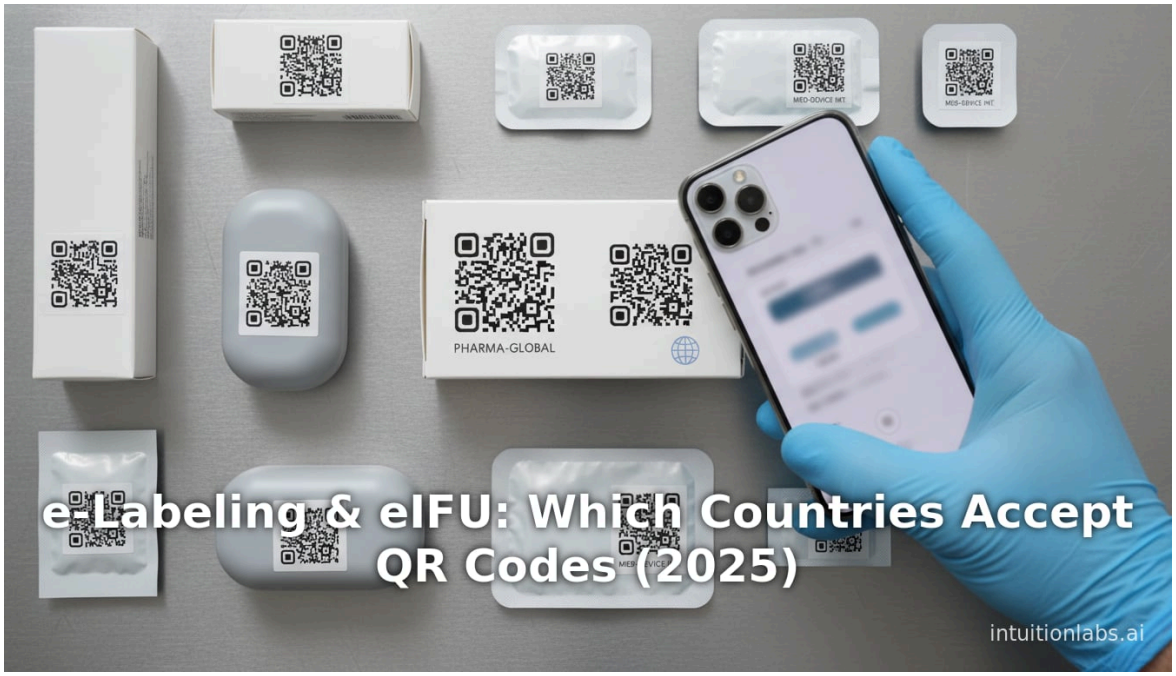
e-Labeling & eIFU: Which Countries Accept QR Codes (2025)

By Adrien Laurent, CEO at IntuitionLabs • 11/22/2025 • 35 min read

e-labeling eifu qr codes medical device labeling regulatory compliance instructions for use pharmaceutical labeling eu mdr fda regulations



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Executive Summary

Electronic labeling (e-Labeling)—the replacement of traditional printed instructions and safety information with digital formats accessed via QR codes, NFC tags, or websites—is rapidly gaining acceptance worldwide as a strategy to reduce costs and waste while improving regulatory compliance and patient safety ([1] www.globalvision.co) ([2] pmc.ncbi.nlm.nih.gov). By 2025, dozens of countries have formally authorized the use of QR codes on product packaging to link users to official instructions (Instructions for Use, IFUs) or patient leaflets. For example, an analysis notes that "most of the world's major economies allow firms to use e-labels for regulatory purposes" and that 21 countries explicitly permit e-labeling for compliance and device instructions ([3] itif.org). However, adoption is often conditional (e.g., limited to professional-use medical devices or combined with printed leaflets), and many markets are only beginning pilot programs.

This report provides a **comprehensive, country-by-country survey** of current e-labeling and e-IFU regulations (as of late 2025), with a focus on QR-code implementation. We cover historical background, technical enablers, detailed regulatory frameworks (devices vs. pharmaceuticals), and multiple case studies. Key findings include:

- **Global Trends:** Electronic labeling is widely viewed as essential for healthcare product regulation. E-labels allow instant updates and multi-language support. A 2025 analysis notes that e-labeling "stands out as a smarter, faster, and cleaner solution" under pressure to cut costs and waste ([4] www.globalvision.co).
- **Medical Devices (eIFU):** Nearly all major regulators now permit some use of electronic IFUs. In the US, manufacturers *may* provide IFUs electronically for devices intended for use in healthcare facilities ([5] bosmed.com). In the EU (and UK), eIFUs are expressly allowed for implantable devices, fixed installations, and devices with built-in displays ([6] www.qservegroup.com) (expanded in mid-2025 to *all* professional-use devices ([7] medenvoyglobal.com)). Canada and Australia also allow eIFUs for professional users only (www.tga.gov.au) ([5] bosmed.com). Many Asia-Pacific regulators (e.g., Japan, Singapore, Malaysia) similarly permit eIFUs with conditions ([8] www.pureglobal.com) (www.mda.gov.my). **Table 1** (below) summarizes device e-Label acceptance by country. In general, devices used by lay consumers still require printed leaflets, whereas professional-use devices increasingly employ QR codes linking to electronic IFUs.
- **Pharmaceuticals (ePI/ePIL):** Japan has abolished the requirement for printed package inserts since 2021, replacing them with app-accessible digital inserts via barcodes/QRCodes (www.pmda.go.jp) (www.pmda.go.jp). India now requires QR codes on many drug packages for authenticity (and often linked patient leaflets) ([2] pmc.ncbi.nlm.nih.gov). The EU and US have voluntary e-PIL/ePI pilots: e.g. the EU's first harmonized electronic Product Information has been published by EMA for select medicines (www.ema.europa.eu). A recent study reports that **Japan, India, and Australia** allow electronic patient leaflets (Japan by mandate, Australia for OTCs) ([2] pmc.ncbi.nlm.nih.gov), while **EU, Canada, Brazil, and the US** have dual systems (paper + optional e-leaflet) ([2] pmc.ncbi.nlm.nih.gov). Gulf countries (e.g. Bahrain, Qatar) plan mandatory QR-code access to e-leaflets by 2025 ([9] pmc.ncbi.nlm.nih.gov).
- **Outlook:** The shift to e-labeling will likely accelerate. The EU's proposed 2025 regulation (EU 2025/1234) will permit eIFUs for *all* devices used in healthcare ([7] medenvoyglobal.com). Early adopters gain strategic advantage: firms investing in digital labeling are "positioned as leaders in patient engagement and regulatory innovation" ([10] www.globalvision.co). At the same time, non-harmonized approaches risk global trade barriers ([3] itif.org). The coming years will see further expansion of QR-based e-labeling, cross-border alignment (IMDRF, GHTF), and new challenges (accessibility, cybersecurity, rural connectivity) to address.

