Available online on 15 Dec, 2025 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Management of Packaging Artwork Design for Medicines in the Pharmaceutical Industry: Standardised Labeling and Package Leaflet Requirements and their Assessment Process in the European Centralised Procedure

Rabab Abdo Mohamed Fadlelmula*

Regulatory Affairs and Quality Assurance Specialist, Faculty of Pharmacy, Ahfad University for Women, Sudan.

Abstract

Artwork design involves creating and developing visual components, layouts, and graphic illustrations used in the packaging and labeling of medicinal products. These designs represent a paramount role in linking essential information about medications and ensuring adherence to regulatory compliance. Despite their significance, pharmaceutical industries confront several hindrances in artwork design, such as meeting regulatory requirements, maintaining brand consistency, addressing multilingual needs, and managing time and cost constraints.

This article discusses the process of managing packaging artwork design within the pharmaceutical industry and outlines the EU regulatory requirements aimed at standardizing artwork compliance. It elucidates the assessment process according to the Directives and Regulations for mock-ups and specimens of immediate (primary) and outer (secondary) labeling, as well as package leaflets for medicinal products in the centralized procedure.

The article also outlines a comparison of labeling workflows and submission processes across the EU, US, Australia, and Japan. Furthermore, it highlights the influence of packaging artwork on brand recognition and marketing approach, emphasizing patient safety through precise pharmaceutical packaging information. Additionally, it expounds the significance of artwork review and change control management. It also shows the proportion of recalls in the US and the EU over the past years. It outlines strategic perspectives and the latest updates that are influencing EU labeling practices in 2025.

Keywords: Artwork design; Packaging; Product leaflet (PL); Labeling; Medicinal Product; Brand identity; Pharmaceutical Industry; European Medicines Agency (EMA); Regulation

Article Info: Received 07 Dec 2025; Review Completed 15 Dec 2025; Accepted 15 Dec 2025

Cite this article as:
Fadlelmula RAM. Management of Packaging Artwork Design for Medicines in the Pharmaceutical Industry: Standardised Labelling and Package Leaflet Requirements and their Assessment Process in the European Centralised Procedure. Int. J. Drug Reg. Affairs [Internet]. 2025 Dec15 [cited 2025 Dec 15]; 13(4):81-90. Available from:
https://ijdra.com/index.php/journal/article/view/831

DOI: 10.22270/ijdra.v13i4.831

*Corresponding author. E-mail address: rabababdo181@gmail.com (R.A.M. Fadlelmula).

1. Introduction

Artwork encompasses blister packs, container labels, patient leaflets, and cartons, all are need to precisely represent the approved regulatory information. Regulatory Authorities accentuate the importance of artwork compliance during both pre-marketing and post-marketing evaluations. (1)

The components of packaging artwork include:

- Branding elements: Company logos, colors, and fonts that identify the products.
- Regulatory information: Includes details such as patient and prescribing information, active and inactive ingredients, warnings, and expiration dates as mandated by the EMA/FDA, required or optional barcodes, and any other relevant information.
- Design elements: The arrangement, typography, images, diagrams, and tables that enhance the clarity and readability of the information
- Security features: Product identifiers. (2)

2. Management of Product Artwork

In the pharmaceutical industries, managing artwork for product packaging is quintessential to guarantee compliance, precision, and adherence to brand standards.

By following the artwork management steps outlined in Figure1, pharmaceutical companies can guarantee that their packaging is precise, meets regulatory requirements, and consistently reflects the brand. (3)

3. Packaging Category and Type:

Packaging in the pharmaceutical industry differs depending on the product and is typically divided into

three levels or categories: primary, secondary, and tertiary packaging.

- Primary packaging (immediate packaging) refers to the material that directly surrounds and contains the product.
- Secondary packaging (outer packaging) is the layer outside the primary packaging, used to group multiple primary packages together, such as injection trays, shipping containers, boxes, and cartons.
- Tertiary packaging is designed for bulk handling and shipping, encompassing products such as barrels, containers, and edge protectors.

