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Review Article

Recent Advances in Pharmaceutical Packaging: Material Safety, Smart Technologies, Anti-Counterfeiting, Sustainability, and Circular Medicine Systems

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ABSTRACT

Pharmaceutical packaging is an essential component of the medicinal product because it protects the formulation from physical, chemical, and microbiological hazards while supporting identification, storage, distribution, administration, and patient use. The packaging landscape is changing in response to persistent concerns about material–product interactions, falsified medicines, temperature excursions, medication errors, pharmaceutical waste, and the environmental burden of conventional materials. This narrative review synthesizes key developments across five interconnected domains: conventional packaging materials and medication safety; functional and intelligent packaging; anti-counterfeiting and digital traceability; sustainable materials and life-cycle considerations; and technology-enabled medicine-return and reuse concepts. Glass, polymers, metals, elastomers, and multilayer systems each provide different barrier, mechanical, and processing characteristics, but require product-specific compatibility assessment, including evaluation of extractables, leachables, adsorption, permeation, and container-closure integrity. Emerging systems—including two-dimensional barcodes, radio-frequency identification, near-field communication, time–temperature indicators, sensors, and connected packaging—can strengthen product authentication and environmental monitoring when supported by reliable data governance and supply-chain integration. Nanocomposites and bio-based or biodegradable polymers may improve selected functional properties, although migration safety, scalability, end-of-life infrastructure, and life-cycle impacts remain decisive considerations.

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Artificial intelligence and computer vision offer opportunities for packaging inspection, defect detection, material-property prediction, and process optimization, but require representative datasets, external validation, and transparent performance reporting. Finally, smart packaging may contribute to medicine-return assessment and circular pharmaceutical supply chains, yet reuse of dispensed medicines must remain subject to stringent quality, stability, legal, and patient-safety controls. Overall, future pharmaceutical packaging should be designed as a validated quality system rather than as a passive container, balancing drug protection, traceability, usability, regulatory compliance, and environmental performance.

INTRODUCTION

Pharmaceutical packaging is not merely an outer covering; it is part of the product system that maintains quality from manufacture through storage, distribution, dispensing, and administration. A suitable package must contain the dosage form, protect it from environmental stress, remain compatible with the formulation, provide information, and support safe handling by healthcare professionals and patients. Packaging performance is therefore linked to stability, microbiological quality, dose accuracy, adherence, and the integrity of the pharmaceutical supply chain.

Packaging is commonly classified into primary, secondary, and tertiary levels. Primary packaging directly contacts or contains the dosage form, such as a vial, ampoule, bottle, blister cavity, sachet, prefilled syringe, or closure. Secondary packaging groups or protects primary packs and commonly carries patient-facing information, while tertiary packaging facilitates bulk handling and transport. The boundary between these levels is important because the risk of direct product interaction is generally greatest for primary components, although inks, adhesives, labels, and external materials may also become relevant through migration, contamination, or transport-related failure.

The choice of packaging is formulation- and route-dependent. Moisture-sensitive tablets may require high-barrier blister materials or desiccant-containing bottles; light-sensitive products may need amber glass or opaque polymers; sterile injectables require container-closure integrity and compatibility; and biologics may require specialized materials and temperature-controlled distribution. Inadequate barrier properties can permit oxygen, water vapour, or light to reach the product, while unsuitable contact materials may release substances, adsorb active ingredients, or alter product performance.

Packaging is also a security and information platform. Counterfeit and substandard medical products can expose patients to ineffective or harmful treatment. The World Health Organization has estimated that at least one in ten medicines in low- and middle-income countries is substandard or falsified, underscoring the public-health importance of effective quality systems and supply-chain controls [1]. Digital identifiers and tamper-evident features can help detect diversion or falsification, but they do not replace pharmaceutical quality testing or regulatory oversight.

At the same time, the environmental impact of pharmaceutical packaging is receiving increasing attention. Material reduction, recyclability, renewable feedstocks, and improved waste management must be considered without compromising sterility, stability, barrier performance, or child-resistant and senior-friendly functions. The purpose of this review is to integrate established packaging science with emerging digital and sustainable approaches, identify practical limitations, and outline research priorities for safer and more responsible pharmaceutical packaging.

