

e-Labeling: The Road to Efficient Pharmaceutical Labeling and Packaging

Next steps for the sector as paper-based labeling gives way to digital alternatives



With e-labeling requirements moving up the agenda, this eBook looks at some recent regulatory developments and expectations applicable to the pharmaceutical industry.

It also looks at technical developments in the area of interoperability and then sets out the practical next steps professionals in the life sciences industry can take now – both to prepare for compliance and to maximize operational opportunities.

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Introduction

The Digital Imperative: The Challenges And Benefits of Pharmaceutical E-Labeling

In so many aspects of everyday life, it has become second nature for customers to access product information online. For instructions of various kinds or additional product insights, safety advice and so on, users can scan a QR code or go to a web address. This takes them to the latest details, in an easily digestible format – sometimes including audio and video options for maximum accessibility.

Although the life sciences industry remains some way behind other sectors in this regard, regulators are making clear moves to change this via new directives and guidance. The aim is to connect patients, physicians and other stakeholders across the healthcare ecosystem with a consistently up-to-date source for product and safety information that isn't dependent on paper. Furthermore, the widespread use of healthcare apps and phasing-in of the Fast Healthcare Interoperability Resources (FHIR) standard for exchanging information is also having a significant impact within the healthcare ecosystem.

East Asian markets, particularly Japan and Singapore, are at the forefront of electronic labeling (e-labeling), but steadily the trend towards e-labeling is moving east and west, with European markets and North America now purposefully promoting electronic alternatives to the folded physical inserts in tiny print that have traditionally accompanied medicinal products. Jordan has mandated e-labeling by early 2025, and Brazil is also moving ahead at a strong pace.

Clarifying Common Terminology

In the European Union (EU), the term Product Information (PI) is used as a broad designation that encompasses the Summary of Product Characteristics (SmPC; intended for healthcare professionals) as well as all labeling (both outer and inner packaging information). This includes the Package Leaflet (PL) or Patient Information Leaflet (PIL), which is aimed at patients and consumers.

See the [European Medicines Agency \(EMA\) glossary](#) for more.

In the United States, commonly used terms include:

- Medication Guide
- Patient Package Insert (PPI) or Patient Information: for patients, caregivers and consumers
- Prescribing Information (PI): for healthcare professionals
- Instructions for Use (IFU): included in packaging for patients, providing detailed guidance for complex medications.
- Patient Medication Information (PMI): Proposed one-page information sheet with essential information with standard content and format. See the US Food and Drug Administration (FDA) website for [more on PMI](#) and an [overview of patient labeling resources](#).

Gain Over Pain

The trend toward e-labeling has many benefits. When paper-based information is replaced by digital alternatives, pharmaceutical companies and others involved in the marketing and distribution of medicines no longer need to worry about inventory shelf life linked to whether current stock contains the latest product information or associated details. Although the trend in most jurisdictions is currently toward augmentation rather than complete replacement, in due course, replacement may lead to entire print runs being eliminated in some jurisdictions and packaging simplified. This reduces the volume and weight of shipped goods, with cost-efficiency and carbon emissions benefits. Healthcare professionals and patients meanwhile would no longer need to worry about product information going astray, or containing out-of-date advice. The latest information and recommendations will always be available on tap, online – and in a more dynamic and searchable form.

In practice, for the foreseeable future, physical labeling will exist alongside digital formats, if not for distribution inside the product then on-demand or through those dispensing the product. Pharmaceutical companies therefore face the challenge of ensuring consistency across digital and physical formats, while maintaining the availability of the most accurate and up-to-date information.

Change rarely happens without pain, however. In the short term, the shift to e-labeling is inevitably causing some disruption for organizations and supply chains as companies adapt systems, processes and skillsets, and adjust packaging and operations. There are benefits to be gained here, too, however. Package inserts are a common bottleneck on production lines. As paper product information gradually gives way to digital equivalents, it will be possible to remove this step entirely in some regulatory jurisdictions, with sizeable productivity and efficiency gains.

Interoperability in an E-Labeling Healthcare Ecosystem

Effective data sharing hinges on interoperability – the ability of different systems to work together seamlessly. Historically, the healthcare sector has faced significant challenges due to a lack of interoperability.

We can categorize interoperability in healthcare into several types:



Technical Interoperability

This involves linking systems through applications and infrastructure, including Application Programming Interfaces (APIs) that enable disparate systems to exchange information and functionality.



