Pharmaceutical Packaging and Labelling Regulations Across Global Jurisdictions: A Comparative Review of Regulatory Requirements, Compliance Challenges and Future Perspectives

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***Abstract*—Pharmaceutical packaging and labelling play a vital role in maintaining the quality, stability, safety, and proper use of medicinal products. Regulatory requirements for packaging materials and labelling vary across different countries and regulatory jurisdictions, although their primary objective is to protect the product and ensure patient safety. This review provides an overview of the regulatory requirements governing pharmaceutical packaging and labelling across major global jurisdictions, including the United States, European Union, India, United Kingdom, Japan, Canada, Australia, and international guidelines issued by the World Health Organization. The review discusses different types of pharmaceutical packaging, commonly used packaging materials, container-closure systems, mandatory labelling information, storage conditions, warning statements, package leaflets, serialization, and anti-counterfeiting measures. A comparative assessment of regulatory requirements is also presented to identify major similarities, differences, and challenges in global compliance. In addition, emerging trends such as digital labelling, smart packaging, track-and-trace technologies, patient-centric labelling, and sustainable packaging are discussed. Understanding these regulatory differences is essential for pharmaceutical manufacturers seeking global market access and regulatory compliance. Greater harmonization of packaging and labelling requirements may help reduce regulatory complexity, improve supply-chain efficiency, and enhance the safe and effective use of medicines worldwide.**

***Index Terms*—Pharmaceutical packaging; Drug labelling; Regulatory requirements; Global regulations; Packaging materials; FDA; EMA; CDSCO; WHO; Patient safety.**

I. INTRODUCTION

Pharmaceutical products are highly sensitive healthcare commodities whose quality, safety, efficacy, and stability must be maintained throughout their life cycle, from manufacturing and packaging to storage, transportation, distribution, and final use. Pharmaceutical packaging is an integral component of pharmaceutical quality assurance because it provides containment and protection while helping maintain the quality and stability of the medicinal product [1,2]. Good Manufacturing Practice (GMP) principles consider packaging, repackaging, labelling, and relabeling as controlled pharmaceutical operations, with particular emphasis on preventing cross-contamination, product mix-ups, and false labelling [1,3].

Pharmaceutical packaging performs several essential functions, including containment, protection, preservation, identification, handling, and transportation. The selection of an appropriate packaging system is important because the container-closure system can influence the protection and quality of the drug product. Regulatory authorities therefore require appropriate assessment of packaging components and container-closure systems. The US Food and Drug Administration (FDA) provide guidance on the information and principles used to evaluate container-closure systems for human drugs and biological products [4,5].

Packaging materials may include glass, plastics, metals, elastomeric components, paper, cardboard,

and multilayer materials. The suitability of a packaging system depends on the characteristics of the pharmaceutical formulation, dosage form, route of administration, storage conditions, and required protection from environmental factors. Consequently, packaging selection is an important consideration during pharmaceutical development and regulatory assessment [4,5].

Pharmaceutical labelling is equally important because it provides essential information for the identification, handling, storage, and appropriate use of medicinal products. Information presented on pharmaceutical labels and package leaflets may include the product name, active ingredient, strength, dosage form, route of administration, batch number, expiry date, storage conditions, warnings, precautions, and manufacturer or marketing-authorization information [6,7].

The accuracy and readability of pharmaceutical labelling are directly relevant to patient safety. WHO identifies incorrect labelling as one of the risks associated with pharmaceutical manufacturing because an incorrectly labelled container may result in a patient receiving the wrong medicine, while inappropriate amounts of active ingredient may result in treatment failure or adverse effects [1,8]. Therefore, regulatory requirements concerning label content, readability, legibility, and presentation are important components of pharmaceutical quality assurance.

Regulatory requirements for medicinal-product labelling vary across jurisdictions. In the European Union, specific guidance addresses packaging information, labelling, package leaflets, readability, and Braille requirements for medicinal products [6,9]. In India, pharmaceutical labelling requirements are established under the Drugs Rules and related regulatory provisions administered by the Central Drugs Standard Control Organization (CDSCO) [10]. These jurisdiction-specific requirements may differ in relation to mandatory information, language, packaging configuration, safety statements, traceability, and other regulatory features.

The globalization of pharmaceutical manufacturing and distribution has increased the importance of regulatory harmonization. Pharmaceutical manufacturers supplying multiple international markets may need to comply with different national or regional requirements for packaging materials, label content, artwork, product information, and safety features. International organizations such as WHO and ICH have contributed to the development and convergence of pharmaceutical quality standards, while regional and national regulatory authorities continue to maintain jurisdiction-specific requirements [2,11].

The pharmaceutical packaging landscape is also evolving with the introduction of serialization, barcoding, track-and-trace technologies, digital product information, and anti-counterfeiting measures. These technologies have expanded the role of packaging from simple containment and protection to product authentication, traceability, and improved access to medicine-related information [6,10,12].

In addition, increasing attention to environmental sustainability has encouraged pharmaceutical manufacturers to investigate recyclable, lightweight, and alternative packaging materials. However, sustainability initiatives must be balanced against the fundamental requirements of product protection, stability, compatibility, sterility, and patient safety. This creates an important regulatory challenge for the pharmaceutical industry and highlights the need for evidence-based approaches to the adoption of innovative packaging materials.

Therefore, the present review aims to provide a comparative overview of pharmaceutical packaging and labelling regulations across major global jurisdictions, with particular emphasis on packaging materials, container-closure systems, mandatory labelling information, readability and accessibility, safety and anti-counterfeiting features, traceability technologies, and emerging regulatory trends. The review further aims to identify similarities and differences among major regulatory frameworks and discuss the challenges and future opportunities for greater global harmonization of pharmaceutical packaging and labelling requirements.

II. PHARMACEUTICAL PACKAGING

Packaging is defined as a technique which allows containment of pharmaceutical product from the time of production in a unit till its use. Role of pharmaceutical packaging is to provide lifesaving drugs, surgical devices, blood and blood products, nutraceuticals, powders, poultices, liquid and dosage forms, solid and semisolid dosage forms. Packaging of pharmaceuticals essentially provides containment,

drug safety, identity, convenience of handling and delivery. Pharmaceutical packaging has to balance lots of complex considerations. Leaving behind relatively simple issues such as developing good designs and communicating with customers, pharmaceutical packagers are concerned to more pressing concerns which include fighting with counterfeiting, encouraging patient compliance, ensuring drug integrity and balancing child-resistance and accessibility for the elderly. Issue of environment safety is also key concern for both developed and developing countries packaging industry. Pharmaceutical packaging firms are some of the industry's leading innovators evident by the recent advancement in technology. The current trends are result of continuous series of challenges faced by industry. Packaging is a science which is continuously evolving and is a major success contributor for pharmaceutical industries. Categorically differentiating pharmaceutical packaging:

1. Primary Packaging: This is the first packaging envelope which is in touch with the dosage form or equipment. The packaging needs to be such that there is no interaction with the drug and will provide proper containment of pharmaceuticals. E.g. Blister packages, Strip packages, etc.