2. Review approach and scope

This manuscript is structured as a narrative review based on the subject areas and source abstracts supplied in the user's document, supplemented by selected authoritative regulatory and scientific sources identified for this draft. The synthesis is organized thematically rather than presented as a systematic review or meta-analysis. Core themes include packaging materials, drug–package interactions, functional and intelligent systems, authentication and traceability, sustainable materials, artificial intelligence, and medicine reuse.

For a journal submission, the authors should complete and report a reproducible literature-search record: databases searched (for example, PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar), exact search dates, full search strings, date limits, language restrictions, inclusion and exclusion criteria, screening

process, and the number of records included. The source document refers to reviews covering 127 articles and 100 studies, but those sample counts belong to the cited source reviews and must not be represented as the number of studies independently screened for the present manuscript [2,3].

Suggested search concepts for the final search record include combinations of: pharmaceutical packaging; container closure; glass; polymer; elastomer; extractables; leachables; migration; blister; smart packaging; RFID; NFC; QR code; serialization; anti-counterfeiting; time-temperature indicator; sustainable packaging; biopolymer; nanocomposite; life-cycle assessment; artificial intelligence; machine learning; medicine reuse; and returned medicines. A PRISMA flow diagram should only be included if the authors actually conduct a systematic or scoping review with documented screening.

3. Pharmaceutical packaging materials and their safety implications

3.1 Glass

Glass is widely used for pharmaceutical bottles, ampoules, cartridges, and vials because it can provide high transparency, rigidity, and an effective barrier to gases and moisture. Type I borosilicate glass is commonly selected for products requiring high hydrolytic resistance, including many parenteral preparations. Other glass compositions may be suitable for less demanding applications depending on the formulation and applicable standards.

Potential concerns include breakage, delamination, surface-related particulate formation, and release of alkali or other glass constituents under certain conditions. Product pH, ionic strength, storage duration, sterilization, and surface treatment can influence glass –product interactions. Amber or otherwise light-protective glass may be required for photolabile products. Compatibility and container-closure performance should be demonstrated for the specific formulation and intended shelf life rather than inferred solely from the glass type.

3.2 Plastics and polymeric materials

Plastic packaging is valued for low weight, design flexibility, impact resistance, and processing versatility. Common polymers include polyethylene (PE), polypropylene (PP), polyethylene terephthalate (PET), polyvinyl chloride (PVC), cyclic olefin polymers/ copolymers, and ethylene-vinyl acetate. They are used in bottles, closures, blister components, flexible films, infusion containers, and device-integrated packaging. The performance of a polymer depends on its chemistry, molecular structure, additives, manufacturing process, thickness, and intended use.

Potential risks include permeation of oxygen or water vapour, sorption of active ingredients or preservatives, and migration of residual monomers, oligomers, plasticizers, antioxidants, stabilizers, pigments, lubricants, or processing aids. These risks are not uniform across all polymers and must be assessed in the context of the drug product. USP chapters on plastic materials and packaging systems provide relevant compendial frameworks for evaluating pharmaceutical plastic components [4,5].

3.3 Metals and foil-based structures

Aluminium and other metals are used in closures, collapsible tubes, aerosol containers, and blister lidding. Aluminium foil offers excellent barrier performance against moisture, oxygen, and light and is therefore valuable for sensitive products. Metal components may also provide mechanical strength and tamper evidence. Limitations include susceptibility to corrosion under unsuitable conditions, potential interaction with aggressive formulations, and the energy and material demands associated with production and recycling. Lacquers, coatings, and laminated structures may be required to ensure compatibility and sealing performance.

3.4 Elastomers and closure systems

Rubber and elastomeric materials are important in vial stoppers, syringe plungers, seals, and closure liners. Their elasticity supports sealing and repeated puncture in appropriate systems. However, formulation ingredients, sterilization, and storage conditions may affect elastomer performance. Additives and curing residues

may migrate, while fragmentation, coring, adsorption, and loss of container-closure integrity may compromise product quality. Selection should consider extractables/leachables profiles, functional performance, sterilization compatibility, and the intended contact conditions.

3.5 Multilayer and laminated packaging

Multilayer structures combine materials to obtain complementary properties such as barrier protection, heat sealability, mechanical strength, printability, and puncture resistance. Examples include polymer–foil laminates and co-extruded films used in sachets and blister-related applications. Their principal environmental limitation is that dissimilar layers can be difficult to separate and recycle. Design improvements include reducing total material thickness, limiting unnecessary layers, selecting compatible polymers, and documenting material composition to support sorting and recycling. These changes must not reduce the barrier or mechanical performance needed to protect the medicine.