Syntactic and Semantic Interoperability

Refers to how data is structured and formatted across different systems, while semantic interoperability pertains to the consistent context and meaning of data, such as terminologies and ontologies.



Organizational Interoperability

Business processes must be compatible to avoid chaos and inefficiency. Effective organizational interoperability is crucial in achieving operational efficiency.

Areas in which interoperability offers the most potential include electronic health records (EHR; e.g. referrals, doctor visits), electronic medical records (EMR; e.g. diagnoses, medications), and Structured Product Labeling (SPL), along with other data for clinical and administrative purposes in healthcare.

FHIR – Next-level Interoperability

FHIR (pronounced “fire”) stands for Fast Healthcare Interoperability Resources and has been developed to remedy some of the data sharing limitations found in the traditional Health Level Seven (HL7) interoperability standard. These limitations have become especially apparent through the growth in use of smartphones, health-focused wearables and healthcare apps. Traditional HL7 interface engines, built on protocols like Transmission Control Protocol (TCP)/Internet Protocol (IP), generally lack the flexibility, scalability, and compatibility needed to integrate with modern web-based systems. An API based system – essentially, a set of rules that allows different systems to interact and communicate – offers more interoperability and flexibility in this regard.

Key general benefits of FHIR

- FHIR offers a more patient-centric approach, facilitating easy access to health data through apps, regardless of healthcare provider or geography. This results in greater transparency and availability of patient data.
- Allows for integration with SMART (Substitutable Medical Applications, Reusable Technologies). For instance, a personal health record (PHR) accessed via a smartphone app can synchronize with an EHR or EMR, allowing patients to view their medical data across various providers. SMART on FHIR describes an app platform that works on FHIR.

These new technical possibilities are further driving the need for, and acceptance of, e-labeling and the electronic exchange of information. While e-labeling is at the sharp end of change, as we see from the above, FHIR also opens up a whole range of new possibilities for information exchange, especially in terms of patient-centricity (e.g. patient-centric healthcare apps).

Regulatory Perspectives on FHIR

By their very nature, regulatory authorities take a low-risk approach to change in order to meet their brief of protecting public health. Regulatory bodies are clearly recognizing the potential of FHIR to improve interoperability in digital / electronic environments and are engaging strongly with FHIR.

In the US, FHIR plays a key role in the US 21st Century Cures Act as FHIR and SMART on FHIR is the minimum conformance standard under the act.

The FDA is also engaging with FHIR on several levels through its CBER-CDER Data Standards Program action plan. As part of its project in the area of Identification of Medicinal Product (IDMP) standards – a set of five ISO standards to identify and describe medicinal products – FHIR is foreseen as the standard for global information exchange. It is working in coordination with the European Medicines Agency (EMA) on this project, reflecting a trend toward greater harmonization across regulatory jurisdictions.

Structured Product Labeling (SPL) is one of the most significant areas in which FHIR is set to have an impact. This XML format (HL7 version 3 SPL) for the exchange of information is the current standard for a range of key FDA drug filings. The FDA is working towards replacing traditional Structured Product Labeling with HL7 FHIR. As an interim stage, the FDA has created a proof-of-concept system that allows it to receive labeling information in either traditional SPL format or in HL7 FHIR.

The traditional SPL specification has enormous strengths in terms of semantic and syntactic interoperability, but the strength of FHIR is its technical interoperability across devices and systems. This is crucial when using different devices in the age of e-labeling, as well as for being able to automate workflows. SPL and its Canadian counterpart, the Structured Product Monograph (SPM), have created windows of opportunity for automation, and FHIR builds on this primary work in structured content.

Meanwhile, across the Atlantic, EMA also has a clear commitment to FHIR. FHIR is integral to EMA's Substance and Product Data Management Services (SPOR) program for managing centralized master data in compliance with ISO IDMP standards. SPOR has four domains. In its Product Management Services (PMS) domain, the current data submission format, the eXtended EudraVigilance Product Report Message (XEVPRM) is being **replaced by HL7 FHIR**.

FHIR in regulatory action can already be seen in EMA's pilot project on electronic product information (ePI), which began in July 2023. This involves adapting statutory product information such as the SmPC, package leaflets and other labeling so that it can be handled and distributed in both physical formats as well as digitally via the web or online platforms. The results of this pilot project, including package leaflets, can be found on the **EMA ePI portal**.