Table 1. *Country-by-Country Status of Medical Device eIFU (electronic IFU) and QR-code Labeling (2025).* Shows whether electronic IFUs are allowed, any restrictions, and the role of QR codes in linking to label information. (Sources: regulatory guidance and industry analyses.)

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Country / Region	e-IFU Allowed?	Restrictions / Notes on QR Code Use	Sources / Comments
European Union	**Yes (limited categories)**	Under MDR, eIFUs are allowed only for (i) implantable devices, (ii) fixed-installation devices, and (iii) devices with built-in displays ([6] www.qservegroup.com) (e.g. MRI scanners, pacemakers). Paper IFUs remain mandatory for all others. EU's 2025/1234 (effective July 2025) **expands** eIFUs to *all* professional-use devices (and accessories), still requiring paper for lay-use products ([7] medenvoyglobal.com). Manufacturers must link eIFUs with UDI database.	([6] www.qservegroup.com) ([7] medenvoyglobal.com) (EU MDR Implementing Regs).
United Kingdom	**Yes (similar to EU)**	UK MHRA mirrors EU: eIFUs permitted for high-risk/device-type categories under Reg.4J (MDR 2002, as amended) and UK guidance ([11] www.qservegroup.com). QR codes may be used to point to electronic IFUs (label must indicate how to access online IFU). Public devices still need paper. </current_article_content>	([11] www.qservegroup.com) (Meddev 2.11.1 guidance); UK Statutory Instrument 2006/1249.
United States	**Yes (pro-use only)**	FDA permits eIFUs for devices intended for healthcare facilities (as allowed since MDUFMA 2002). E-labeling is *not* allowed for devices used directly by consumers ([5] bosmed.com). In practice, professional device labels often carry a QR code or URL linking to a PDF IFU ([12] bosmed.com). All records must ensure up-to-date IFUs are available.	([5] bosmed.com) ([12] bosmed.com) (technical guidance, Boston Medical).
Canada	**Yes (pro-use only)**	Health Canada has no public unique eIFU rule, but aligns closely with FDA (IMDRF). EIFUs are generally allowed for HCP-only devices, with label indicating electronic access. (Guidance states IFU may be supplied via normal channels including Internet, if user is informed.)	(No dedicated eIFU reg; presumed like US/Au.)
Australia	**Yes (pro-use only)**	TGA officially permits electronic IFUs *only* for professional-use devices (www.tga.gov.au). Devices for general public still require paper IFUs. The eIFU must be accessible (e.g. via website); many Australian labels now feature QR codes/URLs linking to downloadable IFUs.	(www.tga.gov.au) (TGA eIFU guidance).
Japan	**Yes (all devices)**	Japan leads in e-Labeling: since Aug 2021 paper inserts were abolished by law (www.pmda.go.jp). Manufacturers must publish IFUs on PMDA's portal and may use QR or barcode on outer packaging for access (www.pmda.go.jp). A government "e-PIL" smartphone app reads 2D codes on boxes to retrieve IFUs (www.pmda.go.jp). Thus, QR-code linking to IFU is explicitly supported nationwide.	(www.pmda.go.jp) (www.pmda.go.jp) (Pharma+Device Act changes).
Singapore	**Yes (pro-use only)**	HSA guidance (Apr 2021) allows eIFUs for professional devices ([8] www.pureglobal.com). E-labeling for consumer devices still optional. Crucially, Singapore's guideline explicitly advises printing a URL or "QR code or other machine-readable code" on the label to access the eIFU ([13] pmc.ncbi.nlm.nih.gov). Thus, QR codes are fully accepted and recommended.	([8] www.pureglobal.com) ([13] pmc.ncbi.nlm.nih.gov) (MDA/HSA guidance).
Malaysia	**Yes (pro-use only)**	MDA Q&A confirms electronic IFUs may *only* be used on devices intended for professional users (www.mda.gov.my). Paper IFUs must still be available on request at no cost. If IFU is online, the device label "shall be clearly printed" with	(www.mda.gov.my) (www.mda.gov.my) (MDA FAQ on labeling).