Material/system	Potential advantages	Key risks or limitations	Typical pharmaceutical uses
Glass	High chemical resistance; strong gas/moisture barrier; transparency	Breakage; delamination/particulates; ion release under some conditions; weight	Vials, ampoules, bottles, cartridges
PE / PP	Lightweight; mouldable; impact resistant; economical	Permeation; additive migration; sorption; variable barrier performance	Bottles, closures, containers
PET / cyclic olefin polymers	Clarity; strength; useful dimensional stability	Formulation-specific compatibility; extractables/leachables; barrier differences	Bottles, syringes, specialty containers
Aluminium / foil	Excellent light, moisture, and gas barrier	Corrosion/compatibility concerns; material-intensive production; laminate recyclability	Blister lidding, tubes, seals
Elastomers	Elastic sealing; puncturable closures	Leachables; coring; adsorption; loss of integrity	Vial stoppers, syringe components
Multilayer laminates	Tailored barrier and mechanical properties	Complex recycling; difficult layer separation; adhesive-related risks	Sachets, flexible packs, blister structures

4. Drug–packaging interactions and quality assurance

A packaging system should be evaluated as a potential source of chemical, physical, and microbiological risk. Extractables are chemical entities that can be released from packaging components under exaggerated laboratory conditions, whereas leachables are substances that migrate into the drug product under actual or simulated storage and use conditions. Extractables studies can help identify potential leachables, but the two terms are not interchangeable. Risk assessment should consider the composition of the formulation, route of administration, duration of contact, surface-area-to-volume ratio, processing conditions, and patient exposure.

Other relevant interactions include adsorption of active pharmaceutical ingredients or preservatives onto packaging surfaces, absorption of formulation components into polymers, permeation of gases or water vapour, and loss of volatile constituents. These processes may change assay, impurity profile, dissolution, pH, preservative effectiveness, or physical appearance. The risk is especially important for low-dose products, biologics, inhalation products, ophthalmics, and parenterals.

Container-closure integrity testing is critical when the package is required to maintain sterility or protect against ingress. Testing strategies should be selected according to the product, package design, and applicable regulatory expectations. The FDA's 1999 guidance provides general principles for documenting container-closure systems for human drugs and biologics; a separate FDA draft guidance issued in August 2026 proposes updated risk-based principles and is explicitly

draft, non-binding guidance at the time of this manuscript [6,7].

A comprehensive packaging qualification programme may include material identity and characterization, dimensional and mechanical testing, seal strength, leak or integrity testing, moisture-vapour and oxygen transmission, light transmission, compatibility, extractables/leachables assessment, microbiological controls, transport simulation, and stability studies. Acceptance criteria should be product-specific and justified by data. Packaging changes should be managed through formal change control and evaluated for their potential impact on stability, safety, regulatory filings, and supply continuity.

5. Functional, active, and intelligent pharmaceutical packaging

5.1 Active packaging

Active packaging is designed to interact with the internal or external environment to maintain or improve product quality. Examples include oxygen scavengers, moisture absorbers, desiccants, and selected antimicrobial or protective systems. Desiccants are commonly used to control humidity in bottles containing moisture-sensitive solid dosage forms. Oxygen-scavenging technologies may be useful for oxidation-sensitive products, provided that the scavenger is appropriately isolated or otherwise demonstrated to be safe and compatible.

In pharmaceutical applications, active components must not introduce unacceptable contamination, migration, or unintended exposure. Their performance should be validated over the full shelf life and under expected distribution conditions. Claims of antimicrobial activity or improved stability require product-specific evidence and should not be extrapolated from food-packaging studies without appropriate pharmaceutical validation.

5.2 Intelligent and sensor-enabled packaging

Intelligent packaging incorporates features that provide information about product identity, condition, location, or use. Technologies include time–temperature indicators, humidity indicators, colourimetric sensors, RFID tags, NFC devices, printed electronics, and connected sensors. These systems may help monitor cold-chain excursions, detect opening or tampering, support inventory management, and communicate selected information to healthcare professionals or patients.

