply chain monitoring. Ultimately, by implementing these coordinated measures, legislative, technological, and collaborative, Nigeria can transform its post-market surveillance into a powerful shield, ensuring medicine quality, protecting public health, and securing its position as a leader in regional health security.

Ethics approval

Not applicable.

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Competing Interests

The authors declare no conflict of interest.

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Underlying data

Derived data supporting the findings of this study are available from the corresponding author on request.

Declaration of artificial intelligence use

Artificial intelligence-based language model, Quillbot, was employed for improving the grammar, sentence structure, and readability of the manuscript. We confirm that all AI-assisted processes were critically reviewed by the authors to ensure the integrity and reliability of the results. The final decisions and interpretations presented in this article were solely made by the authors.

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References

1. World Health Organization. A study on the public health and socioeconomic impact of substandard and falsified medical products. Available from: https://www.who.int/publications/i/item/9789241513432. Accessed: 13 September 2025.
2. Ezeamalu B. Nigerian company to make HIV, malaria test kits after US funding cut. Reuters 2025. Available from: https://www.reuters.com/business/healthcare-pharmaceuticals/nigerian-company-make-hiv-malaria-test-kits-after-us-funding-cut-2025-06-19/. Accessed: 13 September 2025.
3. Macé C, Nikiema JB, Sarr OS, *et al.* The response to substandard and falsified medical products in francophone sub-Saharan African countries: Weaknesses and opportunities. J Pharm Policy Pract 2023;16(1):117.
4. The Guard Nigeria News. Proliferation of substandard medicines worries NAFDAC, 2023. Available from: https://guardian.ng/news/proliferation-of-substandard-medicines-worries-nafdac/. Accessed: 13 September 2025.
5. Ozawa S, Evans DR, Bessias S, *et al.* Prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries: A systematic review and meta-analysis. JAMA Netw Open 2018;1(4):e181662.
6. Walker EJ, Peterson GM, Grech J, *et al.* Are we doing enough to prevent poor-quality antimalarial medicines in the developing world? BMC Public Health 2018;18(1):630.
7. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. Available from: https://www.who.int/publications/i/item/9789240015319. Accessed: 13 September 2025.

8. NAFDAC. Pharmacovigilance and post market surveillance (PV/PMS). Available from: https://nafdac.gov.ng/about-nafdac/nafdac-organisation/directorates/pharmacovigilance-and-post-market-surveillance/. Accessed: 14 September 2025.
9. Okereke M, Anukwu I, Solarin S, *et al.* Combatting substandard and counterfeit medicines in the Nigerian drug market: How industrial pharmacists can rise up to the challenge. Innov Pharm 2021;12(3):10.24926/iip.v12i3.4233.
10. Oyetunde OO, Ogidan O, Akinyemi MI, *et al.* Mobile authentication service in Nigeria: An assessment of community pharmacists' acceptance and providers' views of successes and challenges of deployment. Pharm Pract 2019;17(2):1449.
11. Aminu N, Sha'aban A, Abubakar A, *et al.* Unveiling the peril of substandard and falsified medicines to public health and safety in Africa: Need for all-out war to end the menace. Med Access Point Care 2017;1:maapoc.0000023.
12. Blueprint. NAFDAC to reduce substandard, falsified medicines to 5% by 2025. Available from: https://blueprint.ng/nafdac-to-reduce-substandard-falsified-medicines-to-5-by-2025-dg/. Accessed: 9 September 2025.
13. NAFDAC. Report of risk based post market surveillance of selected medical products innigeria carried out in 2021, 2022, and 2023. Available from: https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Reports/PMS_Reports/Report-Of-Risk-Based-Post-Market-Surveillance-Of-Selected-Medical-Products-In-Nigeria-Carried-Out-In-2021-2022-2023.pdf. Accessed: 9 September 2025.
14. Gabel J, Lächele M, Sander K, *et al.* Quality of essential medicines from different sources in Enugu and Anambra, Nigeria. Am J Trop Med Hyg 2024;111(1):179-195.
15. Think Global Health. Nigeria's counterfeit drug epidemic. Available from: https://www.thinkglobalhealth.org/article/nigerias-counterfeit-drug-epidemic. Accessed: 13 September 2025.
16. Beargie SM, Higgins C, Evans DR, *et al.* The economic impact of substandard and falsified antimalarial medications in Nigeria. PLoS One 2019;14(8):e0217910.
17. Cadwallader AB, Nallathambi K, Ching C. Why assuring the quality of antimicrobials is a global imperative. AMA J Ethics 2024;26(6):472-478.
18. Adetayo O, Acharya B, Adetayo O, *et al.* Nigeria says no record of child deaths from recalled J&J cough syrup. Reuters 2024. Available from: https://www.reuters.com/business/healthcare-pharmaceuticals/nigerian-regulator-no-record-child-deaths-recalled-jj-cough-syrup-2024-04-16/. Accessed: 9 September 2025.
19. Fatokun O. Curbing the circulation of counterfeit medicines in Nigeria. Lancet 2016;388.
20. NAFDAC. Mobile authentication service (MAS). Available from: https://nafdac.gov.ng/our-services/pharmacovigilance-post-market-surveillance/mobile-authentication-service-mas/. Accessed: 14 September 2025.
21. Chinwe U. Audience awareness and use of mobile authentication service (MAS) in identifying fake and substandard drugs in Nigeria. Mgbakoigba J Afr Stud 2022.
22. Desai M. Pharmacovigilance and spontaneous adverse drug reaction reporting: Challenges and opportunities. Perspect Clin Res 2022;13(4):177-179.
23. Adewumi SI, Kaura J, Adeniji AA, *et al.* Survey of knowledge of pharmacovigilance and adverse drug reactions reporting among healthcare providers in Abuja, Nigeria. Afr J Educ Manag Teach Entrep Stud 2024;13(2).
24. Osho F. Knowledge, attitudes and practices of adverse drug reaction reporting among nurses in a tertiary hospital in South West Nigeria. Cape: University of the Western Cape; 2018.
25. World Health Organization. Newly appointed NAFDAC DG seeks to strengthen partnership with WHO Nigeria. Available from: https://www.afro.who.int/news/newly-appointed-nafdac-dg-seeks-strengthen-partnership-who-nigeria. Accessed: 14 September 2025.
26. Promoting the Quality of Medicines. Promoting the quality of medicines in Nigeria 2017. Available from: https://www.usp-pqm.org/where-we-work/field-offices/nigeria. Accessed: 14 September 2025.
27. Allison FI, Ojule AA, Allison I. Medical laboratories in Nigeria (Part 1): Assessment of quality management practices and accreditation status. Eur J Med Health Sci 2024;6(2):21-29.
28. Uchejeso O, Maduka K, Bassey I, *et al.* Improving quality and cost diminution in modern healthcare delivery: The role of the medical laboratory scientists in Nigeria. Int J Bus Environ 2019;8:8-19.
29. Eruaga M, Itua E, Bature J. Enhancing medication quality control in Nigeria: A comprehensive analysis of regulatory challenges and solutions. Int Med Sci Res J 2024;4:284-294.
30. Okaphor EF, Onah CA. An examination of the law of drug offences in Nigeria. Int Rev Law Jurisprud 2024;6:22.