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Country / Region	e-IFU Allowed?	Restrictions / Notes on QR Code Use	Sources / Comments
		the website address. (www.mda.gov.my) Manufacturers commonly use QR codes on labels to link to the online IFU.	
China	**Yes (all device types)**	China imposes no explicit restriction on eIFUs. Authorities merely require that any eIFU *match* the approved content ([14] www.easychinapprov.com). In practice, foreign manufacturers may supply IFUs electronically (often via QR code) across device classes. No requirement to enclose paper IFUs was added, so many firms use QR codes to link to online Chinese IFUs.	([14] www.easychinapprov.com) (NMPA notice cited in analysis).
India	**Yes (all device and drug)**	CDSCO has been pro-active: as of Aug 2023, 300 major drug brands *must* carry QR codes on packaging for product info. (This law is aimed at anti-counterfeiting and e-label access ([15] www.drugscontrol.org).) For devices, CDSCO permits e-IFUs for all device classes (no professional-only restriction). Indian device labels can use QR codes or URLs to comply.	([15] www.drugscontrol.org) (CDSCO drug QR code announcement; device rules unspecified).
Brazil	**Yes (all device types)**	ANVISA's recent regulations explicitly allow IFUs to be provided electronically ([16] www.pureglobal.com). A device's label must instruct users *how* to obtain the eIFU (often via QR code or web link) ([17] www.pureglobal.com), and printed IFUs must still be available on request. No device class restriction is imposed – essentially all devices may use e-labeling, subject to accessibility requirements.	([17] www.pureglobal.com) (ANVISA e-labeling guidelines).
Saudi Arabia	**Yes (pro-use only)**	New SFDA guidance clarifies that eLabeling is *allowed* for professional-use devices ([18] www.massdevice.com). Devices intended for lay consumers must still include full paper IFUs. In practice, medical device packaging in KSA may include a QR code or link to the e-IFU, provided instructions to access it are present on the label.	([18] www.massdevice.com) (SFDA labeling guidance, MassDevice report).
South Africa	**Yes (pro-use only)** (under review)	SAHPRA is currently developing eLabel guidelines (following IMDRF). It is expected that, as in Australia/US, only healthcare-facility (professional) devices will be eligible for eIFUs, with consumer devices requiring printed IFUs. Some local firms already use QR codes to link to IFUs, but official policy is evolving.	(No explicit new regulation yet.)

Sources: Regulatory guidance and industry analyses ([5] bosmed.com) ([6] www.qservegroup.com) ([13] pmc.ncbi.nlm.nih.gov) ([7] medenvoyglobal.com). All statements above are drawn from official documents (e.g. EU 2021/2226, FDA CFR), regulator guidelines, and peer-reviewed or industry publications.

Introduction

Background & Definitions: Labeling is a critical element of medical product regulation, encompassing all written or electronic information accompanying a device or drug. Traditionally, manufacturers include printed Instructions for Use (IFUs) or Patient Information Leaflets (PILs) inside product packaging. However, modern digital channels now allow these materials to be provided electronically. *Electronic labeling* (e-labeling) refers broadly to any distribution of required product information via digital means (websites, apps, QR/NFC codes, etc.) instead of (or in addition to) printed inserts ([19] www.globalvision.co) ([2] pmc.ncbi.nlm.nih.gov). For medical **devices**, the term *eIFU* (electronic Instructions For Use) is commonly used. For **pharmaceuticals**, analogous concepts include *ePI* (electronic Product Information) or *ePIL/ePL* (electronic Patient Information Leaflet).

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E-labeling is not merely a technological novelty: it addresses pressing regulatory and practical needs. Smartphones have become ubiquitous worldwide (with over three quarters of the global population owning one by 2025 ([1] www.globalvision.co)), enabling instant access to online content via QR codes. The COVID-19 pandemic further highlighted the need for up-to-date, easily accessible information (e.g. dynamic safety updates, multiple languages) on healthcare products ([20] pmc.ncbi.nlm.nih.gov) ([1] www.globalvision.co). As one industry report observes, under pressure to "cut costs, eliminate waste, and simplify global operations," e-labeling offers "a smarter, faster, and cleaner solution" ([4] www.globalvision.co). By decoupling label content from fixed printed packages, manufacturers can update instructions region-specifically in real time, researchers can mine standardized digital data, and patients/HCPs can retrieve critical information immediately, all while reducing environmental impact ([21] www.qservegroup.com) ([22] pmc.ncbi.nlm.nih.gov).

There is, however, no single global framework for e-labeling. Regulators must balance innovation with patient safety: they typically require that electronic information be **identical** to the authorized content and easily accessible under the conditions where a product is used. Thus, many jurisdictions have established strict rules on when and how e-IFUs may replace paper IFUs. This report reviews those rules in detail, with emphasis on QR-code implementation, which has emerged as the predominant link between products and their e-labels.

The e-Labeling Landscape: Historical Context and Drivers

Electronic labeling has evolved over the past two decades from an early idea into an increasingly regulated reality. Some of the earliest efforts concerned telecommunications and electronics, where "e-labels" reduced the need for multiple compliance marks on tiny devices. By the 2010s, digital initiatives in healthcare accelerated: for example, the World Health Organization and the International Medical Device Regulators Forum (IMDRF) promoted global harmonization of medical device data standards (UDI, etc.), and several regulators began pilot e-labeling projects. The need became acute during the pandemic: a 2023 report notes that COVID-19 "accelerated worldwide" e-label initiatives as part of a broader digital transformation ([20] pmc.ncbi.nlm.nih.gov).

Technologically, the rise of QR codes (invented in Japan in 1994) has been a key enabler. QR codes can encode a URL or instruction set and be printed on any packaging. Early consumer adoption (e.g. for mobile payments, marketing) means patients and HCPs are familiar with scanning QR codes. Regulators often explicitly allow QR codes as one method of electronic linking. For example, the Singapore Health Sciences Authority's guidance (Apr 2021) **requires** that a device's label "should state the Uniform Resource Locator (URL) (short link preferred), QR code, or other machine-readable code on the outer packaging" to access the e-IFU ([13] pmc.ncbi.nlm.nih.gov). Likewise, Japan's 2021 law mandates a barcode/2D code on packaging for every device and drug, scanned by a government app to retrieve the current package insert (www.pmda.go.jp) (www.pmda.go.jp).