Other jurisdictions are also demonstrating a commitment to FHIR. In mid-2024 the Jordan Food and Drug Administration (JFDA) mandated the use of electronic pharmaceutical leaflets for all registered medicines, and this is based on XML HL7 FHIR (FHIR 5.0.0) and data matrix codes. This was set to become a requirement from mid-January 2025. In Australia, the Australian Digital Health Agency has developed a FHIR gateway as one basis for developers to build apps and other products providing consumer and health-professional access to the **My Health Record system**.

Benefits of FHIR in the Context of E-Labeling

- ✓ **Cost and Time Efficiencies:** Improved information exchange leads to reduced administrative burdens.
- ✓ **Scalability:** FHIR facilitates easier expansion of systems and processes.
- ✓ **Risk Mitigation:** Automation reduces the risk of human error during data entry and processing.
- ✓ **Empowerment of Stakeholders:** Increased accessibility to information empowers patients, physicians, and other stakeholders.
- ✓ **Cross-Device Information Exchange:** FHIR enhances the ability to share information across various devices and media formats.

Chapter 1

Transitioning to e-labeling

While the European Medicines Agency in the European Union (EU) and the US Food and Drug Administration promote e-labeling, physical labeling remains a requirement in both jurisdictions and, with few exceptions, within all jurisdictions.

Singapore stands out as one country that allows for the distribution of labeling (including the package insert (PI) and patient information leaflet (PIL) solely by electronic means, on the condition that a registrant of a therapeutic product has a secure online system, and that this can be reached by a machine-readable code (e.g. QR code) or URL.

In the US, in regard to the use of e-labeling as the sole means of communicating prescribing information, the most significant potential legislative change is a bill known as the Prescription Information Modernization Act of 2023. As of late 2024, this had been introduced into the House of Representatives. It provides for the following:

Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following: “Required prescribing information for drugs subject to section 503(b)(1) may be made available solely by electronic means provided that the labeling complies with all applicable requirements of law, that the manufacturer affords prescribers and dispensers the opportunity to elect to also continue to receive all such information in paper form, or to request paper labeling on an as-needed basis, and after such request, and that the manufacturer promptly provides the requested information without additional cost”.

If enacted in its current form, the bill will still require pharmaceutical companies to maintain physical versions for distribution in some circumstances. See here for its [current status](#).

Clearly, however, the pharmaceutical sector must have processes in place that allow for the co-existence of two versions of the content. This underscores both the complexity of labeling requirements, but also the effort pharmaceutical companies must invest into ensuring continued compliance of their labeling and packaging and the processes supporting compliance.

Taking advantage of the opportunity even on a voluntarily basis to complement paper-based advice with an online equivalent is a necessary strategy, enabling companies to align and hone their content management with a view to gradually reducing or – in some jurisdictions – phasing out the reliance on paper. Patients are not only becoming more comfortable with interacting with online or app-based resources, but adopting these resources for an increasingly wider range of information.

This offers pharmaceutical companies the opportunity to ‘stage’ an e-labeling transition, managing this strategic change program to their own timeframe rather than one dictated by the regulatory authorities. Given current legislative measures, it is imperative to begin this transition now.

Any strategic initiative will have an impact across an entire organization and e-labeling is no different. By acting sooner rather than later, businesses can take early advantage of processes, procedures and solutions that provide a digital platform for the future, deliver efficiencies across today's labeling landscape, and add new value for patients. Given the strength of the momentum toward e-labeling, it is important to act with urgency or risk non-compliance.

Just like the changes required, the potential benefits will span the whole business.

On top of the positive impact on patient safety and adherence, the rollout of e-labeling will help promote:

- ✓ Preparation for compliance (if not already a requirement)
- ✓ Open access to new markets
- ✓ New process efficiencies throughout the supply chain
- ✓ Cost savings spanning resources, procurement, warehousing and transportation
- ✓ Reduced environmental impact, increasing sustainability
- ✓ A positive return to the bottom line and ultimately to shareholders

Many of the operational gains are based on the increased accuracy of content: of getting all aspects of labeling right first time. The more systematically pharmaceutical companies manage their labeling, the better able they are to drive out waste and costs linked to relentless review and approval cycles, and increase their speed to market, while mitigating the risk of rework and potential product recalls due to labeling errors.

These same philosophies and processes will also improve the content and data submitted to Health Authorities (HAs), expediting market approvals with the benefit of increased sales revenue.

The changes required to deliver these benefits will be felt widely, and require a joined-up approach to transformation to minimize the pain and maximize the numerous potential gains.