2. Secondary Packaging: This is consecutive covering or package which stores pharmaceuticals packages in it for their grouping. E.g. Cartons, boxes, etc.

3. Tertiary packaging: This is to provide bulk handling and shipping of pharmaceuticals from one place to another. E.g. Containers, barrels, etc.[14]

Primarily two types of containers are used for packaging:

1. Glass Containers
2. Plastic Containers

Glass Containers: These need to be chemically inert, impermeable, strong and rigid proving FDA clearance. Four types of Glass is being used in pharmaceutical industry,

1. Type I-Borosilicate glass: Highly resistant and chemically inert glass. Alkalis and earth cations of glass are replaced by boron and/or aluminum and zinc. These are used to contain strong acids and alkalis.

2. Type 2-Treated soda-lime glass: These are more chemically inert than Type I glass. The glass surface is de-alkalized by "Sulfur treatment" which prevents blooming/weathering from bottles.

3. Type III- Regular soda lime glass: Untreated soda lime glass with average chemical resistance.

4. Type IV- General Purpose soda lime glass: Glass is not used for parenteral, used only for products intended to be used orally or topically.

Colored glass is used to screen out Ultraviolet rays and is thus effective for protecting contents from light. Amber glass and red colored glass is used for this purpose. Major disadvantage of glass as a packaging material is its fragility and weight.

Plastic Containers: Plastic containers of high quality can be easily formed with different designs. These packages are extremely resistant to breakage and leakage.

Primarily plastic containers are made from the following polymers:

1. Polyethylene (PE): Provides good barrier against moisture, relatively poor one against oxygen and other gases. High density polyethylene is used with density ranging from 0.91-0.96 leading to four basic characteristics of container, (1) Stiffness, (2) Moisture- vapor transmission, (3) stress cracking and (4) clarity or translucency based on polymer density used.

2. Polypropylene (PP): Polypropylene has features of polyethylene in addition it does not stress-crack in any condition. Hot aromatic or halogenated solvents soften the package. It has high melting point making it suitable for boilable packages and products needed to be sterilized. Brittleness at low temperature is its major disadvantages.

3. Polyvinyl Chloride (PVC): Can be produced with crystal clear clarity, will provide good gaseous barrier and stiffness. Reduction in residual vinyl chloride monomers had further enhanced PVC quality. PVC is used as coating on glass bottles providing shatter resistant
coating.

4. Polystyrene: Rigid and crystal-clear plastic. Not useful for liquid products. Polystyrene has high water

and gaseous permeability also Colored glass is used to screen out Ultraviolet rays and is thus effective for protecting contents from light. Amber glass and red colored glass is used for this purpose. Major disadvantage of glass as a packaging material is its fragility and weight.

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4. Polystyrene: Rigid and crystal-clear plastic. Not useful for liquid products. Polystyrene has high water and gaseous permeability also these are easily stretchable and breakable. To increase their strength and quality for permeability polystyrene is combined with rubber and acrylic compounds. Base on the composition these are classified as intermediate impact, high impact and super impact packages.

5. Nylon (polyamide): Many dibasic acids and amines combine to provide numerous varieties of nylon. Nylon is extremely strong and is quite difficult to be destroyed by mechanical means. Nylon provides resistance to wide range of acids and alkali only disadvantage of it is being permeable to water vapor for some amount this can also be dealt with coating of PE over the container. Not used for long term storage of products.

6. Polycarbonate: Has an ability to be sterilized repeatedly. It has immense rigidity and is a possible replacement for glass, vials and syringes. It has qualities like high dimensional stability, high impact strength, resistance to strain, low water absorption, transparency, and resistance to heat and flame. Polycarbonates have impact strength five times greater than any other common packaging plastics.

7. Acrylic multipolymers (Nitrile Polymers): These are polymers of acrylonitrile or meth acrylonitrile monomers. These provide for packaging of those products which are not packed in usual packages as they provide for high gas barrier, good chemical resistance, and good strength.

8. Polyethylene terepthalate (PET): Condensation polymer formed by reaction of terepthalic acid or dimethyl terepthalic acid with ethylene glycol. It has excellent strength and provides barrier for gas and aroma making it as a us it as a useful package for cosmetics, mouth washes and other products.

While there are different packaging materials approved by FDA for packaging it has to be known that FDA doesn't approve the container but its material that is being used. A list of substances considered by FDA are published as, "Generally recognized as safe (GRAS)". It's responsibility of manufacturer to prove the safety of a packaging material and to get an approval from FDA. The specific FDA regulation for drugs states, "Containers, closures and other component parts of drug packages, to be suitable for their intended use, must not be reactive, additive or absorptive to an extent that identity, strength, quality or purity of the drug will be affected." A material that is not included in GRAS can be used by manufacturer but prior to that manufacturer need to test the material and send the report to FDA for New Drug Application, NDA[15].

III. PHARMACEUTICAL LABELLING

Pharmaceutical labelling refers to the process of identifying a medicinal product and providing

essential information required for its proper identification, safe use, storage, handling, and traceability. According to the World Health Organization (WHO), pharmaceutical labelling may include the product name, active ingredient(s), strength or amount, batch number, expiry date, special storage conditions, directions for use, warnings and precautions, and the name and address of the manufacturer or supplier[13].

Proper pharmaceutical labelling is an important component of medication safety because patients and healthcare professionals depend on label information to correctly identify medicines and understand their appropriate use. Evidence from systematic reviews indicates that the content, organization, typography, and readability of medicine labels influence patients' ability to understand medication instructions. Larger fonts, clear headings, adequate white space, simple language, and logical organization have been associated with better readability and comprehension[14,15]. Therefore, pharmaceutical labels should be designed to communicate critical information clearly and minimize the possibility of medication errors[14].

3.1 Mandatory Information on Labels

The specific legal requirements for pharmaceutical labelling vary according to national regulations and the type of medicinal product. However, essential information generally includes the name of the medicine, active ingredient(s), strength, dosage form, batch number, manufacturing/expiry information, storage conditions, directions for use, warnings and precautions, and manufacturer or supplier details[13].

The information should be presented in a manner that is clear, legible, accurate, and easily distinguishable. A systematic review of drug-label interventions reported that changes in information layout, highlighting of important information, and increased font size can improve medicine identification and comprehension[15].

3.2 Batch Number

The batch number or lot number is a unique identification code assigned to a particular batch of a pharmaceutical product. It provides traceability from manufacturing through distribution and use. Batch identification is particularly important during quality investigations, product recalls, adverse-event investigations, and detection of manufacturing defects[13].

WHO guidance recognizes the batch number as an important element of pharmaceutical labelling. Appropriate identification of each batch allows defective or potentially contaminated products to be rapidly traced and withdrawn from the market when necessary[13].

3.3 Manufacturing and Expiry Date

The manufacturing date provides information about when the pharmaceutical product was produced, while the expiry date identifies the end of the period during which the product is expected to remain within its established quality specifications when stored under the recommended conditions[13].