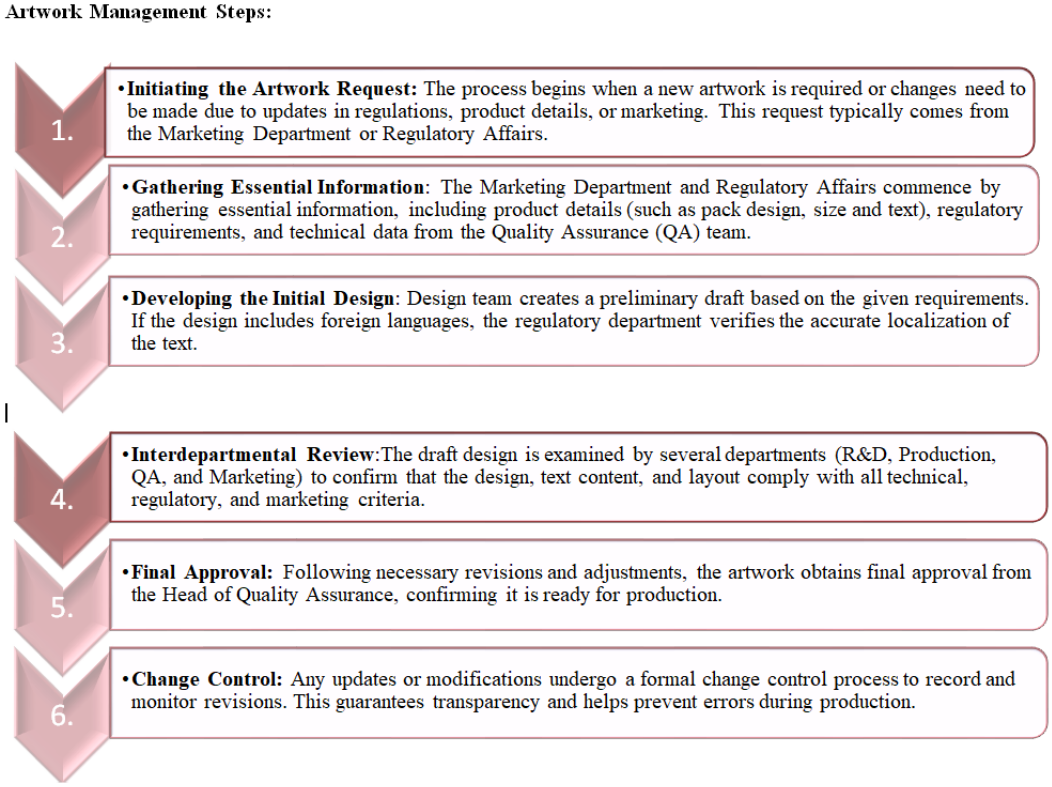

Figure1. Artwork Management steps

The quality of pharmaceutical packaging is vital to maintaining the product's quality. It must protect the product from harmful external elements like light; moisture, oxygen, and temperature fluctuations that could alter its properties and also must prevent biological contamination and guard against physical damage. Additionally, the packaging must provide accurate information and clear identification for the product.

A variety of packaging materials are available, such as glass, metal, plastic, and more. The choice of packaging type and materials must guarantee that does not detrimentally affect the product, and likewise, the product does not adversely affect the packaging or compromise its protective function. These requirements must be conserved all over the product's lifetime. Pharmaceutical packaging material must adhere to the same quality assurance standards as the pharmaceutical product. (4)

4. Pharmaceutical Products in Marketing Approach

The types of pharmaceutical products that significantly influence marketing approaches:

4.1 Marketing of Prescription (Rx) Medicines

Historically, these products received little marketing attention because they are deliberated to a limited circle of healthcare professionals. Consequently, the packaging design for Rx products has traditionally focused only on essential information. This is because doctors prescribe medications based solely on the patient's needs, and patients typically use the medications prescribed by their doctors. Nevertheless, recently, pharmaceutical companies have begun incorporating more strategic marketing elements into their products and packaging. Since traditional advertising methods are not allowed for these medications, companies use distinctive and attractive packaging designs to indirectly promote their brand.

4.2 Marketing of Over-the-Counter (OTC) Medications

Pharmaceutical companies that market OTC products through mass media advertising are attaining consumers directly. This type of marketing offers greater flexibility in generating fascinating product packaging. Effective packaging design enhances the overall product experience and provides companies with a powerful tool to impress favorably on the targeted consumers and attract their loyalty. (5)

5. The Potency of Pharmaceutical Packaging Design on Branding

1. Distinctive Visual Identity

A professionally crafted pharmaceutical packaging design instills trust. Remarkable shapes, embossed logos,

and vibrant color schemes create a premium look. This unique appearance also prevents confusion on pharmacy shelves and enhances positive brand recognition.2. Uniformity across Product Lines

Maintaining consistency in packaging design across various product categories strengthens brand identity and recognition. This uniformity benefits both physical stores and online presence. Consistent design reassures customers that they are choosing the right brand.

3. Emotional Branding through Design Elements like font, color, and material texture play a role. Soft pastel colors can have a calming effect, while bold reds may convey urgency, such as pain relief. This emotional connection allows brands to foster stronger, more positive relationships with consumers. It turns the product into an experience. (6)

6. EU-Wide Artwork Requirements:

According to Directive 2001/83/EC, Article 54, all human medicines are required to include the following fundamental information on both their primary (immediate) and secondary (outer) packaging:

- Name of the product (strength and dosage form)
- Active ingredients and concentrations
- Route of administration
- Expiry date
- Storage condition
- Special warnings (if necessary)
- Batch number
- Manufacturer details
- Braille representation of the medicine's name

These requirements are compulsory throughout all EU member states, providing a uniform standard to ensure patient safety and clear information. (7)

7. Regulatory Procedure in the EU

In Europe, the European Medicines Agency (EMA) performs a review process for mock-ups (flat copy of artwork) and specimens (printed samples of packaging materials and package leaflets) for medicines approved in the centralised procedure, both prior to the medicine's market release and after certain changes to the authorised medicine. (8)

7.1. The Packaging Standardised Requirements for Medicinal Products Authorised by the European Union consist of three parts:

7.1.1. Section A – Labelling (illustrated in Table 1)

7.1.2. Section B – Package leaflet: (illustrated in Table 1) A package leaflet is mandatory for every medicinal product unless all the necessary information is fully provided on the labelling.