Chapter 2

Impact on Regulatory Affairs

Control of Accurate, Structured Content: Moving Away From Document Centricity

As we see from the development and impact of HL7 FHIR, as well as regulatory responses, increasingly, traditional methods of document publishing no longer serve the interests of patients, healthcare providers, regulators or pharmaceutical companies. Boosted by the COVID-19 pandemic, the effort to modernize and digitize the way content is created, stored, managed, published and updated is gaining new momentum. The practice of copying, pasting and amending content from document to document is both time-consuming and prone to risk. To mitigate errors, pharmaceutical companies must further embrace structured content – the ability to rapidly generate assets for a range of different purposes from agreed, standardized master data with minimal manual intervention.

This goes beyond existing structured content provisions required, for example, in any submission for marketing authorization, and master data must of course adhere to these regulatory requirements for structured content and be seamlessly compatible with them.

To fulfil the different requirements for labeling content, standardization can help ensure the successful integration of people, processes, systems to deliver compliant content both online and in printed form.

Vigilance & Post-Market Surveillance

A significant advantage of e-labeling is the ability to offer patients, caregivers and healthcare practitioners almost immediate access – in a structured form – to enhanced product information based on the latest reporting. This in turn relies on that information being updated promptly and regularly, based on post-market surveillance and pharmacovigilance.

EU regulations mandate that marketing authorization holders, national competent authorities, and the European Medicines Agency (EMA) adhere to various pharmacovigilance procedures once a product has been approved.

Similarly, despite thorough premarket reviews in the US by the Center for Drug Evaluation and Research (CDER), post-marketing surveillance and pharmacovigilance is essential to identify unforeseen drug side effects. One primary reason for this is because preapproval studies are limited in scope and the FDA must monitor adverse events after a drug is marketed. This information is used to update labeling and, in rare cases, reconsider the drug's approval or marketing status. Based on its Adverse Event Reporting System, the FDA may require a label to be updated and also send a Dear Healthcare Professional Letter.

Pharmaceutical companies bear direct responsibility for post-market surveillance and pharmacovigilance. Electronic labeling acts as both an efficient facilitator (e.g. via health apps) but also as an accelerator in this regard, as updated product information can be distributed in near-real time to patients, caregivers and healthcare professionals.

Chapter 3

Impact on the Labeling Department

Inevitably, the Labeling Department shoulders the initial burden of any e-labeling initiative. Increased demands, even if in the short term, will include:

- A heavier workload – managing e-labeling initiatives as well as the ongoing day-to-day labeling change programs.
- A rise in the number of packaging and label formats – In the initial phases (but also invariably beyond), e-labeling will result in an increase in both digital and printed formats.
- Multiplication of file types being created and controlled – Artwork, audio and video, FHIR, HTML, and other XML-based formats, etc.
- A proliferation of distribution channels – Depending on the market, there are likely to be numerous Health Authority platforms, print vendors and web sites requiring published content.
- Proof of compliance – Due to increased regulation around content compliance and post-market surveillance and pharmacovigilance.

Here's how that might play out:



Increased workload

In the initial stages of any e-labeling program, there will be a period where printed and online files will co-exist, doubling the graphic and artwork files required. In most jurisdictions, we can expect this double workload to continue well into the foreseeable future. We can, however, expect the amount of physical labeling required to decline significantly over time.

In some instances, a PDF version of the printed artwork suffices as a static, legible, e-labeling document posted online. For the larger multi-language labeling, with complex pagination to insert into cartons, files must be transformed if they are too large and illegible for digital or online consumption on smart devices. It would be unwise from a long-term strategic perspective to rely on static e-labeling formats such as PDF files. This is underscored by the fact that, in its [key principles document](#), the EU does not consider a PDF document to be part of its ePI initiative, precisely for the reason that ePI is semi-structured – it should account for consumption on online platforms and in apps.

Looking to the future, static e-labeling will certainly not fulfil the aspirations of health authorities, healthcare providers or patients who expect intuitive, interactive and dynamic electronic content. Planning for the provision of accurate structured content will be the smarter way of creating a foundation for e-labeling.

Packaging and labels must be amended to include additional content. On-pack information is required to notify healthcare providers and patients that an e-label exists. In other words, pharmaceutical companies must clearly indicate on the label that the product information is supplied in electronic form and how to access it. This information will need to be provided with each medicine, as we see from e-labeling regulations in Singapore.

In some cases, the integrity of carton or packaging may have been originally designed and transit-tested to include a folded paper insert. If this is the case, the pack specification and size of carton may need to be reformatted once the printed labeling is removed.