Time–temperature indicators can provide a visual indication of cumulative thermal exposure, while vaccine vial monitors are an established example of a condition indicator used in immunization programmes. Such indicators must be calibrated to the product's stability profile and should not be treated as a universal substitute for validated temperature monitoring. Sensor accuracy, placement, response time, calibration, data integrity, and the relationship between the measured parameter and actual product quality are essential considerations.

5.3 Patient adherence and medication-use support

Packaging can support medication adherence through calendar blisters, unit-dose systems, reminder-enabled devices, electronic event monitoring, and patient-facing instructions. Connected packaging may record package opening events or prompt users about scheduled doses. However, an opening event does not prove ingestion, and adherence technologies should avoid implying that a recorded interaction confirms correct administration. Human factors, accessibility, affordability, data privacy, and usability across age groups should be considered during design.

5.4 Medicine return and circular pharmaceutical supply chains

The concept of medicine reuse seeks to reduce avoidable pharmaceutical waste by assessing whether certain returned, unopened medicines can be safely reintroduced into an authorized supply chain. This is a complex proposition because the quality of a returned medicine may be uncertain if its storage history, tamper status, chain of custody, or exposure to unsuitable conditions cannot be verified.

A proposed smart pharmaceutical packaging and returns assessment framework described in the literature links condition-monitoring packaging with a returns assessment system. Sensors can record selected environmental parameters during patient possession, while RFID or other identifiers can link the record to the medicine and its batch. A returned product would still

require eligibility assessment against predefined criteria, including product type, packaging integrity, expiry, storage history, and applicable law [8].

Smart records may reduce uncertainty, but they cannot independently prove that a medicine remains suitable for reuse. Many products are legally ineligible for re-dispensing, and sensor coverage may not capture all relevant degradation mechanisms. Any reuse programme therefore requires validated technology, defined exclusion rules, pharmacist or other qualified oversight, legal authorization, traceable custody, and evidence that patient safety is not compromised.

6. Anti-counterfeiting, authentication, and traceability

Falsified medicines may misrepresent identity, composition, or source, while substandard medicines fail to meet quality standards or specifications. Packaging security features are intended to deter, detect, or support investigation of falsification and diversion. Overt features, such as holograms and colour-shifting inks, can be checked visually; covert features, such as forensic markers, taggants, or specialized inks, may require dedicated equipment. No single feature is sufficient in every context, and security is strongest when physical and digital measures are combined.

6.1 Two-dimensional barcodes and QR codes

Two-dimensional codes can encode or link to a unique product identifier and selected product information. In India, the CDSCO FAQ on implementation of G.S.R. 823 (E), dated 17 November 2022, describes barcode or QR-code requirements for specified top 300 brands and lists information including a unique product identification code, proper/generic and brand names, manufacturer details, batch number, manufacturing date, expiry date, and manufacturing licence number. The requirement came into force on 1 August 2023 for the specified products [9].

A code should resolve to a trusted data source and be protected against copying, unauthorized alteration, and fraudulent redirection. A QR code printed on a pack is not inherently proof of authenticity: counterfeiters can copy a legitimate code. Verification systems therefore need unique serialisation, secure data association, duplicate-scan or anomaly detection, and appropriate access controls. In June 2026, India's Ministry of Health and Family Welfare announced an expansion of QR-code-based identification to additional categories, including vaccines, antimicrobials, anti-cancer medicines, and narcotic and psychotropic drugs, with phased effective dates stated in the government release [10].

6.2 RFID and NFC

RFID uses radio-frequency communication to identify and track tagged objects, while NFC supports short-range communication commonly used by smartphones and readers. These technologies can support item-level or case-level traceability, inventory visibility, and data exchange. Compared with a printed code, RFID may allow reading without direct line of sight, but tag cost, reader infrastructure, metal or liquid interference, data security, and interoperability can limit deployment.

6.3 Tamper evidence and layered security

Tamper-evident seals, breakable closures, induction seals, perforated cartons, and anti-tampering devices provide visible evidence that a package may have been opened or altered. In the European Union, the Falsified Medicines framework includes a unique identifier and an anti-tampering device for most prescription medicines and certain other medicines within its scope [11]. These features are complementary: a unique identifier supports verification of identity, while a tamper-evident feature helps reveal physical interference.