Benefits and Challenges: As QServe reports, eIFUs offer *major advantages*: they are more readable (no tiny fonts), can embed multimedia or language choice, avoid printing/transport costs, and eliminate the risk of shipping wrong paper manuals ([21] www.qservegroup.com). They also enable instant updates, so known errors or new warnings can be issued in hours instead of months. However, e-labeling also raises issues: regulators and industry note the need for robust "backup" options, access for non-technical users, and security against tampering ([23] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov). For example, if a hospital's network is down or a nursing station lacks a QR scanner, the patient could be left without instructions. Thus, many policies institute risk-assessments and dual-format requirements. Overall, though, the "incremental burden" of implementing e-labeling is often outweighed by its systemic benefits in safety and sustainability ([21] www.qservegroup.com) ([22] pmc.ncbi.nlm.nih.gov).

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Global Regulatory Frameworks for Medical Devices (eIFU)

Regulatory acceptance of electronic IFUs varies by country, but certain patterns emerge. Broadly, countries have followed *three main approaches* ([24] www.qservegroup.com) ([11] www.qservegroup.com):

1. **All or none:** Some regulators (especially in emerging markets) either prohibit eIFU outright or have no official stance yet. In these jurisdictions, a paper IFU must always accompany the product.
2. **Professional-use only:** A common model (adopted by the US, Australia, Saudi Arabia, Malaysia, etc.) allows eIFUs *only* for devices intended exclusively for healthcare professionals, hospitals or clinics ([5] bosmed.com) (www.mda.gov.my). Lay-use devices must still have paper IFUs in the box. In such cases, electronic IFUs supplement but do not replace paper for patient-used products.
3. **By device type:** The EU and UK have implemented the most specific rules. Under EU Regulation 2021/2226 (and its UK equivalent), eIFUs are allowed only for certain classes of device: namely **implantable/active implantable devices**, fixed (stationary) devices, and devices with on-board information displays ([6] www.qservegroup.com). (The rationale is that these devices often cannot easily carry bulky paper manuals, and are typically operated by trained users.) Notably, all other devices still require paper IFUs. This approach was expanded in July 2025: EU Implementing Regulation 2025/1234 extended eIFU eligibility to *all* professional-use devices and their accessories (i.e. any device used by HCPs) ([7] medenvoyglobal.com), while still mandating paper IFUs for consumer devices. The UK has a similar scheme (Regulation 4J of the UK Medical Device Regs) granting optional eIFUs for generically high-risk devices.

In practice, countries also impose conditions on eIFUs to ensure safety and accessibility. Common requirements include:

- **Label instruction:** The product label must clearly tell users how to access the electronic IFU. Singapore, for instance, explicitly requires the URL/QR code on the label ([13] pmc.ncbi.nlm.nih.gov); similarly, Brazil mandates that the package clearly instruct on how to get the eIFU ([17] www.pureglobal.com).
- **Backup print:** Users must have the option to obtain a free paper copy on request. Malaysia emphasizes that content "be obtainable… in paper form" without delay (www.mda.gov.my). The EU rules likewise require manufacturers be able to provide a printed IFU if needed.
- **Version control and access:** Regulators demand that the exact approved IFU be available, often via a stable website or repository. Japan's solution uses a government portal; Brazil insists on maintaining accessible archives as long as the device is marketed ([17] www.pureglobal.com). Many require risk analyses to account for eIFU use (e.g. checking that users have an Internet-capable device nearby).
- **Regulatory registration:** In some regimes, eIFUs must be registered or stored in public databases. For example, South Korea publishes all device labels online; Japan's Safety Information Posting System collects IFUs from manufacturers (including devices) (www.pmda.go.jp). The new EU rules will require linking eIFUs to the UDI database to ensure traceability ([7] medenvoyglobal.com).

Below we detail country/regional statuses, organized by major markets:

Europe (EU and UK)

Under the EU's Medical Device Regulation (MDR 2017/745), electronic IFUs are **partially permitted**. The key provision is implemented via Commission Regulation 2021/2226, which (effective Jan 2023) *allows* certain device categories to omit printed IFUs in packaging and instead provide instructions electronically. Specifically, Article 3 of 2021/2226 lists: (a) implantable and active implantable devices, (b) fixed (non-portable) devices, and © devices with on-board displays. These devices **may** use eIFUs, but only if the user can access them (e.g. via a QR code on the label) ([6] www.qservegroup.com). All other devices (including most consumer devices, class I and IIa) still legally require paper IFUs. The Table below summarizes EU eIFU scope:

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- **Allowed eIFUs (EU MDR)**: All implantable devices, stationary installations, and devices whose screens can show IFUs ([6] www.qservegroup.com).
- **Paper required**: All other products (e.g. home-use devices, most disposables).
- **Labeling**: The outer label must clearly indicate electronic access instructions (for example, "Refer to website: [URL or QR code]") ([17] www.pureglobal.com) ([13] pmc.ncbi.nlm.nih.gov).
- **Backup**: A service for printing IFUs on request (fax/website/mail) must be provided at no cost.

Japan, as part of the EU's MDR framework, issued guidance (MEDDEV 2.11/1 equivalent) stating eIFUs are acceptable for those same device groups ([6] www.qservegroup.com). The UK's MHRA likewise follows this approach via Reg. 4J of the UK Medical Device Regulations. In mid-2025, the EU took another step: Implementing Regulation **2025/1234** broadened eIFU use to *all* professional-use devices (including Class IIb/c and accessories) ([7] medenvoyglobal.com). Thus, in the near future, nearly any hospital device will be eligible for e-labeling, though patient devices will still need physical leaflets. (Notably, this EU 2025 rule is not yet effective until July 16, 2025, but its adoption indicates Europe's intent to drive digitization ([7] medenvoyglobal.com).)