All the above will increase the number of files in existence and which must be managed and handled through the labeling change process.



Multiplying file formats

Print and online files differ in numerous ways, from file format, resolution and size, to how color is managed. As a result, printed labeling files will need to be converted or transformed to ensure they are fit-for-purpose in emerging digital/online use cases. On top of this, audio and video formats are being increasingly used to provide supplementary information.

Typically, the Labeling Department of an organization will be responsible for managing the creation, review, approval and distribution of all of these file formats, and for associating any audio and video files with the appropriate static content.

Some thought will need to be given to the current skillsets of the responsible teams, to ensure that they remain able to manage, articulate and brief graphic studios while controlling the lifecycle of additional files, as this will be imperative for an optimum and smooth transformation from paper to electronic formats.

Where the provision of information goes beyond the simple act of offering identical paper and digital versions of product information (e.g. PPI) online, it may include text, graphic, audio or video content considered promotional in nature. If it is promotional in nature, review processes for these formats and content acquire even greater complexity, requiring the input of a cross-functional Promotion Advertising Review Committee (PARC).

While promotional material for prescription medicines is allowed in some jurisdictions (e.g. US), it must meet strict criteria and never be false or misleading. In other jurisdictions, such as Singapore, promotional information is prohibited altogether.



Proliferation of distribution channels

As well as new file formats, teams will need to coordinate a growing range of distribution channels for their content. To date, Labeling departments have created and provided files for Health Authority (HA) approval, then contracted these for printing. As a rule, electronic files are now required in HA databases and in some cases on the website of the regulator, as is the case for package inserts according to regulations in Japan.

However, distribution channels invariably include localized company web sites and in due course web application platforms. This will require enhanced control and governance of files to maintain consistency and accuracy across all channels, and so that updates can be managed in a controlled, coordinated and compliant manner.



Proof of compliance

Today all kinds of manual processes exist to meet localized e-labeling regulations across the globe. Yet, as digital channels become more important or a requirement, and the guidance or parliamentary bills become regulation, manual processes will be too resource intensive and error-prone to be sustainable. And any errors or inconsistencies between sources will be much more visible as information becomes more widely accessible and transparent, something the competent authorities will be watching out for.

Maintaining compliance also requires that companies will have effective systems and procedures in place to ensure that patients, caregivers and healthcare professionals (e.g. those who have downloaded instructions for use from the web site) are kept informed of any updates. The ability to handle the distribution of accurate files in various formats, to manage change processes optimally, and to demonstrate compliance at the click of a button, will be imperative.

Furthermore, as with labeling and packaging, advertising and promotion of medicines is subject to strict regulations, and review processes must be put in place for the creation and maintenance of this type of material. The aim of any pharmaceutical promotional review process is to ensure the accuracy and compliance of promotional material with the relevant medical, legal, and regulatory aspects of a specific market. By nature, it requires skill sets ranging from marketing – where material is generally drafted – through to the medical, legal and regulatory (MLR) expertise brought together in the Promotion Advertising Review Committee (PARC).

Chapter 4

Impact on IT infrastructure

Juggling all of this and keeping everything in sync will be impossible for so long as only manual processes and disjointed, function-specific systems are in place. Now, more than ever, teams need centralized visibility and control from one end of the organization to the other, and the assurance that the content they are working with is definitive, correct and consistent with everything else that's currently available, whatever the immediate purpose.

System Integration

Along with interoperability requirements covered earlier, an effective e-labeling platform requires integration across a broader network of systems, platforms and cloud solutions, most obviously including:

- Regulatory Information Management solutions/Content Management Systems (RIM/CMS)
- Artwork Management or Enterprise Labeling Solutions (AMS/ELS)
- Quality Management Systems (QMS)

But this is not the whole picture. **Enterprise Resource Management (ERP)** and **Product Lifecycle Management (PLM)** must also be considered within the context of e-labeling. That's because digital files and physical pack changes affect the bill of materials, and any evolution of labeling content aligned to the development of the product across its lifecycle.

Integration will enable transparency and governance across the whole IT ecosystem. This needs to include the process of content creation and approval, transformation into digital formats, controlled distribution, and product and safety updates. Given how frequently requirements change, pharmaceutical companies need to ensure that the target platform is sufficiently flexible and futureproof too, thus creating a sustainable and compliant labeling/e-labeling foundation for the long term. This is exemplified again by e-labeling regulations laid down by the Health Sciences Authority (HSA) in Singapore, where a secure online system is a specific requirement.