31. Aliyu B, Ugwuoke C. Nigeria's pharmaceutical industry and the challenges of control by regulatory agencies. Niger J Sociol Anthropol 2024;22:36-49.
32. Fatokun O. Fostering local production of essential medicines in Nigeria. Bull World Health Organ 2020;98:507-508.
33. Igbokwe U, Ibrahim R, Aina M, *et al.* Evaluating the implementation of the National Primary Health Care Development Agency (NPHCDA) gateway for the Basic Healthcare Provision Fund (BHCPF) across six Northern states in Nigeria. BMC Health Serv Res 2024;24.
34. Adeyemo KS, Mbata AO, Balogun OD. Combating counterfeit drugs in the U.S. pharmaceutical supply chain: The potential of blockchain and iot for public health safety. Int J Adv Multidiscip Res Stud 2025;4(6):1730-1739.
35. Saidu Y, Shuhidan SM, Aliyu DA, *et al.* Convergence of blockchain, IoT, and AI for enhanced traceability systems: A comprehensive review. IEEE Access 2025;13:16838-16865.
36. Adegbuyi TA, Fadare JO, Araromi EJ, *et al.* Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals working in primary, secondary and tertiary healthcare facilities in Ekiti State, South-West Nigeria. Hosp Pharm 2021;56(6):751-759.
37. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. BMC Health Serv Res 2019;19(1):926.
38. Beck R, Avital M, Rossi M, *et al.* Blockchain technology in business and information systems research. Bus Inf Syst Eng 2017;59:381-384.
39. Muniappan S, Jeyaraman M, Yadav S, *et al.* Applications of blockchain-based technology for healthcare devices post-market surveillance. Cureus 16(4):e57881.
40. Muniappan S, Jeyaraman M, Yadav S, *et al.* Applications of blockchain-based technology for healthcare devices post-market surveillance. Cureus 2024;16(4).
41. Alam N, Hasan Tanvir MR, Shanto SA, *et al.* Blockchain based counterfeit medicine authentication system. Penang: IEEE 11th IEEE Symposium on Computer Applications & Industrial Electronics (ISCAIE); 2021.
42. Nagar A, Gobburu J, Chakravarty A. Artificial intelligence in pharmacovigilance: Advancing drug safety monitoring and regulatory integration. Ther Adv Drug Saf 2025;16:20420986251361435.
43. Huanbutta K, Burapapadh K, Kraisit P, *et al.* Artificial intelligence-driven pharmaceutical industry: A paradigm shift in drug discovery, formulation development, manufacturing, quality control, and post-market surveillance. Eur J Pharm Sci 2024;203:106938.
44. Khinvasara T, Tzenios N, Shanker A. Post-market surveillance of medical devices using AI. J Complement Altern Med Res 2024;25(7):2024.
45. Khinvasara T, Tzenios N, Shankar A. Post-market surveillance of medical devices using AI. J Complement Altern Med Res 2024;25(7):2024.
46. Powell GE, Seifert HA, Reblin T, *et al.* Social media listening for routine post-marketing safety surveillance. Drug Saf 2016;39(5):443-454.
47. Evans RS. Electronic health records: Then, now, and in the future. Yearb Med Inform 2016(Suppl 1):S48-S61.
48. Hek K, Rolfes L, Puijenbroek EV van, *et al.* Electronic health record–triggered research infrastructure combining real-world electronic health record data and patient-reported outcomes to detect benefits, risks, and impact of medication: Development study. JMIR Med Inform 2022;10(3):e33250.
49. Adenyi AO, Okolo CA, Olorunsogo T, *et al.* Leveraging big data and analytics for enhanced public health decision-making: A global review. GSC Adv Res Rev 2024;18(2):450-456.
50. Menachemi N, Collum TH. Benefits and drawbacks of electronic health record systems. Risk Manag Healthc Policy 2011;4:47-55.
51. Malleshwari GN, Afsana M. Post-marketing surveillance and drug safety monitoring: Ensuring patient well-being. Int J Trend Sci Res Dev 2023;7(6):2456-6470.
52. Yu JH, Lee S, Kim YJ, *et al.* Assessing post-marketing requirements for orphan drugs: A cross-sectional analysis of FDA and EMA oversight. Clin Pharmacol Ther 2024;116(6):1560-1571.
53. The Authority News. Customs, NAFDAC sign MoU to forge strategic partnership. Available from: https://authorityngr.com/2024/11/15/customs-nafdac-sign-mou-to-forge-strategic-partnership/. Accessed: 14 September 2025.
54. Sturkenboom M, Bahri P, Chiucchiuini A, *et al.* Why we need more collaboration in Europe to enhance post-marketing surveillance of vaccines. Vaccine 2020;38:B1-B7.