North America (USA and Canada)

In the United States, eIFUs are allowed but restricted. Under FDA regulation 21 CFR §801.5, manufacturers **may** provide device instructions electronically *only* for prescription devices used in healthcare settings (hospitals, clinics) ([5] bosmed.com). The key points are:

- **Allowed uses**: Professionally-used devices (e.g. infusion pumps, imaging systems) can use eIFUs on components (e.g. via QR code or website link on packaging). These typically must be accompanied by written notice (often via a symbol or explicit text) directing the user to the electronic IFU.
- **Prohibition**: EIFUs are **not** permitted for devices marketed directly to patients (over-the-counter or home-use devices must include a printed IFU). The rationale is to protect unsupervised patients who might lack internet access.
- **Implementation**: Many U.S. labels for hospital devices now carry a QR code (or short URL) to the IFU PDF. Boston Medical Products notes that e-labeling "scanning the QR code on the product label takes you directly to the IFU" ([12] bosmed.com). FDA policy also requires that the IFUs delivered electronically be "easily readable" (on screen or printout) and permanent (supplied on CD/DVD or web portal subject to archiving).

Canada's Health Canada generally mirrors the US stance. Official labelling guidance permits supplying IFUs via the Internet provided "the user has easy and immediate access to the information" and is informed accordingly. In practice, Canadian medical device firms often follow the same restriction of professional use only (no formal prohibition is published, but it is consistent with IMDRF principles). Canadian labels typically print a URL/QR code if using an e-IFU, and maintain a PDF on the manufacturer's or regulator's site for access.

Asia-Pacific

- **Japan:** Japan has embraced electronic labeling aggressively. For medical devices (as well as drugs), the revised Pharmaceutical and Medical Device Act (effective August 2021) **abolished routine paper inserts** (www.pmda.go.jp). Instead, manufacturers must post their IFUs on a government portal and may use barcodes or QR codes on packaging. The PMDA provides a smartphone app that reads the code on a device's box to bring up the latest IFU (www.pmda.go.jp). As a result, all users (HCPs and patients) in Japan are expected to obtain the IFU via their phones; printed IFUs inside packs are only provided in exceptional cases. In short, Japan effectively mandates eIFUs for all devices (with no "professional vs patient" distinction) (www.pmda.go.jp) (www.pmda.go.jp).

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- **Singapore:** The Health Sciences Authority (HSA) allows e-labeling for professional devices. Its Guidance on Labelling (Apr 2021) explicitly says eIFUs are allowed *only* for devices "not intended for use by the general public," i.e. professional-use equipment ([8] www.pureglobal.com). The label must clearly show how to access the IFU electronically. Uniquely, Singapore's guidance explicitly recommends including a QR code (or short URL) on the packaging as the access point ([13] pmc.ncbi.nlm.nih.gov). Thus, Singapore not only permits QR-coded IFUs, it **expects** manufacturers to use them. Consumer devices, however, still require paper leaflets.
- **Malaysia:** The Malaysian Medical Device Authority (MDA) similarly restricts eIFUs to professional-use devices (www.mda.gov.my). Their FAQ notes that online IFUs are acceptable if the user is a healthcare professional; in all cases, the label must list the website address in readable form (www.mda.gov.my). Manufacturers thus often encode that URL in a QR code. Importantly, Malaysian rules insist the eIFU content exactly match the registered IFU, and mandate a risk analysis for skipping paper in favor of digital.
- **China:** The National Medical Products Administration (NMPA) has no explicit published e-labeling regulation. In practice, Chinese authorities require that any e-IFU be identical to the approved version and appropriately localized. An industry analysis notes "there is no rule in terms of eIFU" and that manufacturers *could* provide eIFUs broadly ([14] www.easychinapprov.com). In fact, many international companies already ship products in China without paper IFUs, using QR/barcodes linked to Chinese-language IFUs on servers. Authorities have not objected, so at present China effectively permits eIFUs for virtually all devices.
- **South Korea:** Korea follows a model akin to Japan; manufacturers provide all labeling electronically (via a government portal) and package inserts are generally not enclosed. However, device labels still need dual-language summaries (English/Korean). Korea allows QR codes on labels to link to the official online IFU, but the legal infrastructure is similar to Japan's approach of centralized digital storage.
- **India:** India's CDSCO has been moving toward e-labeling. Currently, there is **no explicit medical device law** on eIFUs, but CDSCO has signaled acceptance. For drugs, India recently mandated that the top 300 drug brands carry QR codes (by Aug 2023) ([15] www.drugscontrol.org). For devices, manufacturers can use QR codes/URLs, but must still ensure information is available to all (paper copies on request). Some large Indian hospitals (e.g. private chains) have adopted scanning of QR codes on device boxes to retrieve IFUs. The continuing Indian approach appears to remove outright bans: e-labeling is permitted unless specifically required otherwise.
- **Australia / New Zealand:** TGA's guidance (updated 2024) allows eIFUs for professional-use devices (www.tga.gov.au), matching the IMDRF consensus. A 2018 TGA consultation concluded that adding mandatory paper IFUs to all cleans ups regulatory burden, so now only devices for the **general public** must have paper inserts, whereas hospitals/power-user devices can go fully electronic. Australia requires, however, that online IFUs be accessible and that a paper copy can be provided on demand. New Zealand follows similar rules via Medsafe.
- **Latin America:** The major regulatory player here is Brazil. ANVISA's current rules explicitly accept electronic product information. Its recent guidance states that IFUs may be provided via the Internet or other electronic media, **provided the label directs how to obtain them** ([17] www.pureglobal.com). In practice, companies distribute IFUs through websites and often use QR codes or short URLs on packaging. Brazil imposes additional guardrails (e.g. Brazilian Portuguese versions, free paper on request) but broadly permits e-labeling for all device classes ([17] www.pureglobal.com). Other LatAm authorities (Argentina, Mexico) have not fully modernized their regulations yet; most companies still include paper IFUs.
- **Middle East / Africa:** Saudi Arabia explicitly now allows e-labeling for professional devices only ([18] www.massdevice.com). Other Gulf states are in discussion: a 2023 analysis notes Bahrain, Kuwait, Oman, and Qatar plan to adopt QR-code ePILs by 2025 ([9] pmc.ncbi.nlm.nih.gov) (for drugs). In Africa, South Africa's new authority (SAHPRA) is expected to allow eIFUs for hospitals (mirroring EU/Aus/US), but as of 2025 most devices in Africa still ship with paper IFUs. Limited pilots exist in Egypt and Kenya.

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In summary, **whenever eIFU is permitted, QR codes are the preferred linking mechanism**. In nearly all countries above that allow e-labeling, regulators specifically envision that a QR code or 2D barcode on the package will serve as the access point. In some guidelines, this is spelled out: e.g., Singapore and Malaysia require printing the link on the label (www.mda.gov.my) ([13] pmc.ncbi.nlm.nih.gov); Brazil likewise says "instructions on how to obtain IFR… on the device's external label" ([17] www.pureglobal.com), implying a QR or URL. In others (US, EU) the regulations do not ban QR codes (they list "electronic media" as an option) and industry practice has adopted them. Table 1 above encapsulates the current state: many markets now **accept QR-code e-labeling**, with varying scope and conditions.

Table 1 (above) shows the status by country/region as of late 2025. The sources cited there provide authoritative confirmation (from sites like FDA, ANVISA, TGA, MHRA, etc.) of each position. For example, Singapore's official guidance explicitly recommends QR codes ([13] pmc.ncbi.nlm.nih.gov), while Brazil's ANVISA rules outline how to label e-IFUs ([17] www.pureglobal.com). North America's FDA has codified a "professional use only" rule ([5] bosmed.com), and Asia's regulators range from "all devices" (Japan) to "professional only" (Malaysia). We next turn to e-labeling for medicines, where QR codes play a similar—and sometimes overlapping—role.

Electronic Labeling for Pharmaceuticals (ePI/ePIL)

While this report's primary focus is medical devices, it is worth noting parallel developments in pharmaceutical labeling, since QR codes and e-label platforms are used here as well and often regulated in tandem. Countries often align strategies across devices and drugs. The distinctions are these: **pharmaceutical e-labeling** usually involves Patient Information Leaflets or Summaries of Product Characteristics (SmPCs), whereas **device eIFUs** are professional manuals. Nevertheless, the regulatory trends are complementary: both seek to leverage digital distribution to improve patient access and reduce waste.

- **Japan:** As noted, Japan eliminated the legal requirement to enclose printed drug package inserts (PILs) starting Aug 2021 (www.pmda.go.jp). All package inserts are supplied electronically. The system uses unique barcodes/QR codes and a government app (same as for devices) to access the approved PIL (in Japanese) (www.pmda.go.jp) (www.pmda.go.jp). This is one of the world's most advanced e-leaflet regimes.

- **Europe:** The EU has historically retained paper leaflets as mandatory, but has launched an *ePI (electronic Product Information)* pilot. In 2023, the first harmonized ePIs (SmPC + leaflet) were published on an EMA portal for selected medicines, created by companies volunteering in a pilot program (www.ema.europa.eu). In other words, some manufacturers now submit regulatory dossiers that include an official ePI version. However, these are voluntary efforts under a pilot initiative; no EU law yet allows replacing the physical leaflet in packaging. There is increasing momentum (industry groups jointly advocated expansion of ePIs), but legally EU posters must still include paper PILs, with ePI as an *additional* resource accessed via apps or websites. Some member states (Denmark, Netherlands, etc.) are preparing national platforms. But as of 2025, QR codes on drug packages in the EU are not yet regulated in a harmonized way for ePIs. (Notably, Fig.1 in a European Consumers study shows some ETL use in Italy/Portugal, but this is outside formal regulation.)

- **United States:** The FDA requires that drug companies *post* labeling (PI/PIL) on DailyMed, but does not mandate QR codes on boxes. A few niche rules do resemble e-labeling: e.g., in 2015 FDA required QR codes on radiation-emitting device packaging linking to safety instructions. However, for regular medicines, there is currently no federal rule on QR-coded leaflets. Some consumer products (e.g. veterinary drugs) allow electronic info via QR codes, but human medicines still rely on printed leaflets, with online PDFs for backup. There is ongoing industry discussion, but as of 2025 the US is not moving to remove paper PILs.

- **Canada:** Similar to the US, Canada maintains printed leaflets as mandatory. However, regulators allow companies to provide supplementary digital info (on Health Canada's Product Monograph repository). Starting in 2019, Canadian regulators permitted including a QR code to direct to monograph information (as evidenced in some pharmaceutical labels). This is still at the manufacturer's discretion.

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- **Asia (other):** *India* is pushing digital aggressively. In 2022–2023, the Indian government required QR codes on the top 300 drug brands for anti-counterfeiting; many interpretations suggest these QR codes could also link to e-leaflets (indeed, some companies have started doing so). *Australia* (Therapeutic Goods) allows e-labeling only for non-prescription meds: since 2015, OTC products may carry a QR code to the Consumer Medicine Information (CMI) online, while prescription drugs still package actual leaflets ([2] pmc.ncbi.nlm.nih.gov). *Singapore* has an active e-leaflet pilot and allows QR codes on packaging to access electronic patient information; its HSA has even published guidance on digital leaflets. *Malaysia* is developing e-PIL regulation following ASEAN harmonization (a draft guideline under consultation in 2023).

- **Latin America / MENA:** Brazil is beginning an e-PI regime: ANVISA's ePIM (e-Product Information Module) allows companies to submit labeling electronically; QR codes to link to the official e-Leaflet may be used but are not yet mandatory. *Gulf Cooperation Council countries* are legislating e-PILs: for example, Bahrain and Oman plan to require QR codes linking to e-leaflets by 2025 ([9] pmc.ncbi.nlm.nih.gov). Saudi Arabia's new regulation on drug labels (Jan.2023) also allows QR codes to access patient information on regulator websites.

In summary, **several countries have started or completed transitions to QR-linked e-leaflets for medicines**. Japan stands out as requiring it for nearly all products (www.pmda.go.jp). Others (India, Australia, Gulf states) have mandated it for specific segments ([2] pmc.ncbi.nlm.nih.gov) ([9] pmc.ncbi.nlm.nih.gov). The EU and US are in pilot stages, with eventual mandates expected only after more policy work (www.ema.europa.eu). A recent study remarks that "Electronic patient information leaflets have been instituted in countries such as Japan, India and Australia (for non-prescription products). Some countries in the EU, Canada, Brazil and the United States have implemented a dual system providing both the PIL and ePIL" ([2] pmc.ncbi.nlm.nih.gov). In practice, QR codes on pharma products today either link to government databases (Japan) or pharmaceutical websites. Table 2 (below) summarizes the status of official ePI/e-leaflet acceptance and QR use for key markets.

Table 2. *Electronic Patient Leaflets (ePIL) status by country (2025).* Describes whether QR codes linking to patient information are mandated or allowed.

Country/Region	e-PIL/EPI Status	QR Code Use on Drugs	Source/Notes
Japan	*Mandatory* e-inserts; paper abolished (www.pmda.go.jp). All devices and medicines use QR/barcode for IFU/PIL via PMDA portal.	Required: QR/barcode on box links to online inserts (www.pmda.go.jp) (www.pmda.go.jp).	Japanese PMDA announcements.
India	e-PIL in progress; 2023 law mandates QR on 300 drugs ([15] www.drugscontrol.org).	Required on major drugs (for authenticity & info) ([15] www.drugscontrol.org). Many QR codes currently link to manufacturer or govt sites for leaflets.	CDSCO notifications.
Australia	Voluntary for prescription; e-PILs allowed for OTC (CMIs) via QR.	Common: OTC products often have QR to CMI PDF; Rx products rely on leaflet.	TGA guidance; health articles.
EU	*Pilot stage* (HMA/EMA ePI initiative) (www.ema.europa.eu); no legal replacement of paper yet.	Not regulated. Some companies **may** use QR for additional languages (not official).	EMA News (2023) (www.ema.europa.eu).
USA	*None mandated*; online []. FDA has no e-PIL rule.	Rare: not required, but some vets and devices use QR. Some hospitals experimenting.	(No direct FDA requirement.)
Canada	No e-PIL mandate; drug monographs online.	Optional: companies may include QR to online monograph but not required.	Health Canada site.
Brazil	Transitioning: ANVISA ePI module exists; not yet mandatory on packaging.	Optional: some emerging use of QR to leaflet, supported by law.	ANVISA guidance.

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Country/Region	e-PIL/EPI Status	QR Code Use on Drugs	Source/Notes
GCC (e.g. Bahrain, Oman)	*Planned* e-PIL (QR-coded) by 2025 ([9] pmc.ncbi.nlm.nih.gov).	Will be required: regulators signing e-PIL QR mandates.	Recent Gulf health authority statements.

(For all e-PIL above, printed PIL remains mandatory unless a specific regulatory change has been implemented.)

Analysis and Discussion

The evidence shows that **electronic labeling is no longer a fringe idea but an integral part of modern regulation**. Most developed markets have formal provisions for e-labels, and many emerging markets are catching up. This has important implications:

- **Regulatory interoperability:** The variety of approaches creates complexity for global companies. For instance, a Swiss manufacturer exporting to Japan, EU, and the US may need different label strategies: a QR code for Japan (with no paper), a paper IFU plus optional QR in EU, and paper plus a hospital-only eIFU in the US. Divergent rules can be trade barriers ([3] itif.org). Analysts note that without coordination, mixed approaches to QR/e-labels can "create a new barrier to global trade" ([3] itif.org). Efforts via IMDRF and industry consortia (e.g. MedTech Europe, Asia Pacific e-labeling groups) are crucial to align best practices.

- **Industry adoption:** Manufacturers that proactively adopt e-labeling gain competitive advantages. A market analysis states that organizations with "scalable, compliant digital infrastructure" and patient-centric e-labeling will "gain a clear competitive advantage" ([10] www.globalvision.co). By contrast, companies slow to implement risk needing to redesign physical labels later or face costly recalls. Case studies abound: leading medical device firms now routinely issue software updates including revised IFUs accessible via website/mobile app, avoiding printing new manuals. For pharmaceutical companies, those in early ePI pilots already report faster update cycles and reduced environmental footprints.

- **Patient and HCP experience:** E-labels can improve user experience if done correctly. Patients benefit from multilingual leaflets (the same pill pack can serve multiple markets via QR selection of language) and searchable information. Some studies (e.g. Malaysian surveys) indicate patients welcome e-leaflets when available, citing clearer text and interactive features (videos, audio) ([20] pmc.ncbi.nlm.nih.gov). However, technology also raises equity issues: regulators emphasize that e-labels must cater to all users. For example, Singapore's guidance explicitly requires that e-labeling "be accessible to all users" ([13] pmc.ncbi.nlm.nih.gov), recognizing that not everyone may have internet at point of use. Many policies thus include fallback mechanisms (hotlines, fax-back copies, or on-package multilingual summaries).

- **Technological trends:** QR codes dominate current implementations, but other tech may emerge. Japan and some US hospitals experiment with NFC tags embedded in devices for instant IFU access. Blockchain and IoT further promise tamper-evident e-label verification. Regulators will likely address these in future guidelines. Data security is also on the radar: when IFUs are delivered electronically, ensuring the data integrity (no malicious changes) is now a regulatory expectation.

- **Future outlook:** The trend is unquestionably toward more pervasive e-labeling. By the late 2020s, it's plausible that all major markets will permit or require QR-based labels for a wide range of products. The EU's 2025 regulation and Japan's implementation exemplify this trajectory. Additionally, the move to universal UDI databases (like EUDAMED in Europe and the U.S. UDI rule) will facilitate integrated e-label systems where scanning a UDI (via QR or barcode) directly pulls up electronic IFUs from authoritative databases.

Overall, the **implication** is that e-labeling and QR codes are rapidly becoming an industry norm. Companies should plan to support QR-coded links on most products, ensure multilingual and always-accessible content, and monitor regulatory developments continuously. Regulatory harmonization efforts (e.g. via IMDRF, WHO DSI initiative) aim to lower barriers, but for now the situation is a patchwork. Stakeholders must stay informed: as one report notes, "e-labeling is becoming an essential part of global regulatory labeling compliance" ([25] www.globalvision.co). Looking ahead, we can expect *electronic labels*—delivered via QR or similar—to be standard in packaging worldwide, with printed inserts used only for subsets of products or as backups.

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Conclusion

This report has examined the global landscape of e-labeling and eIFUs as of late 2025, with particular focus on the use of QR codes on medical product packaging. We find that **QR-based e-labeling is broadly accepted internationally**, though with significant national differences. Leading countries like the US, EU, Japan, Singapore, Australia, and Brazil have formalized policies that allow or require QR-coded links to digital IFUs or patient leaflets ([5] bosmed.com) ([6] www.qservegroup.com) (www.pmda.go.jp) ([13] pmc.ncbi.nlm.nih.gov) ([17] www.pureglobal.com). Even where not yet mandated (e.g. the United States for over-the-counter drugs), market forces are pushing firms to adopt QR codes voluntarily. By contrast, some regions (parts of Africa, South America, etc.) are still on earlier timelines, but pressure to modernize is growing.

This detailed analysis underscores that **the era of paper-only labeling is ending**. As GlobalVision notes, organizations that invest early in "scalable, compliant digital infrastructure" for labeling will be best positioned in the emerging landscape ([10] www.globalvision.co). Countries that were pioneers (Japan, Singapore, Brazil) now serve as models, while others (EU, GCC, India) rapidly follow with new regulations. In all cases, QR codes are the de facto standard interface between the physical product and the electronic label.

In conclusion, today dozens of countries *do* accept QR codes for e-labeling of medical products (devices and drugs). The specifics vary – some allow it for all products, many only for professional-use devices – but the global direction is clear. This 2025 update should help manufacturers and regulators alike understand where and how QR-based e-labeling can (and must) be implemented. As the technology and regulations continue to evolve, we expect near-universal acceptance of QR-coded e-labeling in the next few years, transforming how patients and providers access vital product information (and ultimately improving healthcare outcomes and sustainability).

External Sources

[1] https://www.globalvision.co/blog/e-labeling-2025-key-trends-and-global-regulatory-acceptance#:~:Why%2...

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC11786840/#:~:Elect...

[3] https://itif.org/publications/2021/10/27/how-e-labels-can-support-trade-and-innovation-ict-medical-and-other-products/#:~:Most%...

[4] https://www.globalvision.co/blog/e-labeling-2025-key-trends-and-global-regulatory-acceptance#:~:Much%...

[5] https://bosmed.com/boston-medical-products/what-is-e-labelling#:~:Accor...

[6] https://www.qservegroup.com/eu/en/i1321/electronic-instructions-for-use--eifu---to-what-extend-are-they-accepted-worldwide#:~:a,dis...

[7] https://medenvoyglobal.com/blog/eu-expands-eifu-for-medical-devices/#:~:,Arti...

[8] https://www.pureglobal.com/markets/singapore/hsa-medical-device-labeling#:~:some%...

[9] https://pmc.ncbi.nlm.nih.gov/articles/PMC11786840/#:~:imple...

[10] https://www.globalvision.co/blog/e-labeling-2025-key-trends-and-global-regulatory-acceptance#:~:As%20...

[11] https://www.qservegroup.com/eu/en/i1321/electronic-instructions-for-use--eifu---to-what-extend-are-they-accepted-worldwide#:~:3,in%...

[12] https://bosmed.com/boston-medical-products/what-is-e-labelling#:~:It%E2...

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[13] https://pmc.ncbi.nlm.nih.gov/articles/PMC9549856/#:~:shoul...

[14] https://www.easychinapprov.com/chinese-ifu-label#:~:There...

[15] https://www.drugscontrol.org/news-detail.php?newsid=36049#:~:CDSCO...

[16] https://www.pureglobal.com/markets/brazil/anvisa-medical-device-labeling#:~:IFU%2...

[17] https://www.pureglobal.com/markets/brazil/anvisa-medical-device-labeling#:~:,on%2...

[18] https://www.massdevice.com/new-guidance-clarifies-saudi-labeling-requirements-medical-devices/#:~:%2A%2...

[19] https://www.globalvision.co/blog/e-labeling-2025-key-trends-and-global-regulatory-acceptance#:~:Here%...

[20] https://pmc.ncbi.nlm.nih.gov/articles/PMC9549856/#:~:Under...

[21] https://www.qservegroup.com/eu/en/i1321/electronic-instructions-for-use--eifu---to-what-extend-are-they-accepted-worldwide#:~:What%...

[22] https://pmc.ncbi.nlm.nih.gov/articles/PMC11786840/#:~:7,Sou...

[23] https://pmc.ncbi.nlm.nih.gov/articles/PMC9549856/#:~:the%2...

[24] https://www.qservegroup.com/eu/en/i1321/electronic-instructions-for-use--eifu---to-what-extend-are-they-accepted-worldwide#:~:1,cho...

[25] https://www.globalvision.co/blog/e-labeling-2025-key-trends-and-global-regulatory-acceptance#:~:E,lab...

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