Within this integrated environment, any changes to regulations should trigger an impact analysis of all the printed and online collateral requiring amendment. The artwork or enterprise labeling solution should support this change program, and approval of any impacted content distributing the updated files and data in a controlled manner.

Customer Relationship Management (CRM) functionality will also play an important role, in capturing patients' interactions with the e-labeling so that notifications of any changes can be issued to them. Fully time-stamped audit reports should capture these transactions and log them within the quality systems to show compliance.

Content Management

At the heart of this integration is content, and specifically the agreed 'source of truth' from which all labeling will flow. Much has been written about end-to-end content management and the role of master data, but each company must determine how best to approach the subject, starting with the end goals in mind.

Structured Content Management allows pharmaceutical companies to confidently manage all the individual elements that come together to create packaging and labeling components for a product, in a streamlined way. Without starting from scratch each time, and without incurring new risk of errors or inconsistency, they can build the various sections in a labeling document (text, tables, images, and other elements that make up the finished insert and packaging) from the latest approved content elements or fragments.

Moving from a document-centric, unstructured way of working to a managed content approach will futureproof existing printed and online labeling processes, allowing these to encompass dynamic e-labeling. Managing content as a series of approved content blocks or elements will allow pharmaceutical companies to achieve a dynamic interaction through links and associations across localized e-labeling. The result will be an efficient and cost-effective way of updating online product information, within the timeframes dictated by regulators, while also creating an audit trail to demonstrate compliance.

Controlled Distribution of Content

Beyond content management and approval, a robust distribution platform is required to manage the transfer of content, in whatever format and via all of the relevant channels.

Tight control and governance will be needed across all communication channels to ensure content is error-free, accurate and compliant with local regulations, and that it can be updated or recalled at any point.

Any solution or platform adopted for e-labeling will need to be scoped for long-term use and flexibility to meet new requirements and interoperability standards.

Any personal data, meanwhile, must be subject to the highest standard of privacy and protection and comply with local data protection principles. Consent must be provided by the user for data to be collected and stored from electronic or digital services, such as information from product searches.

Website Hosting

Keeping web content up to date is particularly important, given the assumption that online resources are easier to update than printed paper documents already circulated.

Any labeling should be provided in a commonly used format that can be read with freely available software. Both the internet platform and address must be stable and directly accessible.

Version control of e-labeling files must be robust and automated where possible.

Within the EU, e-labeling should be available in an official language of the Union determined by the Member State in which the pharmaceutical is made available.

Impact on Production & the Supply Chain

The wider supply chain is also being affected by the shift to e-labeling. While large steps have been taken toward harmonization of regulations, pharmaceutical companies must always factor regulatory divergence into operations. In many cases, paper and digital formats can be expected to co-exist well into the future – if not in one market requirement, then due to the regulatory divergence in different markets.

Furthermore, the increase in packaging formats will also affect the procurement department. Depending on the product, configuration of the supply chain and end user markets, pharmaceutical companies may end up having products packed to go into healthcare settings, without leaflets, and into patient end user channels with printed inserts included, or vice versa. In Japan, for instance, paper package inserts are provided with the initial delivery of the drug (e.g. to pharmacies and institutions).

All this adds to the complexity of the supply chain. Ultimately, as regulations evolve and increasingly allow the removal of printed labeling under certain conditions, the wider patient safety, business and environmental benefits will be felt.

Chapter 5

Why start now?

Any e-labeling initiative or program will serve as a catalyst to drive continuous improvement. Ensuring the accuracy of content as it is transformed throughout the lifecycle, will reduce the risk of non-compliance, rework, and the ultimate sanction of product recalls. Strategic e-labeling initiatives also shine a light on the endless sustainability possibilities. Fewer printed materials, smaller pack sizes, a reduced transportation footprint and greater production efficiencies all play a part in improved Environmental, Sustainability and Governance (ESG) performance.

Although e-labeling is evolving at differing rates around the world, with patient-facing materials often the last phase, the explosion of e-commerce and mobile use shows how quickly and dramatically shifts in consumer behavior can happen once new and convenient options are made available to them. It therefore makes good business sense to be ahead of this trend.

As pharmaceutical companies prepare for a digital-first future, there are three fundamental steps that will provide the perfect springboard to this:



RIGHT FIRST TIME

Ensure content is correct, controlled and compliant at source



ERROR-FREE

Ensure content is transformed accurately across print and online platforms



CONTROLLED DISTRIBUTION

Ensure global transparency and governance across the distribution and lifecycle of content

These three essential capabilities afford pharmaceutical companies the ability to transform accurate content into any format, to be published in a physical or virtual form, as well as posted to competent authority databases.

Underpin all of this with an integrated infrastructure and simplified processes, with real-time controls, and pharmaceutical companies will be ready to fulfil any e-labeling requirements, avoiding the need for major 11th-hour resources and costs to meet impending deadlines.

Chapter 6

Practical next steps

First, start with the end goals in mind and review all existing guidance and proposed regulations and standards in order to gain an understanding of today's regulatory landscape and tomorrow's potential.

Research those industry sectors that have already adopted electronic labeling, such as the chemicals industry, to understand their evolution and any pitfalls experienced.

Then, take proactive steps to create and execute a coordinated e-labeling strategy and plan:

Understand the regulatory landscapes & timeframes

Consider the current and upcoming products in scope and their target user groups.

- Keep abreast of regulatory initiatives in your markets by putting in place processes and systems to monitor changes possibly affecting your products.

Map the existing labeling process

Assess and map the existing labeling landscape, procedures and stakeholders to understand the company's readiness for electronic labeling. Create a gap analysis to feed into any business case.

Scope the e-labeling project

Scope the e-labeling project to align with any immediate needs, focusing on current and future target markets and the products sold into those jurisdictions. Also consider developing foundations for the future, and start with that vision in mind: including patient interaction with online resources to boost the safe use of the product. Look to more established markets (e.g. Singapore, Japan, Jordan) for examples of best practice, and target benefits.

Target quick wins that can be championed and will provide evidence of early success.

Create a high-level project plan

Produce a high-level project plan, including key champions and stakeholders to be involved. This should include a cross-functional team to mirror the scope of e-labeling impact on the organization. For some members of the e-labeling team, digital communication may be uncharted territory, so training and knowledge transfer must be built into the resource planning.

Build, understand and communicate the ROI/business case

Build, understand and communicate in a targeted fashion the return on investment (ROI) and business case, highlighting the benefits of the e-labeling initiative to patient safety and the business, including wider environmental sustainability gains. Review the Chairman's Statement to ensure alignment with any published strategic imperatives and ally e-labeling benefits to those ambitions, targets and goals. Ensure you encapsulate the four strategic priorities of any organization: Financial; Patient; Operational; and Growth related.

Once senior leadership has approved this strategic initiative, the real work begins. Devote time to defining the scope, objectives and key performance results. Remember, on an ongoing basis, to monitor and control the project progress against these criteria. Finally, be sure to communicate and celebrate all wins, as this digital journey will not be an easy undertaking though the paybacks will be extensive and enduring.

Appendix I

Region	Regulatory Authority	Explanation	HA Link
Australia	TGA	Sets out labeling and packaging requirements, with links to aspects of this, including the use of data matrix codes.	https://www.tga.gov.au/labeling-and-packaging
		See latest standards for labeling.	https://www.legislation.gov.au/F2016L01285/latest/text
Brazil	ANVISA	Agência Nacional de Vigilância Sanitária is in the advanced planning stages of introducing e-labeling.	https://www.gov.br/anvisa/pt-br/english
Canada	Health Canada	Draft Guidance Document - Electronic media in prescription drug labeling	https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/drug-products/electronic-media-prescription-drug-labeling/document.html
Egypt	EDA	Guideline on E-Labeling of Medical Leaflets of Medicinal and Biological Products for Human Use	https://www.edaegypt.gov.eg/media/lwlr1gm/guide-line-e-labelling-of-medical-leaflets-of-medicinal-products-for-human-use.pdf
Europe	EMA	Electronic Product Information (ePI) on the EMA website, with links leading to latest developments in this field.	https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi
India	CDSCO	Labeling must comply with directives of Drugs and Cosmetics Act, 1940 and The Drugs Rules, 1945.	https://cdsco.gov.in/opencms/opencms/en/Home/
Japan	PMDA	Japan is a leading country in terms of e-labeling, with requirements to provide labeling online.	https://www.pmda.go.jp See https://youtu.be/3JzezZ2aAuA?si=2ZkLjHDYvfk7InPs for current e-labeling requirements in Japan.
Jordan	JFDA	JFDA's ePI site with guidance, instructions, and validation leaflet. Jordan is mandating e-labeling and the use of FHIR from early 2025.	https://leaflet.healthcare/portal/debug/
Saudi Arabia	SFDA	Explanation of e-labeling requirements in Saudi Arabia, with submission requirements for e-labeling. “The SFDA now requires every pharmaceutical product entering the Saudi market to have a digital leaflet in addition to a printed leaflet. This is reviewed and approved by the SFDA during the product registration period. The SFDA requires digital information to be in the form of fully searchable text. This enables users and health professionals to easily search for and access certain information in the leaflet.”	https://www.sfda.gov.sa/en/node/87601

Appendix I (continued)

Region	Regulatory Authority	Explanation	HA Link
Singapore	HSA	Guidance on e-labeling. Registrants may distribute “HSA-approved PI and/or PIL in the form of an e-PI/PIL. The e-PI/PIL may be distributed with or without physical printed copies contained in the products.”	https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/tpb-gn-021-000_appendix-7a-guidance-on-electronic-labeling-for-therapeutic-products.pdf?sfvrsn=1f3ad3d0_5
		Also see:	https://www.hsa.gov.sg
Taiwan	TFDA	Regulations for Registration of Medicinal Products	https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030057
UK	MHRA	Main page for guidance on labeling in the UK.	https://www.gov.uk/guidance/medicines-packaging-labeling-and-patient-information-leaflets#labeling-for-medicines
		Also see Labeling and packaging of medicinal products for human use following agreement of the Windsor Framework	https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework
USA	FDA	FDA's Labeling Resources for Human Prescription Drugs.	https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs
		Link to the FDA's draft FHIR Implementation Guide	https://build.fhir.org/ig/HL7/fhir-spl/branches/main/index.html

Note on harmonization: For many years, the life sciences industry has grappled with diverse regulatory requirements across countries and regions. Regulatory bodies, however, have made commendable progress in addressing this challenge. The European Union (EU) has been a key driver of European harmonization, while the U.S. Food and Drug Administration (FDA) has led by example, with its standards widely accepted beyond US borders. Within the framework of the World Health Organization, the African Medicines Regulatory Harmonization Initiative (AMRHI) is advancing technical, legislative, and procedural coordination. Since 1990, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) has been proactively addressing technical standards. Today, digital technologies are playing a pivotal role in continued regulatory harmonization, with improved interoperability enabling better communication and data exchange across jurisdictions.

While provision has been made in most regulatory jurisdictions for e-labeling, regulations vary considerably. Japan and Singapore have advanced well-down the road of e-labeling. All regulatory authorities listed above promote e-labeling.

Appendix II

Page	Explanation	Full Link
2	European Medicines Agency glossary	https://www.ema.europa.eu/en/glossary-terms/product-information
2	FDA Patient Medication Information	https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-medication-information-pmi
2	FDA overview of patient labeling resources	https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resource
4	EMA SPOR initiative and Product Management Services	https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services
4	EMA Electronic Product Information (ePI)	https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi
4	Australian Digital Health Agency	https://developer.digitalhealth.gov.au/resources/services/my-health-record/my-health-record-fhir-gateway
5	HSA guidance on e-labeling in Singapore	https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/tpb-gn-021-000_appendix-7a-guidance-on-electronic-labeling-for-therapeutic-products.pdf?sfvrsn=1f3ad3d0_5
5	US Prescription Information Modernization Act in the US. Current status.	https://www.congress.gov/bill/118th-congress/house-bill/1503/text
8	ePI in the EU. Key principles document	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
13	The Parliament Magazine on e-labeling in industry (general)	https://www.theparliamentmagazine.eu/partner/article/why-electronic-labelling-could-be-good-news-for-consumers-and-the-planet

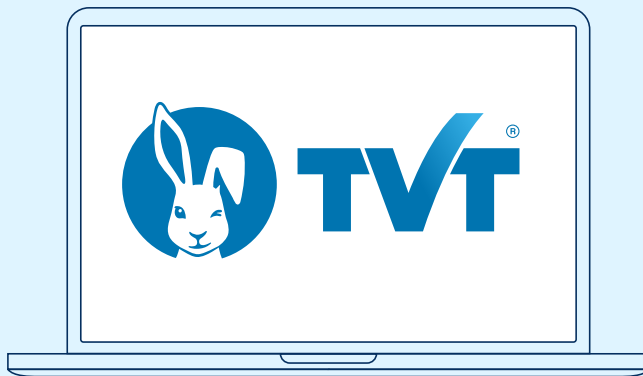


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