55. Torcel-Pagnon L, Bauchau V, Mahy P, *et al.* Guidance for the governance of public-private collaborations in vaccine post-marketing settings in Europe. Vaccine 2019;37(25):3278-3289.
56. Hayek A, Sridhar SB, Rabbani SA, *et al.* Exploring pharmacovigilance practices and knowledge among healthcare professionals: A cross-sectional multicenter study. SAGE Open Med 2024;12:20503121241249908.
57. World Health Organization. Global surveillance and monitoring system for substandard and falsified medical products. Geneva: World Health Organization; 2024.
58. Alum EU, Manjula VS, Uti DE, *et al.* Metabolomics-driven standardization of herbal medicine: Advances, applications, and sustainability considerations. Nat Prod Commun 2025;20(8):1934578X251367650.
59. Mandava H. Improving the integrity of pharmaceutical serialization with enterprise technologies. Int J Sci Res Comput Sci Eng Inf Technol 2024;10:514-520.
60. Sarkar S. Why pharmaceuticals serialization is a fairytale for third world. In: Kaaraman R, editor. Novel aspects on pharmaceutical research, volume 5. West Bengal: BP International; 2023.
61. United Nations. World drug report 2021. Available from: //www.unodc.org/unodc/en/data-and-analysis/wdr2021.html. Accessed: 14 September. 2025.
62. Kiguba R, Olsson S, Waitt C. Pharmacovigilance in low- and middle-income countries: A review with particular focus on Africa. Br J Clin Pharmacol 2023;89(2):491-509.
63. Pascu GA, Hancu G, Rusu A. Pharmaceutical serialization, a global effort to combat counterfeit medicines. Acta Marisiensis Ser Med 2020;66(4):132-139.
64. U.S Food and Drug Administration. Centers of excellence in regulatory science and innovation (CERSIs). Available from: https://www.fda.gov/science-research/advancing-regulatory-science/centers-excellence-regulatory-science-and-innovation-cersis. Accessed: 14 September 2025.
65. Ezeodimegwu AC, Iloabuchi FC, Onyia IMA, *et al.* Assessment of the State of Pharmacovigilance in the federal capital territory of Nigeria, using WHO pharmacovigilance indicators. Ther Innov Regul Sci 2024;58(6):1148-1158.