7. Sustainable pharmaceutical packaging

Sustainable pharmaceutical packaging must reduce environmental burdens without undermining the primary obligation to protect the medicine and the patient. Potential strategies include material lightweighting, elimination of unnecessary components, improved pack design, renewable feedstocks, recycled content where appropriate, recyclable mono-material structures, and better collection and waste-management systems. The choice of strategy depends on the dosage form, barrier requirements, sterility, contamination risk, product value, and local waste infrastructure.

7.1 Bio-based and biodegradable materials

Bio-based polymers are derived partly or wholly from renewable biological feedstocks, whereas biodegradable polymers are capable of undergoing biological degradation under specified conditions. These are different attributes: a bio-based polymer is not necessarily biodegradable, and a biodegradable polymer may be fossil-derived. Candidate materials discussed in packaging research include polylactic acid, starch-based materials, cellulose derivatives, chitosan, and other natural-polymer systems.

Potential advantages include reduced reliance on fossil feedstocks and opportunities for compostable or biologically degradable end-of-life routes. Limitations may include moisture sensitivity, brittleness, inadequate barrier performance, variability in feedstock quality, limited industrial composting infrastructure, and uncertain degradation under real disposal conditions. Pharmaceutical use additionally requires evaluation of chemical purity, microbial quality, extractables/leachables, and compatibility with sterilization and storage.

7.2 Nanocomposites and functional fillers

Nanocomposites incorporate nanoscale fillers into a polymer matrix to modify mechanical, thermal, optical, or barrier properties. Depending on filler chemistry and dispersion, nanofillers may improve stiffness, reduce gas or moisture transmission, or contribute selected antimicrobial or UV-blocking functions. Their use in pharmaceutical packaging requires careful characterization of particle size, aggregation, surface treatment, migration, toxicological profile, and exposure. Claims of improved barrier performance or antimicrobial action should be supported by reproducible testing in the final packaging system.

7.3 Life-cycle assessment and end-of-life decisions

A material should not be labelled sustainable solely because it is bio-based, recyclable, or biodegradable. Life-cycle assessment (LCA) should consider raw-material extraction, manufacturing energy, transport, packaging mass, product protection, shelf-life effects, collection, sorting, recycling, composting, incineration, and disposal. A lighter package that increases product spoilage or compromises stability may have a worse overall environmental outcome than a heavier high-barrier system. Similarly, industrial composting may be beneficial only where suitable facilities and collection routes exist.

For pharmaceutical packaging, LCA must include the environmental consequences of product loss and potential patient harm, not only the packaging material itself. Sterile and high-value medicines may require packaging designs that prioritize protection and integrity. A responsible approach therefore uses life-cycle evidence alongside cost, regulatory, safety, and infrastructure assessments. A recent scoping review of sustainable pharmaceutical packaging identified biodegradable materials, design, smart technologies, and waste management as major innovation themes, while highlighting regulatory, safety, and economic barriers to adoption [3].

8. Artificial intelligence and digital manufacturing in packaging

Artificial intelligence (AI), machine learning (ML), and computer vision are increasingly investigated for packaging development and manufacturing. In pharmaceutical packaging, potential applications include visual inspection of labels and seals, detection of cracks or foreign particles, verification of print quality and codes, counting or classification of dosage units, prediction of polymer or composite properties, and optimization of manufacturing parameters. These systems may support quality-by-design and process analytical technology when appropriately integrated into validated manufacturing controls.

8.1 Computer vision and automated inspection

Convolutional neural networks and object-detection models can be trained to identify defects or classify packaging features in images. Potential inspection tasks include missing tablets, damaged blister cavities, incomplete seals, incorrect labels, print defects, and package component presence. The value of such systems depends on the representativeness of training images, defect prevalence, annotation quality, lighting and camera consistency, and the ability to detect rare but critical failures.

Performance should be reported using appropriate metrics such as sensitivity/recall, specificity, precision, F1 score, false-acceptance and false-rejection rates, and, where relevant, mean average precision. For tablet counting, count error and exact-count accuracy should also be reported. External validation across different batches, cameras, packaging designs, and operating conditions is essential. An AI model should not be described as validated for pharmaceutical release decisions solely because it performs well on a limited test dataset.