7.1.3. Section C – Presentation of the medicinal product

- Pack Size: All pack sizes authorised may be accessible in every Member State. Consequently, the suitable pack size should be selected based on the treatment duration(s) and the dosage instructions (posology) provided in the product's summary of characteristics.
- Pack design (color, logo, style, etc.): Considering functional and linguistic matters, Marketing Authorisation Holders (MAHs) preferred to provide the product packaging in multiple languages and/or "national" versions (i.e., including the relevant boxed sections). In these cases, the logo, style, format, color pattern, layout, and, if feasible, the packaging dimensions should be consistent across all versions of the product packaging all over the Union.
- Pack composition

❖ Multi-packs: These packs consist of multiple single packs containing the same dosage strength of the product.

❖ Treatment initiation pack: These Product packs include various dosage strengths. They are designed to provide patients with all the necessary strengths at once for the initial treatment period, as the dosage may vary during this time. (9)

8. EMA Assessment Process

The assessment process of mock-ups and specimens of immediate (primary) and outer (secondary) packaging labels, as well as package leaflets of medicinal products, in the centralized procedure

8.1. Principles Applied for the Assessment of Mock-ups and Specimens

The process for assessing mock-ups and specimens follows these key principles:

➢ -The EMA, through its translation checking policy, guarantees that accurate and reliable product information is available throughout the entire EU. Languages prepared by the Marketing Authorization Holder (MAH) and reviewed by Member States before the Marketing Authorization (MA) is granted is included in Commission Decisions for centrally authorized medicinal products.

➢ MAHs are responsible for accurately implementing the approved product information texts on their printed packaging materials, in accordance with the Commission Decision and applicable EU legislation.

➢ The EMA does not conduct a detailed linguistic review of mock-ups and specimens but performs a general readability check to help ensure the safe use of medicines.

➢ The EMA does not maintain a complete collection of specimens for the entire product range across all Member States. Instead, it only keeps examples of mock-ups and printed packaging materials for all centrally authorized products as reference samples representing the entire product commercialized in the EU.

Table 1. Section A – Labelling & 7.1.2. Section B – Package leaflet

Parameter	Section A- Labelling	Section B – Package Leaflet
1-The Text Labelling	The labeling text must be consistent throughout the European Union. The information required must be displayed on the outer (secondary) package of the medicinal product or, if there is no outer package, it should be provided on the immediate (primary) packaging. The Directive (Article 61(2)), the labeling must adhere to the requirements set out in Title V and include the details specified in the SmPC. The information on the labeling must be easy to read, clearly intelligible, and inerasable.	The package leaflet text must be consistent throughout the European Union. A package leaflet is mandatory for every medicinal product unless all the necessary information is provided directly on the label. The Directive Articles 59(1) and 61(2), the package leaflet must adhere to the requirements set out in Title V and include the details specified in the SmPC. The package leaflet should incorporate feedback from target patient groups to guarantee that it is readable, clear, and intelligible.
2-Language	The labeling must be provided in the Member State(s) languages wherever the product is commercialized. If multiple languages are used, the information in all language versions must be the same.	The package leaflet must be in Member State languages or in an official language wherever the medicine is commercialized. If multiple languages are included, the content must be uniform in all language versions.
3. Additional Labelling Information Required by Certain Member States	Article 60 of the Directive states that Member States cannot forbid or obstruct the marketing of a medicinal product if its labeling and package leaflet meet the requirements set out in Title V. However, according to Article 57, Member States may require the use of particular types of labeling to determine: − Medicinal product price. − The reimbursement conditions by social security organizations. − The legal status for dispensing to the patient, as specified in Title VI of the Directive. − Identification and authenticity in line with Article 54a(5). Information specific to a Member State must be placed within a single boxed section on the label (referred to as the ‘blue box’), which should be appear on one side of the packaging. Each ‘blue box’ should be written only in the Member State’s official language(s) and must include the name of that Member State. Ideally, the position of the ‘blue box’ on the package should be consistent across all Member States. Whenever a single package is meant for marketing in multiple Member States, the box will include different information specific to each Member State. A blank 'blue box' on the package should be printed onto which a sticker containing the relevant information for each Member State can be securely	-----