Expiry information is important because pharmaceutical products may undergo changes in potency, stability, purity, or physical characteristics over time. Consequently, the expiry date should be clearly and unambiguously displayed on the packaging. It also assists healthcare professionals and patients in avoiding the use of expired medicines[13].

3.4 Strength

The strength of a medicinal product refers to the quantity or concentration of the active pharmaceutical ingredient present in a specified dosage unit, volume, or mass. For example, a tablet may contain 500 mg of an active ingredient or an oral solution may contain 10 mg/mL.

Clear display of strength is essential because many medicines are marketed in multiple strengths. Confusion between different strengths can result in under-dosing or overdosing. Research on medication labels indicates that prominent presentation of key information such as the medicine name, dose/strength, and instructions can improve recognition and reduce the possibility of errors[14,15].

3.5 Storage Conditions

Pharmaceutical labels should specify special storage conditions and handling precautions whenever these are necessary to maintain the quality and stability of the product [13]. Examples include:

- Store below 25°C.
- Store at 2–8°C.

- Protect from light.
- Protect from moisture.
- Do not freeze.

Incorrect storage conditions can adversely affect the stability and quality of medicines. Therefore, storage instructions should be clearly displayed and should correspond to the stability characteristics of the pharmaceutical product[13].

3.6 Manufacturer Details

The label should identify the manufacturer and/or responsible supplier, including the relevant name and address as required by applicable regulations[13]. Manufacturer information provides accountability and enables healthcare professionals, regulatory authorities, and patients to identify the organization responsible for the medicinal product.

Manufacturer details are also useful during product recalls, quality complaints, pharmacovigilance investigations, and regulatory inspections[13].

3.7 Warning and Precaution Statements

Warnings and precautions are essential components of pharmaceutical labelling because they communicate information about potential risks, contraindications, adverse effects, drug interactions, special populations, and precautions associated with medicine use[13].

The information should be written in clear and understandable language. A systematic review of textual elements in drug-label instructions found that certain features, including complicated wording and inappropriate presentation of information, can make medication instructions more difficult for patients to understand, particularly those with limited health literacy[16]. Another systematic review found that changes in label layout, highlighting important information, and improving font size can improve comprehension and medicine identification[15].

Consequently, important warnings should be prominent, concise, readable, and appropriately separated from less critical information[14,15,16].

3.8 Package Leaflet

A package leaflet (patient information leaflet) is a written document supplied with a medicinal product that provides detailed information for patients and/or caregivers. It may include information concerning the medicine's indications, dosage, method of administration, contraindications, warnings, precautions, adverse effects, interactions, and storage conditions.

Package leaflets are particularly important because all relevant information cannot always be accommodated on the immediate container or outer package. However, readability is a major concern. A systematic review of medicinal package leaflets identified problems such as complex language, small font size, poor readability, and inadequate use of illustrations[17].

Similarly, systematic-review evidence concerning prescription-drug labels suggests that simple language, larger fonts, headings, lists, white space, and logical organization can facilitate patient understanding[14]. Therefore, package leaflets should be designed according to principles of patient-centred communication and health literacy.

3.9 Braille and Accessibility

Accessibility of pharmaceutical information is particularly important for blind and visually impaired patients, older adults, and individuals with limited literacy or other communication difficulties. Patients with visual impairment may experience difficulties in identifying medicines, reading labels, distinguishing strengths, and interpreting expiry dates and instructions[18].

Braille labelling can assist visually impaired patients in identifying medicines. Research has reported that Braille and large-print information can improve access to medicine information; however, simply placing Braille on the outer package may not provide all the information necessary for safe medicine use[18,19].

A review concerning visually impaired patients emphasized that information such as drug name and strength alone is insufficient; important information including contraindications, storage instructions, dosage information, and expiry dates also needs to be accessible[19]. Therefore, pharmaceutical accessibility should extend beyond Braille alone and may include large-print labels, audio information, electronic formats, tactile identification, accessible package leaflets, and appropriately designed pictograms.

Pictograms may also support understanding of medication instructions. A recent systematic review

found that pictograms improved comprehension in several studies, although differences in pictogram design, cultural interpretation, and study quality prevented definitive conclusions about their universal effectiveness[20].

IV. GLOBAL REGULATORY REQUIREMENTS

4.1 World Health Organization (WHO)

The World Health Organization (WHO) develops internationally recognized guidelines and technical standards that support national regulatory authorities and pharmaceutical manufacturers in maintaining the quality, safety and efficacy of medicinal products. WHO guidance considers pharmaceutical packaging an important component of product quality because packaging must protect medicines from environmental and physical factors that may adversely affect stability. Packaging systems should therefore be appropriately selected and controlled to ensure compatibility with the pharmaceutical product and adequate protection throughout storage, transportation and use [21].

WHO principles also emphasize appropriate labelling and packaging controls to prevent product mix-ups, contamination and deterioration during pharmaceutical manufacturing and distribution. Although WHO guidelines are not directly equivalent to national legislation, they provide an important international reference for countries developing or implementing pharmaceutical regulatory requirements [21].

4.2 United States – US FDA

In the United States, pharmaceutical packaging and labelling are regulated primarily by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations. FDA requirements address both the information provided on drug labels and the suitability of the container-closure system used to package the drug.

FDA's guidance on container-closure systems provides principles for evaluating packaging materials used for human drugs and biologics, including considerations related to the suitability and protection provided by the packaging system [22]. In August 2026, FDA also issued a new draft Level 1 guidance on Container Closure Systems for Human Drugs and Biological Products, which provides updated principles for evaluating container-closure systems, including systems used in combination products [23]. Because this document is a draft, it should not be treated as binding law.

Pharmaceutical labelling in the United States generally provides information necessary for the identification and safe use of the medicine, including the drug name, active ingredients, strength, dosage form, indications, dosage and administration, contraindications, warnings and precautions, adverse reactions and storage information. Packaging requirements also consider container-closure integrity, compatibility, protection from environmental factors and, where applicable, tamper-evident and child-resistant features[22,23].

The U.S. regulatory system additionally places considerable emphasis on pharmaceutical supply-chain security and product traceability through the Drug Supply Chain Security Act (DSCSA). These requirements have increased the importance of standardized product identification, serialization and electronic tracing within the pharmaceutical supply chain.

4.3 European Union/EMA

In the European Union (EU), pharmaceutical labelling and packaging operate within a harmonized legislative framework, supported by the European Medicines Agency (EMA) for centrally authorized medicines. Product information generally comprises the Summary of Product Characteristics (SmPC), labelling and Package Leaflet (PL)[24].

EMA provides Quality Review of Documents (QRD) templates that establish standardized headings, terminology and presentation requirements for product information. The QRD system is intended to promote consistency and facilitate the preparation and review of product information across EU/EEA languages[24,25].

EU pharmaceutical packaging generally includes information such as the medicinal-product name, strength, pharmaceutical form, active substances, route of administration, batch number, expiry date, storage conditions, marketing-authorization information and relevant warnings. The package leaflet provides patient-oriented information, while the SmPC provides information primarily intended for healthcare professionals[24,25].

An important feature of the EU framework is the emphasis on readability and patient comprehension. EMA has been revising its QRD template to improve the structure, clarity and patient-friendliness of package leaflets. The proposed changes include improved organization of warnings, reduced unnecessary length and more logical grouping of information[25].

The EU framework also increasingly accommodates digital technologies. EMA permits applicants and marketing-authorization holders to request the inclusion of QR codes and other mobile-scanning technologies in labelling and/or package leaflets, subject to regulatory assessment[24,26.]

4.4 India – CDSCO

In India, pharmaceutical packaging and labelling are primarily regulated by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare, together with the Drugs and Cosmetics Act, 1940 and Drugs Rules, 1945.

Indian pharmaceutical labelling requirements generally address the identification and safe use of medicinal products. Information may include the drug name, active ingredient(s), strength, dosage form, batch number, manufacturing details, manufacturing licence number, manufacturing date, expiry date, storage conditions and relevant statutory warnings[27].

Specific labelling provisions apply to medicines falling under regulatory categories such as Schedule H, Schedule H1 and Schedule X. These provisions impose additional requirements concerning prescription status and statutory warnings[27].

Packaging operations must also be appropriately controlled to prevent mix-ups and errors involving printed packaging materials. Pharmaceutical manufacturers are therefore required to establish appropriate controls for packaging components, coding, batch identification, line clearance and finished-product packaging.

India's pharmaceutical regulatory environment continues to evolve toward greater regulatory harmonization, risk-based oversight and improved traceability. For multinational manufacturers, an important challenge is ensuring that Indian packaging requirements are simultaneously compatible with the requirements of export markets.

4.5 United Kingdom – MHRA

In the United Kingdom, pharmaceutical packaging and labelling are regulated principally by the Medicines and Healthcare products Regulatory Agency (MHRA) under the Human Medicines Regulations 2012 and associated regulatory guidance[28].

UK medicines require appropriate information on the packaging and accompanying Patient Information Leaflet (PIL) to enable safe and effective use. Information generally includes the product name, strength, pharmaceutical form, active ingredients, route of administration, pack size, batch number, expiry date, storage information, warnings and information relating to the marketing authorization[28].

The UK regulatory environment has become increasingly distinct from the EU following Brexit. In particular, UK-specific packaging and labelling requirements have been introduced for medicines supplied in Great Britain. MHRA guidance provides recommendations concerning medicine packaging, labelling, patient information leaflets and the implementation of approved artwork[28,29].

Consequently, pharmaceutical companies supplying both the EU and UK may need to maintain separate packaging components or artwork versions, increasing the complexity of global artwork management and regulatory change control.

4.6 Japan – PMDA

In Japan, pharmaceutical regulation is administered principally by the Ministry of Health, Labour and Welfare (MHLW), with scientific review and safety-related regulatory activities supported by the Pharmaceuticals and Medical Devices Agency (PMDA).

Japan has developed a distinctive approach to pharmaceutical product information through the introduction of electronic package inserts. Following amendments to the Pharmaceuticals and Medical Devices Act, paper-based package inserts that were traditionally enclosed with medicinal products were abolished in principle from August 2021, with package information generally made available electronically[30].

The electronic package-insert system enables healthcare professionals and other users to access current regulatory information digitally and facilitates more rapid dissemination of safety-related changes.

Paper package inserts continue to be provided for certain products, including medicines purchased directly by consumers such as OTC medicines[30].
This approach demonstrates the increasing integration of pharmaceutical labelling with digital technologies and pharmacovigilance systems.

4.7 Canada – Health Canada

In Canada, pharmaceutical labelling is regulated under the Food and Drugs Act and Food and Drug Regulations, with Health Canada providing detailed regulatory guidance for pharmaceutical drugs intended for human use.
Health Canada's Labelling of Pharmaceutical Drugs for Human Use: Guidance Document was revised on 18 December 2024. The guidance provides recommendations concerning the content and presentation of pharmaceutical labelling and emphasizes the importance of clear, comprehensible and appropriately presented information[31].
Canadian pharmaceutical labelling may include the product name, medicinal ingredients, strength, dosage form, directions for use, indications, warnings and precautions, storage requirements, manufacturer information, lot number and expiry date. Product information may also be provided through professional and patient-oriented documents such as the Product Monograph[31].
An important characteristic of the Canadian approach is its emphasis on readability, clarity and appropriate communication of safety information. Health Canada's guidance is administrative rather than itself having the force of law, although manufacturers remain responsible for meeting applicable statutory and regulatory requirements[31].

4.8 Australia – TGA

In Australia, pharmaceutical packaging and labelling are regulated by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989 and associated standards.
The Australian framework distinguishes between prescription/related medicines and non-prescription medicines. Therapeutic Goods Order No. 91 (TGO 91) establishes requirements for labels of prescription and related medicines, while TGO 92 applies to non-prescription medicines[32,33].
Australian medicine labels are intended to communicate information critical to prescribers, dispensers and consumers. The TGA emphasizes that poor identification of medicines or difficulty locating and understanding safety information can contribute to medication errors [33].
Australian requirements cover information such as the medicine name, active ingredients, strength, dosage form, quantity, directions for use, warnings, advisory statements, batch information and expiry information. The TGA also maintains the Required Advisory Statements for Medicine Labels (RASML) and regulatory requirements concerning serialization and data-matrix codes [34].
The Australian system therefore combines detailed statutory labelling standards with increasing emphasis on readability, advisory statements, digital identification and traceability.

Table 1. Comparative Summary of Global Requirements

Jurisdiction	Principal regulatory authority	Packaging/labelling framework	Characteristic
WHO	WHO	WHO pharmaceutical quality and packaging guidelines	International harmonization and quality principles
USA	FDA	FD&C Act, 21 CFR, FDA guidance	Detailed labelling, container-closure assessment and supply-chain security
EU	EMA/European Commission + national authorities	EU pharmaceutical legislation, QRD templates	SmPC, labelling, package leaflet, multilingual requirements and readability
India	CDSCO	Drugs and Cosmetics Act, 1940; Drugs Rules, 1945	Statutory labelling and Schedule-based requirements

UK	MHRA	Human Medicines Regulations 2012	UK-specific packaging and patient-information requirements
Japan	MHLW/PMDA	Pharmaceuticals and Medical Devices Act	Electronic package inserts
Canada	Health Canada	Food and Drugs Act/Regulations	Readability and comprehensive product information
Australia	TGA	TGO 91, TGO 92 and related standards	Detailed label standards, advisory statements and serialization

V. SPECIAL REGULATORY CONSIDERATIONS

Certain pharmaceutical products require additional packaging and labelling controls because their characteristics create specific risks related to sterility, stability, dosing accuracy, temperature, abuse potential, or toxicity. Regulatory authorities therefore impose product-specific requirements in addition to general pharmaceutical packaging and labelling regulations.

5.1 Injectable Medicines

Injectable medicines require particularly stringent packaging controls because they are administered directly into the body and may bypass normal physiological barriers. Packaging must maintain sterility, stability, compatibility and container-closure integrity throughout the product's shelf life[35].

Common primary packaging systems include glass vials, ampoules, prefilled syringes and cartridges. Selection of the container-closure system should consider compatibility with the formulation, protection against contamination, extractables and leachable, and protection from moisture, oxygen and light where applicable[35,36].

Labelling should clearly communicate the product name, strength or concentration, dosage form, route of administration, storage conditions, batch/lot number and expiry date. Clear differentiation of concentrations is particularly important for injectable medicines because similar packaging or different concentrations can contribute to medication errors.

5.2 Vaccines and Biologicals

Vaccines and biological products are generally more sensitive to environmental conditions than many conventional pharmaceutical products. Their packaging must therefore protect potency, stability, sterility and biological integrity.

Temperature control is a major regulatory consideration. Vaccines may require specific refrigerated or frozen storage conditions, and manufacturers must demonstrate that the product remains within its approved specifications throughout the intended storage period. WHO guidance emphasizes appropriate temperature management throughout the vaccine supply chain[37].

Important labelling information may include:

- Product and antigen name.
- Dose and strength.
- Route of administration.
- Storage temperature.
- Protection from light, where applicable.
- Batch/lot number.
- Expiry date.
- Reconstitution instructions.
- Diluent information, where applicable.
- Relevant warnings and precautions.

Traceability is particularly important for vaccines and biologicals because it supports recall management, investigation of adverse events and identification of affected batches.

5.3 Pediatric Medicines

Pediatric medicines require special packaging and labelling because children differ from adults in physiological characteristics, dosage requirements and ability to understand medication instructions. Packaging should therefore minimize dosing errors and accidental ingestion.

Important considerations include:

- Age-appropriate and/or weight-based dosing instructions.

- Clear differentiation of different concentrations.
- Appropriately designed measuring devices.
- Child-resistant packaging where required.
- Clear preparation and administration instructions.
- Appropriate warnings for parents and caregivers.
- Storage instructions.

The European Medicines Agency emphasizes that medicines intended for children should be developed in age-appropriate formulations and with suitable information for pediatric use[38].

For liquid pediatric medicines, the relationship between the drug concentration, prescribed dose and measuring device is particularly important. Poorly designed labels can result in confusion between milligrams and milliliters and may lead to accidental overdose.

5.4 Controlled Medicines

Controlled medicines require additional regulatory controls because of their potential for abuse, dependence, diversion and illicit distribution. Packaging and labelling therefore have both therapeutic and legal functions.

Depending on the jurisdiction and classification of the medicine, packaging may include:

- Prescription-only or controlled-drug statements.
- Specific statutory warnings.
- Product strength and dosage.
- Quantity of dosage units.
- Batch/lot number.
- Expiry date.
- Storage requirements.
- Security or tamper-evident features.
- Manufacturer or marketing-authorization-holder information.

In the United States, controlled substances are regulated under the Controlled Substances Act, in addition to applicable FDA requirements[39]. In India, medicines classified under Schedule H, H1 and X have additional statutory labelling and prescription-related requirements under the Drugs and Cosmetics Rules[40].

Secure packaging and traceability are increasingly important for preventing diversion and supporting pharmaceutical supply-chain security.

5.5 Temperature-Sensitive Products

Temperature-sensitive products include vaccines, many biological medicines, certain insulin products and other medicines whose quality can be affected by temperature excursions.

Packaging systems must maintain the required temperature range during storage, transportation and distribution. Consequently, pharmaceutical packaging is an integral part of the overall cold-chain system.

Regulatory considerations include:

- Thermal insulation.
- Qualified shipping containers.
- Temperature-monitoring devices.
- Cold-chain validation.
- Stability data.
- Temperature-excursion management.
- Clearly stated storage conditions.
- Appropriate transportation controls.

WHO Good Storage and Distribution Practices emphasize maintaining appropriate environmental conditions and ensuring that storage and distribution processes do not adversely affect pharmaceutical quality[41].

Importantly, a label stating "store refrigerated" is only one component of temperature control. The manufacturer must establish appropriate stability data and validated conditions demonstrating that the product remains suitable under the labelled storage conditions.

5.6 Hazardous Medicines

Hazardous medicines require special packaging and labelling because accidental exposure may cause serious health risks to patients, healthcare workers, caregivers and the environment. This category includes certain cytotoxic medicines and other substances with carcinogenic, mutagenic, reproductive or toxic properties.

Packaging should, where appropriate, incorporate:

- Robust and leak-resistant primary containers.
- Suitable containment systems.
- Tamper-evident features.
- Secondary containment for transportation.
- Clearly identifiable hazard information.
- Appropriate warnings.
- Safe handling instructions.
- Storage requirements.
- Disposal instructions.

NIOSH has developed resources concerning hazardous drugs and occupational exposure controls for healthcare workers[42]. Although NIOSH recommendations should not be confused with legally binding pharmaceutical labelling regulations, they provide an important occupational-safety reference.

For cytotoxic and other hazardous medicines, packaging design should minimize breakage, leakage, aerosol generation and accidental exposure. Appropriate warnings and handling information allow healthcare professionals to implement suitable protective measures.

Table 2: Special Regulatory Considerations for Different Pharmaceutical Products

Product category	Primary packaging concern	Labelling requirements	Regulatory objective
Injectable medicines	Sterility and container-closure integrity	Strength/concentration, route, storage, batch and expiry	Sterility and medication-error prevention
Vaccines/biologicals	Temperature and biological stability	Storage temperature, dose, route, batch and expiry	Potency, stability and traceability
Pediatric medicines	Dosing accuracy and accidental ingestion	Age/weight-based dose, concentration, measuring instructions	Child safety and prevention of dosing errors
Controlled medicines	Security and diversion prevention	Prescription status, warnings, strength and quantity	Abuse prevention and traceability
Temperature-sensitive products	Temperature excursions	Defined storage and handling conditions	Cold-chain integrity and product stability
Hazardous medicines	Leakage and exposure	Hazard warnings, handling and disposal instructions	Patient, worker and environmental safety

The special requirements associated with these pharmaceutical categories demonstrate that packaging and labelling are not simply administrative requirements; they are an important part of the overall risk-management strategy of a medicinal product.

For injectable medicines, the emphasis is on sterility and container-closure integrity; for vaccines and biologicals, on stability and cold-chain control; for pediatric medicines, on safe dosing and child protection; for controlled medicines, on security and prevention of diversion; for temperature-sensitive products, on validated temperature control; and for hazardous medicines, on containment and protection from exposure.

Therefore, modern pharmaceutical packaging should follow a risk-based and product-specific approach, integrating regulatory requirements with quality-by-design, human-factors engineering, patient safety and supply-chain controls.

VI. EMERGING TRENDS

Pharmaceutical packaging is rapidly evolving due to advances in digital technology, supply-chain security, patient-centred design and environmental sustainability. Emerging technologies such as smart packaging, QR codes, digital labelling, serialization, anti-counterfeit systems and sustainable materials are increasingly being incorporated into pharmaceutical packaging to improve product security, traceability, accessibility and patient safety[61,62,63,64].

6.1 Smart Packaging

Smart packaging refers to packaging systems incorporating technologies that can monitor, communicate or respond to information about the

product or its surrounding environment. Technologies such as sensors, RFID, NFC, electronic indicators and connected devices can be incorporated into pharmaceutical packaging to monitor temperature, detect tampering, authenticate products and provide information to patients[61,65].

Smart packaging can be particularly useful for temperature-sensitive pharmaceutical products because integrated indicators or sensors may help identify inappropriate temperature exposure. Connected packaging can also support medication adherence by providing reminders and access to instructions or educational information[65].

The major advantages of smart pharmaceutical packaging include improved product monitoring, enhanced authentication, better supply-chain visibility and increased patient engagement. However, implementation may be limited by high cost, cybersecurity, data privacy, interoperability, regulatory acceptance and disposal of electronic components[61,65].

6.2 QR Codes and Digital Labelling

QR codes and digital labelling provide a connection between physical pharmaceutical packaging and electronic information. A QR code printed on the package can allow healthcare professionals, pharmacists and patients to access additional product information using a smartphone or other scanning device[65,66].

Digital labelling can provide:

- Updated product information.
- Multilingual information.
- Instructions for use.
- Safety information.
- Authentication information.
- Patient education materials.
- Accessibility features for patients with specific needs[62,66].

The European Medicines Agency (EMA) has recognized the potential use of mobile scanning and other technologies in medicinal-product labelling and package leaflets, subject to applicable regulatory requirements[62].

Japan provides an important example of digital transformation. Electronic package inserts were introduced as the principal mechanism for package-insert information for many medicines, with paper package inserts abolished in principle from August 2021, subject to specified exceptions[66].

Dgital labelling can therefore improve the availability and updating of pharmaceutical information; however, essential information required for safe medicine use must remain accessible to patients who may have limited access to smartphones or the internet[62,66].

6.3 Serialization and Track-and-Trace

Serialization involves assigning a unique identifier to an individual pharmaceutical package. When combined with electronic databases and supply-chain systems, serialization enables pharmaceutical products to be tracked through different stages of distribution[63,67].

The major objectives of serialization and track-and-trace systems are:

- Prevention and detection of counterfeit medicines.
- Improved supply-chain visibility.
- Product authentication.
- Faster and more accurate recalls.
- Identification of specific packages or batches.
- Reduction of unauthorized distribution[63,67].

In the United States, the Drug Supply Chain Security Act (DSCSA) establishes requirements for an electronic, interoperable system to identify and trace certain prescription drugs throughout the U.S. pharmaceutical distribution system[63].

The European Union has also introduced safety features for many medicinal products, including a unique identifier and an anti-tampering device, under the framework for preventing falsified medicines[67].

Serialization therefore represents an important transition from conventional batch-level traceability toward package-level identification and verification.

6.4 Anti-Counterfeit Technologies

Counterfeit or falsified medicines present a significant threat to public health and pharmaceutical supply-chain integrity. Packaging therefore increasingly incorporates authentication and tamper-detection technologies to make unauthorized reproduction and manipulation more difficult[64,68].

Common anti-counterfeit technologies include:

- Holograms.
- Security inks.

- Microtext.
- Color-changing inks.
- Tamper-evident seals.
- Invisible or covert markers.
- RFID/NFC technologies.
- QR codes.
- Serialized identifiers.
- Digital authentication systems.

The World Health Organization (WHO) emphasizes the importance of measures to prevent, detect and respond to substandard and falsified medical products[64].

Modern pharmaceutical manufacturers increasingly use a multi-layered authentication strategy, combining visible security features with covert technologies and digital verification. For example, a pharmaceutical package may contain a tamper-evident seal, a unique serialized code and a covert authentication feature simultaneously[64,68].

6.5 Sustainable/Eco-Friendly Packaging

Environmental sustainability is becoming increasingly important in pharmaceutical packaging. Manufacturers are exploring ways to reduce the environmental impact of packaging while maintaining the required quality, stability, sterility and protection of medicinal products[69,70,71].

Sustainable packaging strategies include:

- Reduction in packaging material.
- Lightweight packaging.
- Use of recyclable materials.
- Use of recycled materials where appropriate.
- Reduction of unnecessary secondary packaging.
- Improved packaging-to-product ratio.
- Development of lower-environmental-impact materials.
- Improved recycling and waste-management systems.

However, pharmaceutical packaging cannot be redesigned solely on the basis of environmental considerations. Any new material must demonstrate appropriate chemical compatibility, container-closure integrity, stability and protection of the medicinal product[70,71].

Therefore, the future of sustainable pharmaceutical packaging requires a balance between environmental sustainability and pharmaceutical quality requirements.

Table 3: Emerging Trends in Pharmaceutical Packaging

Emerging trend	Major technologies	Objective	Benefits	Challenges
Smart packaging	Sensors, RFID, NFC, electronic indicators	Monitoring and interaction	Product monitoring, authentication and patient engagement	Cost, cybersecurity and regulatory acceptance
QR codes & digital labelling	QR codes, mobile applications, electronic information	Digital access to information	Updated information, accessibility and multilingual communication	Digital access and data security
Serialization & track-and-trace	Unique identifiers, Data Matrix codes, electronic databases	Supply-chain traceability	Authentication and efficient recalls	Infrastructure and interoperability
Anti-counterfeit technologies	Holograms, security inks, covert markers, NFC/RFID	Product authentication	Protection against falsified medicines	Increasing sophistication of counterfeiters
Sustainable packaging	Recyclable materials, lightweight designs, material reduction	Environmental protection	Reduced waste and material consumption	Maintaining stability, sterility and product protection

The future of pharmaceutical packaging is expected to involve increasing integration of physical packaging, digital technologies, regulatory databases and patient-facing information systems. Smart packaging may provide real-time information about product conditions, while QR codes and electronic product information may improve access to current safety and usage information.

Serialization and anti-counterfeit technologies are also expected to become increasingly sophisticated as pharmaceutical supply chains become more digitalized[63,64,67]. The combination of unique identifiers, digital authentication and track-and-trace systems may provide stronger protection against falsified medicines.

At the same time, environmental sustainability is likely to become a major consideration in packaging development. Future pharmaceutical packaging will therefore need to achieve a balance between regulatory compliance, product protection, patient safety, supply-chain security, digital functionality and environmental sustainability[69,70,71].

Thus, pharmaceutical packaging is evolving from a conventional protective container into a multifunctional platform for protection, identification, authentication, communication, traceability and sustainability.

VII. CHALLENGES IN GLOBAL HARMONIZATION

Global harmonization of pharmaceutical packaging and labelling is essential for ensuring consistent product quality, patient safety and efficient international distribution. However, pharmaceutical manufacturers operating across multiple jurisdictions face significant challenges because regulatory requirements are not completely uniform. Differences in legal requirements, language, labelling formats, packaging standards, serialization systems and regulatory procedures can increase manufacturing complexity and compliance costs [43,44,45].

7.1 Different Country-wise Requirements

One of the major challenges in global harmonization is the existence of country-specific regulatory requirements. Although organizations such as WHO and ICH have promoted international convergence, individual regulatory authorities continue to establish requirements according to their national legislation and public-health priorities[43,46].

For example, the United States, European Union, India, United Kingdom, Japan, Canada and Australia may require different information, symbols, warnings, package inserts, serialization systems or packaging features. Consequently, a package that complies with one jurisdiction may require modification before it can be marketed in another.

These differences increase the complexity of regulatory submissions, artwork management, production planning and quality control.

7.2 Language Requirements

Language is another important barrier to global harmonization. Pharmaceutical information must generally be presented in the language or languages required by the target market.

The European Union presents a particularly complex example because medicinal products may need product information in multiple official languages depending on the Member State and authorization route[44]. Similarly, Japan requires regulatory product information in Japanese, while other countries have their own language requirements.

Multilingual packaging creates several challenges:

- Translation accuracy.
- Regulatory review of translations.
- Limited packaging space.
- Maintenance of multiple artwork versions.
- Prevention of translation errors.
- Updating all language versions following regulatory changes.

Incorrect translation of dosage instructions, warnings or storage requirements may create a patient-safety risk, making translation a critical component of regulatory compliance rather than simply an administrative activity.

7.3 Labelling Differences

Although most jurisdictions require basic information such as the product name, strength, batch number, expiry date, storage conditions and warnings, the exact content and presentation may differ considerably[44,47].

Differences may include:

- Product-name conventions.
- Required warning statements.

- Prescription-status statements.
- Excipient declarations.
- Braille requirements.
- Local regulatory symbols.
- Package leaflet format.
- Manufacturer/marketing-authorization-holder information.
- Serialization requirements.
- National identification numbers.
- Patient information requirements.

For example, the EU uses standardized Quality Review of Documents (QRD) templates for product information, while the United States uses its own FDA-approved labelling framework[44,47]. Such differences make the development of a single universal label difficult.

7.4 Cost of Compliance

Compliance with multiple international packaging regulations can significantly increase the operational cost of pharmaceutical companies. Costs may arise from:

- Regulatory consultations and submissions.
- Artwork development and review.
- Translation and localization.
- Packaging-material qualification.
- Stability studies.
- Serialization infrastructure.
- Printing of multiple packaging versions.
- Regulatory variations and change management.
- Destruction of obsolete packaging.
- Training and quality-control activities.

For multinational companies, maintaining numerous packaging configurations may also increase inventory and warehousing costs. Small and medium-sized pharmaceutical manufacturers may face proportionally greater financial pressure when entering multiple international markets.

Therefore, regulatory harmonization can provide substantial economic benefits by reducing unnecessary duplication of regulatory and packaging activities[43,47].

7.5 Packaging Redesign

Differences in regulatory requirements frequently necessitate packaging redesign when a pharmaceutical product is introduced into a new market or when regulations change.

Redesign may involve modifications to:

- Label dimensions.
- Artwork.
- Typography.
- Warning statements.
- Language.
- Braille.
- Barcode/Data Matrix codes.
- Tamper-evident features.
- Child-resistant systems.
- Package inserts.
- Container-closure systems.

Packaging redesign can also affect manufacturing equipment, printing systems and packaging-line validation. Changes to a primary packaging system may require additional compatibility, stability or container-closure studies[47].

Furthermore, regulatory changes can make previously printed packaging obsolete. Managing obsolete stock while ensuring uninterrupted medicine supply is therefore an important operational challenge.

7.6 Counterfeit Medicines

Counterfeit or falsified medicines are a major challenge to global pharmaceutical supply chains. WHO identifies substandard and falsified medical products as a significant public-health concern because such products may contain incorrect ingredients, insufficient quantities of active ingredients or harmful substances[48].

Packaging plays an important role in combating counterfeiting through:

- Tamper-evident features.
- Holograms.
- Security inks.
- Microtext.
- Covert authentication technologies.
- QR codes.
- RFID/NFC technologies.
- Serialization.
- Track-and-trace systems.

The United States has developed pharmaceutical supply-chain security requirements through the Drug Supply Chain Security Act (DSCSA), while the European Union has implemented safety features including unique identifiers and anti-tampering devices for applicable medicinal products[49,50].

However, counterfeiters continuously adopt new technologies, meaning that anti-counterfeit systems must also evolve. A major future challenge is therefore maintaining a balance between effective authentication, affordability and interoperability across international supply chains.

7.7 Regulatory Changes

Pharmaceutical packaging and labelling regulations are continuously evolving in response to developments in technology, pharmacovigilance, patient safety, sustainability and supply-chain security.

Regulatory changes may involve:

- New warning requirements.
- Changes in safety information.
- New serialization requirements.
- Digital labelling initiatives.
- Changes in packaging materials.
- Environmental requirements.
- New accessibility requirements.
- Changes in national legislation.
- Updated regulatory guidance.

For example, Japan has moved toward electronic package inserts, while the EU continues to develop approaches to digital product information and improve the readability of package leaflets[44,51].

Frequent regulatory changes require pharmaceutical companies to maintain effective regulatory intelligence, change-control systems and artwork-management processes. Failure to implement an approved regulatory change within the required timeframe can result in non-compliance, product recall, supply disruption or regulatory action.

Table 4: Major Challenges in Global Harmonization of Pharmaceutical Packaging and Labelling

Challenge	Major issue	Impact on pharmaceutical industry
Different country-wise requirements	Different national laws and regulatory expectations	Multiple packaging configurations
Language requirements	Different languages and translation requirements	Increased artwork and translation complexity
Labelling differences	Different warnings, formats and information requirements	Difficulty developing universal labels
Cost of compliance	Regulatory, printing, testing and technology costs	Increased overall product cost
Packaging redesign	Market-specific packaging modifications	Additional validation and production requirements
Counterfeit medicines	Increasing sophistication of falsified products	Need for advanced authentication and traceability
Regulatory changes	Frequent updates to laws and guidance	Continuous artwork and compliance management

The challenges associated with global harmonization demonstrate that complete standardization of pharmaceutical packaging and labelling has not yet been achieved. International organizations such as WHO and ICH have promoted regulatory convergence, but national differences continue because pharmaceutical regulation is closely linked to individual healthcare systems, legislation, languages and public-health requirements[43,46].

The most effective approach for multinational pharmaceutical companies is therefore to establish a global packaging strategy combined with country-specific regulatory adaptation. A standardized global core artwork can be developed, while market-specific components such as language, warnings, regulatory symbols and serialization information can be incorporated according to local requirements.

Future harmonization is likely to depend on increased use of electronic regulatory submissions, standardized data structures, digital product information, interoperable serialization systems and international regulatory cooperation. These developments may reduce duplication while maintaining the country-specific information necessary to protect patients.

VIII. FUTURE PERSPECTIVES

The future of pharmaceutical packaging and labelling is expected to be shaped by international regulatory convergence, digital transformation, patient-centred communication, environmental sustainability and advanced product-authentication technologies. These developments aim to improve medicine safety and

accessibility while reducing regulatory complexity and strengthening pharmaceutical supply-chain security[52,53,54,55].

8.1 Global Harmonization

Global harmonization is expected to remain an important objective of pharmaceutical regulation. Organizations such as the International Council for Harmonization (ICH) and the World Health Organization (WHO) continue to promote convergence of technical and regulatory requirements among different countries[52,53].

Greater harmonization of packaging and labelling requirements could reduce duplication in regulatory submissions, minimize the need for multiple packaging versions and facilitate international distribution. Harmonized approaches could also support common standards for:

- Product identification.
- Safety information.
- Stability and storage statements.
- Serialization.
- Electronic product information.
- Packaging materials and quality requirements.

However, complete harmonization is unlikely in the immediate future because individual countries retain different legal systems, languages, healthcare structures and public-health priorities[52,53].

8.2 Digital Labelling

Digital labelling is expected to become one of the most important developments in pharmaceutical product information. Technologies such as QR codes, electronic package inserts, mobile applications and web-based platforms can provide access to current regulatory and safety information[54,55].

Digital labelling can provide several advantages:

- Rapid updating of safety information.
- Access to multilingual information.
- Improved accessibility.
- Reduced dependence on large printed package inserts.
- Additional space for detailed information.
- Integration with patient-support technologies.

Japan provides an important example of this transition through its electronic package-insert system, implemented in principle from 2021 for many medicinal products[55]. The EU is also exploring and implementing approaches to electronic product information and mobile-scanning technologies[54].

Nevertheless, digital labelling should be developed with consideration for patients who have limited digital literacy, limited internet access or disabilities. Essential information required for safe use must remain appropriately accessible.

8.3 Patient-Centric Labelling

Future pharmaceutical labelling is likely to become increasingly patient-centric, focusing not only on regulatory completeness but also on whether patients can understand and correctly use the information provided.

Patient-centric labelling may involve:

- Plain-language instructions.
- Larger and more readable typography.
- Improved colour contrast.
- Clear differentiation between strengths.
- Simplified dosage instructions.
- Improved organization of warnings.
- Appropriate pictograms.
- Accessible information for visually impaired patients.
- User testing and human-factors evaluation.

The EMA's ongoing work on improving the readability and user-friendliness of package leaflets reflects this broader regulatory direction[54]. Patient-centric design can help reduce medication errors and improve adherence by making important information easier to locate and understand.

Future packaging development is therefore likely to incorporate human-factors engineering and user testing more systematically during the design and regulatory-development process.

8.4 Sustainable Packaging

Environmental sustainability is expected to become an increasingly important component of pharmaceutical packaging development. Pharmaceutical manufacturers are under growing pressure to reduce packaging waste, material consumption and environmental impact while maintaining product quality[57,58].

Future approaches may include:

- Lightweight packaging.
- Reduction of unnecessary secondary packaging.
- Recyclable or appropriately recyclable materials.

- Increased use of recycled materials where suitable.
- Reduced material consumption.
- More efficient packaging designs.
- Improved waste-management systems.
- Lifecycle-based packaging assessment.

However, pharmaceutical packaging has an essential role in protecting medicines from moisture, oxygen, light, contamination and physical damage. Therefore, environmental improvements cannot compromise stability, sterility or patient safety[58].

The future is likely to involve greater use of life-cycle assessment (LCA) to evaluate environmental impacts while considering the entire pharmaceutical packaging system rather than focusing only on the material itself.

8.5 Advanced Authentication Technologies

Counterfeit and falsified medicines will continue to require sophisticated authentication technologies. Future pharmaceutical packaging is expected to combine physical security features with digital authentication and traceability systems[59,60].

Potential technologies include:

- Advanced holographic systems.
- Digital watermarks.
- Security inks.
- Micro- and nano-level identifiers.
- RFID.
- NFC.
- Serialized QR/Data Matrix codes.
- Blockchain-supported traceability.
- Artificial-intelligence-assisted authentication.
- Smartphone-based verification systems.

The most effective future systems are likely to use multiple layers of authentication. For example, a single package could contain a unique serialized identifier, a tamper-evident feature and a covert authentication marker.

The U.S. DSCSA and EU Falsified Medicines framework demonstrate the continuing movement toward stronger pharmaceutical supply-chain security and package-level identification [59,60].

Table 5: Future Perspectives in Pharmaceutical Packaging and Labelling

Future trend	Expected development	Potential benefit	Major consideration
Global harmonization	Greater convergence of regulatory standards	Reduced regulatory duplication and easier global distribution	National legal and language differences
Digital labelling	QR codes, electronic package inserts and digital platforms	Rapidly updated and accessible information	Digital accessibility and cybersecurity
Patient-centric labelling	Plain language, improved typography and human-factors design	Reduced medication errors and improved comprehension	User testing and accessibility
Sustainable packaging	Material reduction, recyclable materials and lifecycle assessment	Reduced environmental impact	Must maintain stability and product protection
Advanced authentication	NFC/RFID, advanced security features, serialization and digital verification	Improved anti-counterfeiting and traceability	Cost, interoperability and cybersecurity

The future of pharmaceutical packaging and labelling will increasingly involve the integration of regulatory science, digital technology, patient safety and environmental sustainability. The conventional concept of packaging as simply a container for protecting a medicine is gradually evolving toward a multifunctional system capable of providing product

identification, authentication, traceability and patient information[54,55,59].

Greater global regulatory convergence could reduce the complexity faced by multinational pharmaceutical manufacturers, while digital labelling may allow product information to be updated more efficiently. At the same time, patient-centric design is expected to make pharmaceutical information easier to understand and use.

Sustainability will also become increasingly important, but environmental improvements must remain compatible with the fundamental pharmaceutical requirements of quality, safety, efficacy and stability[57,58]. Similarly, advanced authentication technologies will need to balance security with affordability, interoperability and ease of implementation.

Overall, the future direction can be summarized as a transition toward "harmonized, digital, patient-centred, sustainable and secure" pharmaceutical packaging and labelling systems.

IX. CONCLUSION

Pharmaceutical packaging and labelling play a vital role in ensuring the quality, safety, efficacy, stability and proper use of medicines. Regulatory authorities across the world have established specific requirements to control pharmaceutical packaging and labelling. Although basic requirements are similar, differences in country-wise regulations, language, warnings and packaging standards create challenges for global harmonization. Special pharmaceutical products such as injectables, vaccines, pediatric medicines, controlled medicines and hazardous products require additional safety measures. Emerging technologies such as serialization, QR codes, digital labelling, smart packaging and anti-counterfeit systems are improving product traceability and supply-chain security. Patient-centric labelling is also becoming important for improving understanding and reducing medication errors. At the same time, sustainable packaging is gaining importance due to increasing environmental concerns. Overall, the future of pharmaceutical packaging and labelling will depend on regulatory harmonization, digital innovation, patient safety, advanced authentication and environmentally sustainable packaging solutions.

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