8.2 Predictive modelling for materials and process optimization

ML models may estimate mechanical, thermal, or barrier properties from polymer composition and processing variables, helping researchers prioritize candidate formulations. Regression, tree-based ensembles, support-vector methods, and neural networks can model nonlinear relationships, but model quality depends on dataset size, measurement consistency, and the range of conditions represented. Extrapolation beyond the training domain can be unreliable.

8.3 Digital twins, traceability, and connected quality systems

Connected sensors and manufacturing data can support process monitoring, predictive maintenance, and digital records across production and distribution. Blockchain or distributed-ledger technologies are sometimes proposed for traceability because they can make recorded transactions difficult to alter retrospectively. However, a ledger cannot guarantee that the original data were correct, that sensors were calibrated, or that a physical medicine is genuine. Data provenance, identity management, cybersecurity, interoperability, and governance remain essential.

8.4 Challenges and responsible implementation

Common barriers include small or unbalanced datasets, inconsistent image acquisition, lack of standardized defect taxonomies, limited external validation, model drift, explainability, cybersecurity, integration costs, and regulatory uncertainty. Human oversight and a documented validation lifecycle are needed when AI outputs influence product quality decisions. For high-risk applications, the system should have defined intended use, controlled software versions, traceable training data, change management, audit trails, and predefined acceptance criteria.

Technology	Potential pharmaceutical packaging use	Main validation or implementation need
QR / 2D data matrix	Product identification, batch and expiry information, verification	Unique serialisation, trusted database, duplicate detection, code readability
RFID / NFC	Item tracking, inventory, data exchange, sensor connectivity	Interoperability, reader coverage, tag durability, cybersecurity
Time–temperature indicator	Visual indication of cumulative thermal exposure	Product-specific calibration and stability correlation
Humidity / gas sensors	Monitoring selected storage conditions	Calibration, sensor placement, drift and data integrity
Computer vision / AI	Seal, label, print, defect and tablet inspection	Representative datasets, external validation, false-negative analysis
Nanocomposites	Barrier, mechanical, UV or functional enhancement	Migration, toxicology, dispersion, long-term compatibility
Smart returns assessment	Evidence supporting eligibility assessment of returned packs	Validated sensing, chain of custody, legal eligibility, qualified oversight

9. Regulatory and quality considerations

Pharmaceutical packaging is subject to requirements that vary by jurisdiction, product type, route of administration, and intended use. Core expectations generally concern suitability of materials, protection of product quality, labelling, tamper evidence where required, traceability, and control of manufacturing and distribution. Compendial standards and regulatory guidance

should be checked in their current versions at the time of product development and submission.

In the United States, USP chapters address plastic materials and pharmaceutical plastic packaging systems [4,5], while FDA guidance describes documentation principles for container-closure systems [6]. The FDA also issued a draft container-closure systems guidance in August 2026; because it is draft and non-binding, it should be cited as a proposal rather than a final requirement [7].

In India, G.S.R. 823 (E) and the associated CDSCO FAQ describe QR/barcode information for specified top 300 brands [9]. The June 2026 government announcement describes a wider phased expansion for selected therapeutic categories [10]. In the European Union, the Falsified Medicines framework and Delegated Regulation (EU) 2016/161 establish safety-feature requirements within their defined scope [11]. Regulatory claims should always be tied to the exact product category, jurisdiction, effective date, and current legal text.

A robust packaging control strategy should link material specifications, supplier qualification, incoming inspection, component processing, container-closure integrity, compatibility studies, stability data, serialization, labelling control, transport qualification, and change management. Digital tools should be treated as controlled elements of the quality system when they affect product identity, release, distribution, or patient-facing information.

10. Research gaps and future perspectives

First, more product-specific evidence is needed on long-term compatibility of emerging polymers, coatings, nanofillers, and printed electronics with pharmaceutical formulations. Studies should report formulation composition, packaging surface area, storage conditions, analytical methods, detection limits, and toxicological interpretation of relevant migrants.

Second, intelligent packaging requires validated links between sensor outputs and clinically or pharmaceutically meaningful quality attributes. A temperature record is useful only when it is linked to a justified stability model and reliable data capture. Future work should address sensor calibration, battery life, data loss, cybersecurity, interoperability, and affordability.