	attached. In rare cases where multiple 'blue boxes' are needed for different Member States, they should preferably be the same size and placed on the same side of the package.	
4.Legal Status	The CHMP scientific opinion and the Commission's decision regarding the marketing authorisation must each clearly state any conditions or limitations that need to be applied to the supply or use of the medicinal product in line with the criteria set out in Title VI of Directive 2001/83/EC. Moreover, being included in Annex II of the Commission decision that grants the marketing authorisation, the legal status may also be indicated in the labeling text found in Annex III A of the Commission decision.	-----
5.Marketing Authorisation Number	The marketing authorisation number starts with "EU" then a nine-digit number (e.g., "EU/1/96/000/000"). This number must be displayed on the packaging, whereas the (national) identification number, if applicable, may only appear once in the 'blue box'.	-----
6.Optional Information According to Article 62 of the Directive	The labeling may feature symbols or pictograms intended to clarify specific information, along with other details consistent with the product's summary of characteristics that provide benefits to the patient. **Local Representative**: Article 54(k) of the Directive states that the label must include the Marketing Authorisation Holder's name and address. If applicable, the name of the representative appointed by the MAH to represent them in the Member States.	The package leaflet may feature symbols or pictograms intended to clarify specific information, along with other details consistent with the product's summary of characteristics that provide benefits to the patient. **Local Representative**: Article 59(1) f) vi) of the Directive states that the package leaflet must include the Marketing Authorisation Holder's name and address. If applicable, the name of the representative appointed by the MAH to represent them in the Member States.
7. Partially-Sighted and Blind Patients	The Directive (Article 56a) mandates that the name of the medicinal product (as mentioned in Article 54(a)) must be shown in Braille on the packaging.	The Directive (Article 56a) mandated the marketing authorization holder to provide patients' organizations, upon request, with the package information leaflet in formats that are accessible to individuals who are partially sighted or blind.
8. Verification of Label Compliance with the Directive	The submitted outer and immediate packaging will be examined for adherence to the requirements outlined in the Directive during the scientific evaluation and language review of the application.	The submitted package leaflet will be examined for adherence to the requirements outlined in the Directive during the scientific evaluation and language review of the application.
9. Changes to the Labelling	In the directive (Article 61(3)), If a marketing authorisation holder wants to add any label text beyond what is stated in the decision or alter any part of the labelling that is not related to a change in the SmPC, they are required to inform the EMA beforehand. The EMA will inform them within 90 days of the request if the proposed change is disapproved. If needed, the EMA will notify the Commission, which will then amend the decision granting the marketing authorisation. If the labelling change results from a modification of the SmPC in the framework of variation or renewal, it will be handled according to the particular method set up for that purpose.	In the directive (Article 61(3)), If a marketing authorization holder wants to add any new information to the package leaflet attached to the Commission decision granting the marketing authorization, or to alter any part of the package leaflet that is not related to a change in the Summary of Product Characteristics (SmPC), they are required to inform the EMA beforehand. The EMA will inform the holder within 90 days on condition that the change is disapproved. If needed, the EMA will notify the Commission, which will then amend the decision granting the marketing authorization. If the change to the package leaflet results from a modification to the SmPC as part of a variation or renewal, it will be handled according to the particular method set up for that purpose.

- The EMA may request specific specimens from the Marketing Authorisation Holder (MAH) at any time for review, for instance, in response to safety concerns or product defects.
- Detailed evaluations of the labeling and leaflet content, including their translations, will occur during the scientific assessment and linguistic review of the application. The presentation of information—such as print size, color, and layout—is a key aspect of the overall readability of the labeling and leaflet. This will be precisely verified on the submitted mock-ups and specimens.
- The review is carried out by specialised EMA staff that communicates with the product team leader and the QRD secretariat. If there are any comments regarding the specimens, the EMA will collaborate with the applicant/MAH to determine the most appropriate and practical corrective action, considering the type and extent of the matters found. However, if significant safety concerns arise, the EMA may ask for updated specimens to be submitted for evaluation prior to marketing or may even demand a recall of products that have already been launched on the market.

8.2 The Mock-up and Specimen Assessment Stages and Timelines for New Marketing Authorisation Applications and Extension Applications

Mock-ups:

At the time of the initial submission (day 0), applicants should provide mock-ups that are considered final drafts. The EMA may include provisional feedback on these mock-ups in the validation letter, which applicants should consider when further refining their packaging designs.

The EMA will then conduct a detailed review of the mock-ups alongside the scientific assessment, and any remarks on the mock-ups will be communicated together with the PIQ(Product Information Quality) feedback on the English product information by day 120. If EMA has any remarks or if the applicant modifies the overall design, updated mock-ups should be submitted as part of the responses to the list of questions by day 121.

Feedback on the (revised) mock-ups will be provided along with the QRD (Quality Review of Documents) comments by day 155. If a QRD sub-group meeting takes place on day 165, the EMA may also use this opportunity to discuss the draft mock-ups to complement the review of the product information. By day 181, the EMA will ensure that any remaining comments from day 155 have been addressed before issuing the opinion. After the Opinion has been adopted, submitting additional mock-ups for review is not necessary. However, if applicants request it before printing the specimens, the EMA is open to conducting an extra review of updated mock-ups during the post-opinion phase.