Third, anti-counterfeiting solutions should move beyond code presence toward robust end-to-end verification. This includes secure product identity, serialization, authentication at appropriate supply-chain points, anomaly detection, tamper evidence, and integration with regulatory and manufacturer systems. Systems should be evaluated against code cloning, offline use, poor connectivity, and unauthorized database access.

Fourth, sustainable design requires pharmaceutical-specific LCA methods that include product protection, medicine wastage, sterility, patient safety, and local disposal infrastructure. Comparative studies should avoid assuming that compostable or bio-based materials are automatically preferable. Recyclability, migration safety, and the practical availability of end-of-life routes must be measured.

Fifth, AI studies should provide transparent dataset descriptions, independent test sets, model versions, uncertainty estimates, subgroup performance, and failure-mode analysis. Prospective evaluations in production-like settings are needed before AI inspection is relied upon for critical quality decisions.

Finally, medicine reuse remains an area requiring cautious, jurisdiction-specific evaluation. Smart packaging may help document storage history and support assessment, but it cannot replace legal authorization, qualified review, or product-specific quality evidence. Future research should prioritize stakeholder acceptance, chain-of-custody design, eligibility criteria, and controlled pilot studies before any broad implementation.

CONCLUSION

Pharmaceutical packaging is evolving from a predominantly protective container into an integrated platform for product quality, patient safety, authentication, monitoring, and environmental responsibility. Conventional materials—including glass, polymers, metals, and elastomers—remain indispensable, but their selection must be based on formulation compatibility, barrier performance, mechanical function, and risk-based evaluation of extractables, leachables, and

container-closure integrity. Smart identifiers, RFID/ NFC, condition indicators, and connected sensors can strengthen traceability and monitoring when supported by validated data systems. Sustainable materials and design strategies offer important opportunities, but must be judged through pharmaceutical-specific safety assessments and life-cycle evidence. AI may improve inspection and process optimization, although external validation and transparent reporting remain essential. The most promising future direction is therefore not a single novel material or digital technology, but a risk-based packaging ecosystem that combines material science, regulatory compliance, secure information, usability, and measurable sustainability.

REFERENCES

1. World Health Organization. Substandard and falsified medical products. Fact sheet. 3 December 2024. Available from: https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
2. Lv Y, Liu N, Chen C, Cai Z, Li J. Pharmaceutical packaging materials and medication safety: a mini-review. Safety. 2025;11 (3):69. doi:10.3390/safety11030069.
3. Jackman S, McGuinness P, Brennan L, Pereira R, Tyrrell A, Barry AM, et al. Global innovations in sustainable pharmaceutical packaging in the last 25 years: a scoping review. Sustainability. 2025;17 (23):10716. doi:10.3390/su172310716.
4. United States Pharmacopeia. General Chapter <661.1>: Plastic materials of construction. USP–NF. Rockville (MD): United States Pharmacopeia. Available from: https://doi.org/10.31003/USPNF_M8008_14_01
5. United States Pharmacopeia. General Chapter <661.2>: Plastic packaging systems for pharmaceutical use. USP–NF. Rockville (MD): United States Pharmacopeia. Available from: https://doi.org/10.31003/USPNF_M8009_06_01
6. US Food and Drug Administration. Container closure systems for packaging human drugs and biologics: chemistry, manufacturing, and controls documentation. Guidance for Industry. July 1999. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-systems-packaging-human-drugs-and-biologics
7. US Food and Drug Administration. Container closure systems for human drugs and biological products. Draft Guidance for Industry. August 2026. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-systems-human-drugs-and-biological-products
8. Gerrans J, Donyai P, Finlay K, Sherratt RS. An efficient smart pharmaceutical packaging technology framework to assess the quality of returned medication through non-intrusively recording storage conditions after dispensation. Technologies. 2023;11 (3):75. doi:10.3390/technologies11030075.
9. Central Drugs Standard Control Organization. FAQs on implementation of G.S.R. 823 (E) dated 17 November 2022 with respect to barcode or QR code on top 300 brands. 21 July 2023. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Final%20FAQs%20on%20QR%20code%2021.07.2023.pdf
10. Ministry of Health and Family Welfare, Government of India. Union Health Ministry notifies amendments in Drugs Rules, 1945 [press release]. 25 June 2026. Press Information Bureau. Available from: https://www.pib.gov.in/PressReleasePage.aspx?PRID=290478
11. European Commission. Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use. Official Journal of the European Union. 2016. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0161

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