8.3 Specimens:

Specimens of outer and immediate packaging, as well as the package leaflet (including mock-ups and samples), must be submitted to the EMA for review not less than 15 days before to the launch of each strength:

- Prior to the product's initial marketing in the EU.
- Prior to marketing it as a multilingual pack in the EU.
- Whenever a new multi-language pack is introduced that includes more languages than any previously reviewed multi-language pack(s).

Providing specimens for one pack size is adequate; if multiple pack sizes are being launched simultaneously, the EMA prefers to receive specimens of the smallest pack size.

The EMA will conduct a general review within 15 working days to verify whether any prior feedback on mock-ups or specimens has been properly addressed. The applicant/ MAH will be informed of the consequences of this review. (10)

9. Comparison of Labeling Process Regulations:

Table 2. Comparison of Labeling Regulations Across Europe United States Australia and Japan (11-13)

Parameters	Europe	US	Australia	Japan
Regulatory Authority	European Medicines Agency (EMA)	U.S. Food and Drug Administration (FDA)	Therapeutic Goods Administration (TGA)	The Pharmaceuticals and Medical Devices Agency (PMDA)
Applicable Guidelines /Directive	Directive 2001/83/EC establishes the legal basis for labeling requirements within the European Union.	21 CFR Part 201: Regulates the overall labeling standards for both prescription and over-the-counter medications.	TGA Labelling Guidance: Details the Product Information (PI) and Consumer Medicine Information (CMI) requirements, revised according to Therapeutic Goods Order (TGO 91/92).	PMDA Labeling Guidance: Outlines the requirements for package inserts and artwork compliance.
Template	QRD Templates	Standardized Word or XML templates	Official CMI and PI templates (TGA)	Package insert formats (PMDA).
eCTD Publishing Platforms	Lorenz docuBridge, Extedo eCTD Manager, that use for submission integration.	Lorenz docuBridge or Extedo eCTD manager that use for labeling integration into dossier submissions.	Lorenz docuBridge, Extedo eCTD manager that use for eCTD submission integration.	Lorenz docuBridge, Extedo eCTD manager that use for eCTD submission integration.

Table 3. Comparison of the Labeling Processes Follow Structured Workflows and Submission: (11- 13)

Parameters	Europe	US	Australia	Japan
1-Draft Preparation	The regulatory staff composes the SmPC, PL, and artwork using dossier information and QRD (Quality Review of Documents) templates.	The regulatory staff composes the initial labeling content using clinical, nonclinical, and CMC information. **Cross-Functional Review:** The labeling is examined by teams from regulatory affairs, medical affairs, pharmacovigilance, and legal departments.	The regulatory team composes the TGA Product Information (PI) and Consumer Medicine Information (CMI) using clinical, nonclinical, and Chemistry, Manufacturing, and Controls (CMC) data.	Package inserts (PI) are composed using clinical, nonclinical, and Chemistry, Manufacturing, and Controls (CMC) data.
2- Formatting	**Translation**For centralised authorisations, the labeling is required to be translated into all official languages of the European Union. **Validation**: The EMA and national authorities verify the formatting, terminology, and adherence to QRD (Quality Review of Documents) guidelines.	The labeling is structured following the PLR format and SPL XML specification. **Electronic Conversion**: The labeling is transformed into SPL format utilizing FDA-approved software. **Validation:** Sponsors verify that SPL files comply with FDA technical requirements.	Ensure compliance with TGA TGO 91/92 specification.	Ensure adherence to PMDA Blue Box regulations.
3- Submission	Labeling documents are provided in eCTD format as part of Marketing Authorization Applications (MAAs), variations, or renewals.	Labeling is provided as part of NDA, ANDA, BLA, or post-marketing supplement submissions through eCTD.	Labels are included in NDA/MAA submissions through eCTD for the TGA.	Labels are included in NDA/MAA submissions through eCTD for the PMDA.
4- Regulatory Review	By EMA	By USFDA	By TGA	By PMDA
5- Approval & Publication	Approved SmPC and PL are published on the EMA and national regulatory websites.	The FDA publishes approved labeling information on DailyMed.	Approved labeling is published on official regulatory websites for both healthcare professionals and patients.	Approved labeling is published on official regulatory websites for both healthcare professionals and patients.
6- Post-Marketing Updates	Sponsors are required to revise labels to include safety warnings, recent clinical information, or pharmacovigilance results.	Regular Updates: Changes to product labels after marketing approval (such as safety warnings) demand continuous attention.	Sponsors are required to provide updated labels whenever safety concerns or regulatory instructions necessitate modifications.	Sponsors are required to provide updated labels whenever safety concerns or regulatory instructions necessitate modifications.

10. The Significance of Managing Artwork Changes in the Pharmaceutical Industry

Proper management of artwork change control ensures that all changes are deliberate, checked, and meet compliance requirements.

Main advantages are:

- **Improved Patient Safety**: Precise and clear artwork.
- **Assurance of Compliance**: Validate conformity with regulations.

- **Increased Operational Efficiency**: Reduces delays in launching or updating products.
- **Enhanced documentation**: Creates a thorough audit trail essential for inspections and audits.

11. Guidance Steps for Managing Artwork Change Control

11.1. Initiation and Change Request

- **Recognize the Need**: If the change is required because of regulatory modifications, error fixes, or branding adjustments.
- **Submit a Change Request**: Complete a standardized Artwork Change Request Form outlining the scope and justification for the change.
- **Preliminary Review**: The quality assurance (QA) team should assess the request to evaluate its effect on the product safety standard**.**

11.2. Impact Assessment

- Risk Evaluation
- Stakeholder Engagement: Engage cross-functional teams, including regulatory affairs, marketing, and manufacturing, to thoroughly evaluate the change.
- Regulatory Review: Ensure the proposed change adheres to the requirements set by regulatory authorities.

11.3. Approval Process

- **Documentation Review**: Verify that all required documents, such as risk assessments and regulatory references, are fully completed.
- **Approval Committee**: Submit the change to the corresponding committee for final authorization.

11.4. Implementation

- **Version Control:** Updated the artwork with version numbers and effective dates.
- **Training:** Arrange an appropriate training program for the relevant staff to ensure they are acquainted with the updated artwork.

11.5. Verification and Validation

- **Quality Inspections**: Conduct thorough quality inspections to confirm that the revised artwork complies with all design standards, regulatory guidelines, and readability criteria.
- **Record**: Maintain records of all approvals and related evidence for future audit purposes.

11.6. Post-Implementation Assessment

- **Monitor Feedback**: Collect input from stakeholders and end users to confirm the change has been effective.
- **Audit Trail:** Keep detailed documentation of the change process for both internal and external auditing purposes.
- **Continuous Improvement**: Establish robust Standard Operating Procedures (SOPs) that connect the regulatory, quality assurance, and design teams to ensure efficiency. (14)

12. Pharmaceutical Products Recalls

Products are recalled from the market due to a safety issue or inadequate compliance with the regulations. Recalls are initiated in response to adverse effects, product defects, or manufacturing errors. (15)

Approximately 50% of the recalls in the pharmaceutical sector are due to labeling mistakes. Even small packaging errors can cause thousands of fatalities and cost pharmaceutical companies millions annually. (16)

12.1. Recalls in Europe

Recalls in the pharmaceutical sector increased 7.7%, from 311 in 2022 to 335 in 2023, as shown in Figure (2).

In 2023, Safety concerns were the leading cause of recalls, accounting for 107 incidents of foreign materials or contamination and labeling errors. (17)

12.2. Recalls in the US

Over the past several years, a remarkable elevation (41%) in FDA warning letters and recalls reached a climax in 2024 and 2025. (18)

The U.S. Food and Drug Administration (FDA) provided recall events over the period 2012–2023, where the most common reasons for these recalls were identified as impurities and contaminants (37 %), followed by control (28 %) and labeling/packaging (19 %) issues, as represented in Figure (3).

There were 3,718 recalls reported in total, averaging about 330 recalls annually. When combined with earlier research, this indicates a global rise over the past twenty years, emphasizing the critical need to improve quality in the pharmaceutical sector. (19)

13. Strategic Perspectives and Latest Updates

In 2025, several emerging trends are influencing EU labelling practices:

- **Electronic Labelling (e-Labelling) or Electronic product information (ePI):** This refers to the approved product information for medicines (such as the summary of product characteristics, package leaflet, and labeling), which allow healthcare providers and patients to more easily obtain precise and current product details
- **Patient-Centric Labelling:** There is a growing focus on using clear, simple language and effective risk communication.
- **Global Reliance Frameworks**: EU Summary of Product Characteristics (SmPC) and Package Leaflets (PL) frequently act as reference documents for regulatory approvals in other regions.
- **AI Utilization**: Sponsors are employing AI tools to ensure translation accuracy and identify errors across various languages.
- **Regulatory Transparency**: The EMA makes approved labels publicly available in electronic

formats and distributes them through websites, electronic platforms, and printed materials to promote accessibility, searchability, and multilingual capabilities.

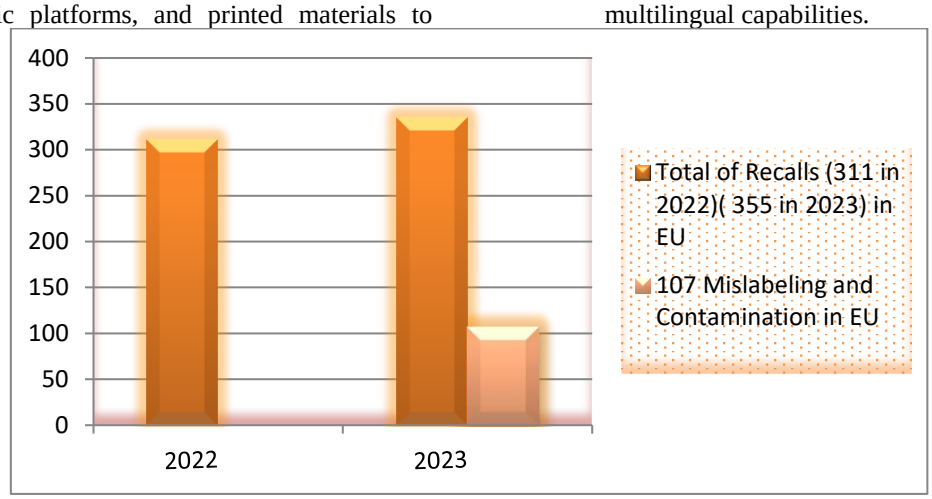

Figure 2. Recalls (2022-2023) in the EU

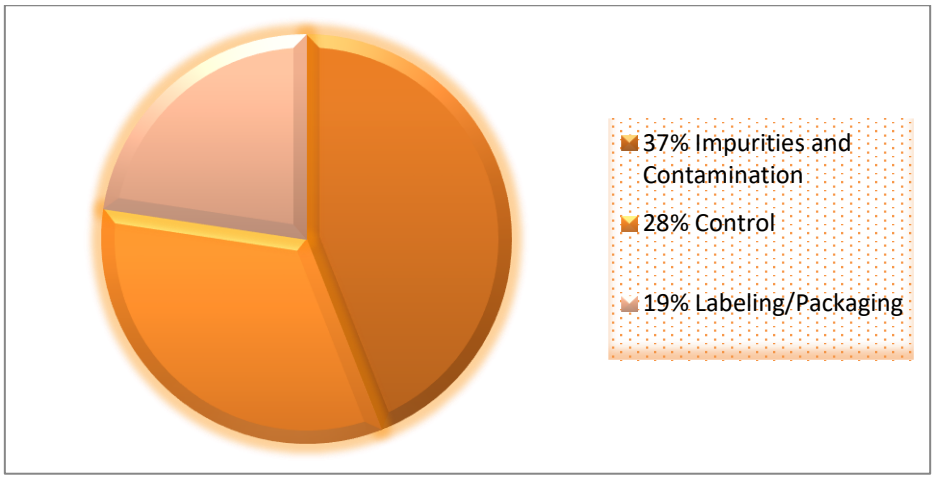

Figure 3. Recalls over Period of (2012-2023) in the US

From a strategic perspective, EU labelling should be viewed as an ongoing compliance process. Companies that focus on strong translation practices, centralised management, and digital labelling technologies can reduce regulatory risks, accelerate approval processes, and boost patient trust across the European market. (11,20)

14. Conclusion

Pharmaceutical products are stringently regulated, and even small changes to artwork can have major consequences. Errors in packaging information may result in medication errors, regulatory fines, and negative impacts on the brand's reputation.

Regular updates are essential; particularly when regulations change or products are modified. Proper management of artwork change guarantees that every modification is verified and complies with the regulations.

A standard operating procedure for reviewing artwork and samples for new applications and renewals ensures that labels remain up-to-date and compliant, facilitating an efficient assessment process throughout the product's market lifecycle.

Pharmaceutical companies can gain advantages by partnering with artwork regulatory service providers to efficiently handle regulatory issues. By adopting these strategies, pharmaceutical firms can improve their brand image and recognition, ultimately attaining higher success in a competitive marketplace.

Acknowledgements

I would like to express my gratitude to the International Journal of Drug Regulatory Affairs who gave me the opportunity to publish the article.

Conflict of Interest

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

Financial Disclosure statement:

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

Reference

1. Artwork Review Checklists Explained: Ultimate Guide to Regulatory Labelling and Packaging Compliance [Internet]. PharmaRegulatory.in – India's Regulatory Knowledge Hub; 2025 [cited 2025 Nov 15]. Available from: https://www.pharmaregulatory.in/artwork-review-checklists-explained-ultimate-guide-to-regulatory-labelling-and-packaging-compliance/
2. Ravindranath V, Navigating FDA Guidelines for Pharmaceutical Packaging: A Focus on Packaging Artwork [Internet]. Schlafender Hase; 2025 Apr 02 [cited 2025 Jun 01]. Available from: https://www.schlafenderhase.com/shblog/navigating-fda-guidelines-pharmaceutical-packaging-artwork
3. Effective Artwork Management in Pharmaceutical Industry [Internet]. Pharmadigests; 2024 Nov 23 [cited 2025 May 02]. Available from: https://pharmadigests.com/effective-artwork-management-in-pharmaceutical-industry/#google_vignette
4. Guidelines on Packaging for Pharmaceutical Products | Part I [Internet]. Pharmadigests; 2023 Sep 22 [cited 2025 Jul 05]. Available from: https://pharmadigests.com/guidelines-on-packaging-for-pharmaceutical-products-part-i/
5. Keller D, Why is Packaging Design Artwork Key in Pharmaceutical Marketing? [Internet]. Catalpha; 2025 [cited 2025 Sep 17]. Available from: https://blog.catalpha.com/why-is-packaging-artwork-key-in-pharmaceutical-marketing
6. How Does Pharmaceutical Packaging Box Design Enhance Brand Identity? [Internet]. Chemzingraphics 2025 Jul 21 [cited 2025 Oct 26]. Available from: https://www.chemzingraphics.com/pharmaceutical-packaging-box-design/
7. Freyr solutions. Package Label Requirements Across the European Union [Internet]. Freyrsolutions; 2025 May 26 [cited 2025 Jun 18]. Available from: https://www.freyrsolutions.com/blog/package-label-requirements-across-the-european-union
8. European Medicines Agency. Mock-ups and specimens [Internet]. EU:EMA;2025 [cited 2025 Dec 01]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/mock-ups-specimens
9. European Medicines Agency. Guideline on the packaging information of medicinal products for human use authorised by the Union [Internet]. European Commission; 2023 Sep [cited 2025 Oct 14]. Available from: https://health.ec.europa.eu/system/files/2023-09/2018_packaging_guidelines_en_1.pdf/
10. European Medicines Agency. Checking process of mock-ups and specimens of outer/immediate labelling and package leaflets of human medicinal products in the centralised procedure [Internet]. EU:EMA; 2022 Sep 27 [cited 2025 Jul 09]. Available from: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/checking-process-mock-ups-and-specimens-outer-immediate-labelling-and-package-leaflets-human-medicinal-products-centralised-procedure_en.pdf
11. EU Drug Labelling Explained: Ultimate Guide to EMA Compliance and QRD Templates [Internet]. PharmaRegulatory.in – India's Regulatory Knowledge Hub; 2025 [cited 2025 Oct 10]. Available from: https://www.pharmaregulatory.in/eu-drug-labelling-explained-ultimate-guide-to-ema-compliance-and-qrd-templates/
12. US Drug Labelling Explained: Ultimate Guide to FDA Compliance and Submission Best Practices [Internet]. Pharma Regulatory; 2025 Aug 15 [cited 2025 Nov 18]. Available from: https://www.pharmaregulatory.in/us-drug-labelling-explained-ultimate-guide-to-fda-compliance-and-submission-best-practices/
13. TGA & PMDA Labelling Explained: Ultimate Guide to Regulatory Compliance in Australia and Japan [Internet]. PharmaRegulatory.in – India's Regulatory Knowledge Hub; 2025 [cited 2025 Nov 29]. Available from: https://www.pharmaregulatory.in/tga-pmda-labelling-explained-ultimate-guide-to-regulatory-compliance-in-australia-and-japan/
14. Artwork Change Control Management in the Pharma Industry [Internet]. Zamann Pharma Support; 2025 Feb 24 [cited 2025 May 22]. Available from: https://zamann-pharma.com/2025/02/24/artwork-change-control-management-in-the-pharma-industry/
15. Drug Recall, What are the common causes [Internet] Sen Pharma; 2024 Jul 24[cited 2025 Aug 29]. Available from: https://senpharma.vn/en/what-are-the-common-causes-of-drug-recall/
16. Artwork and Label Management for Life Sciences and Pharma [Internet]. Artwork Flow by Esko: 2024 Dec 24 [cited 2025 Nov 18]. Available from: https://www.artworkflowhq.com/resources/artwork-and-label-management-for-life-sciences-and-pharma
17. Occleshaw C, 2023 was a record-breaking year for European product recalls [Internet]. Sedgwick; 2024 Mar 2025 [cited 2025 Jul 17]. Available from: https://www.sedgwick.com/blog/2023-was-a-record-breaking-year-for-european-product-recalls/?loc=af-me
18. Why Drug Recalls Are Rising and What Quality Leaders Can Do to Reverse the Trend [Internet]. Compliance Quest; 2025 Sep 11 [cited 2025 Oct 30]. Available from: https://www.compliancequest.com/blog/rising-drug-recalls-how-quality-leaders-can-reverse-trend/#:~:text=FDA%20drug%20warning%20letters%20and,compliance%2C%20and%20supply%20chain%20oversight.
19. Ghijs S, Wynendaele E, Spiegeleer B. The continuing challenge of drug recalls: Insights from a ten-year FDA data analysis. Journal of Pharmaceutical and Biomedical Analysis. [Internet]. 2024[cited 2025 Oct 30]; 249. doi.org/10.1016/j.jpba.2024.116349
20. Electronic product information (ePI) [Internet] European Medicines Agency (EMA); 2025 [cited 2025 Nov 27]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi