ePI for Pharma:

Separating Obligation From Expectation

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Perigord
LIFE SCIENCE SOLUTIONS
A TECH MAHINDRA COMPANY

Contents

1. Executive summary 3
2. Why ePI is confusing 4
2.1. ePI versus ePIL 6
3. EU / EMA: voluntary now, legislation adopted 7
3.1. Track 1: EMA ePI rollout (operational) 7
3.2. Track 2: EU pharmaceutical legislation (legal) 7
3.3. What this means for EU operations 8
4. US / FDA: electronic format mandatory, paper retained 9
5. Rest of the world: a balancing perspective 10
5.1. Points to note 10
6. Standards explained 11
6.1. What this means in practice 11
7. Options available 12
8. Decision matrix 13
9. The case for waiting 14
10. Evaluating providers across the ePI lifecycle 15
11. Recommendations 17
12. ePI readiness checklist 18
12.1. Regulatory 18
12.2. Content and process 18
12.3. Organisation 18
12.4. Technology and compliance 18
13. About Perigord 19
14. Reference list 21

1.

Executive summary

Much of the market confusion about companies' current and future obligations regarding ePI comes from treating pilots, proposals and voluntary roadmaps as mandates. As 2026 draws to a close, none of the EMA, FDA or PMDA requires pharma companies to submit FHIR-based ePI, although the EU has now adopted the legislation that will require electronic product information for new medicines.

In the EU: ePI submission to the EMA is voluntary today. Phased go-live for centrally authorised products (CAPs) is planned to start in Q4 2026 with vaccines, followed by oncology and then all CAPs.[1,2,3] Most provisions of the new EU pharmaceutical legislation will apply 24 months after it enters into force: the end of 2028 at the earliest, and more likely early 2029.[4,5] From that point, the EMA states that ePI will become mandatory for all newly authorised medicines; existing medicines have five years from entry into force.[1,6] Separately, Member States may permit electronic-only leaflets, provided patients can obtain paper on request.[5] The Council adopted its first-reading position on 28 September 2026, and the European Parliament approved it at second reading on 25 November 2026, completing adoption. Once the acts are published in the Official Journal, the 24-month clock will start.[7,8,34]

In the US: Structured Product Labeling (SPL) is already mandatory and is the FDA's electronic label format.[9,10] Paper prescribing information is still required.[11] The Patient Medication Information (PMI) rule is at final-rule stage on the federal regulatory agenda, with a target of December 2026 and a proposed five-year implementation timeline.[12,13] No final rule had been published by November 2026, so the final adoption decision is still pending.

Some regulators have gone further. Japan has required electronic package inserts since 2021, in a national XML format, and Jordan and Canada have adopted structured formats.[14,15,16,17]

The EU format is now stable. The EMA has published version 1.0.0 of its FHIR R5 implementation guide (current release September 2026), and its centralised-procedure guidance (September 2026) sets out how to submit.[18,19] The open decision for 2027 is how label content is produced: as documents converted market-by-market, or as governed components that generate each format. Any product expected to be authorised after the legislation applies will need ePI from first approval, and existing medicines follow within five years of entry into force.[1]

2.

Why ePI is confusing

Most of the confusion about ePI comes from three things being treated as one: regulator roadmaps, legislation that hasn't yet taken effect, and obligations that already apply. Read market-by-market, the picture is narrower than common commentary suggests.

In the EU, ePI is not mandatory. Yet.

The EMA plans to accept voluntary ePI submissions for centrally authorised products from Q4 2026.[19] This is part of a regulatory roadmap and has no binding legal force, so companies can choose when to adopt. The legal deadline is now set in adopted legislation but does not take effect until that legislation applies.

Two separate EU obligations are often confused: the structured ePI format and the removal of paper leaflets. The EMA has stated that once the new pharmaceutical legislation applies, ePI will become mandatory for all newly authorised medicines, an obligation set at EU level.[6] Removing paper leaflets remains a Member State choice. Treating the two as one leads teams to wait on national leaflet decisions, when the format obligation for new products is set centrally.

The new legislation lets Member States allow electronic-only leaflets, but patients must still be able to obtain a paper copy on request, free of charge.[5] Because this is a Directive, the outcome depends on how each Member State transposes it. The likely result is a patchwork of national approaches, not a single EU-wide switch, so packaging and labelling teams should expect to support both formats for some time.

The document format is a separate question from obligation. HL7 FHIR is the EU common standard for ePI, but it is not a global one.[20] The US uses Structured Product Labeling (SPL), and other markets, such as Japan, use national formats. Because each regulator sets its own standard, a company supplying both the EU and the US has to plan for several output formats, not one.

The US has not gone paperless. Statute and regulation still require paper prescribing information. The FDA proposed electronic-only distribution in December 2014, and Congress barred it from finalising the rule through the FY2016 appropriations act, enacted in December 2015.[11,21]

Outside the EU and US, Japan shows that removing paper and adopting FHIR are separate steps: paper inserts for prescription medicines were phased out between 2021 and 2023, using a national XML format rather than FHIR.[14,22]

Secondary commentary adds to the confusion. Material published during 2026 variously describes EU ePI requirements as still developing, as already mandatory, or with go-live dates that differ from the EMA's roadmap; one source places vaccines in Q3 2026 and oncology in Q4 2026.[23] Much of it is EU-centric and rarely addresses US obligations. Where EMA and FDA sources exist, this paper uses their dates.

Common statement	Status in November 2026
“ePI is mandatory in the EU”	Not yet. EMA ePI submission is voluntary for CAPs from Q4 2026. The legislation was adopted on 25 November 2026; EMA states ePI will become mandatory for newly authorised medicines once it applies (end of 2028 at the earliest, more likely early 2029)
“The EU is removing the paper leaflet”	Member States may allow electronic-only leaflets; paper must be available on request
“FHIR is the global ePI standard”	FHIR is the EU common standard. The US uses SPL and other markets, such as Japan, use national formats
“The FDA has gone paperless”	Paper prescribing information is still required; a 2014 proposal to remove it was blocked by Congress in the FY2016 appropriations act (December 2015)

Table 1: Common statements about ePI and their status

Treating voluntary roadmaps as mandates leads teams either to over-invest early in submission mechanics or to delay altogether.

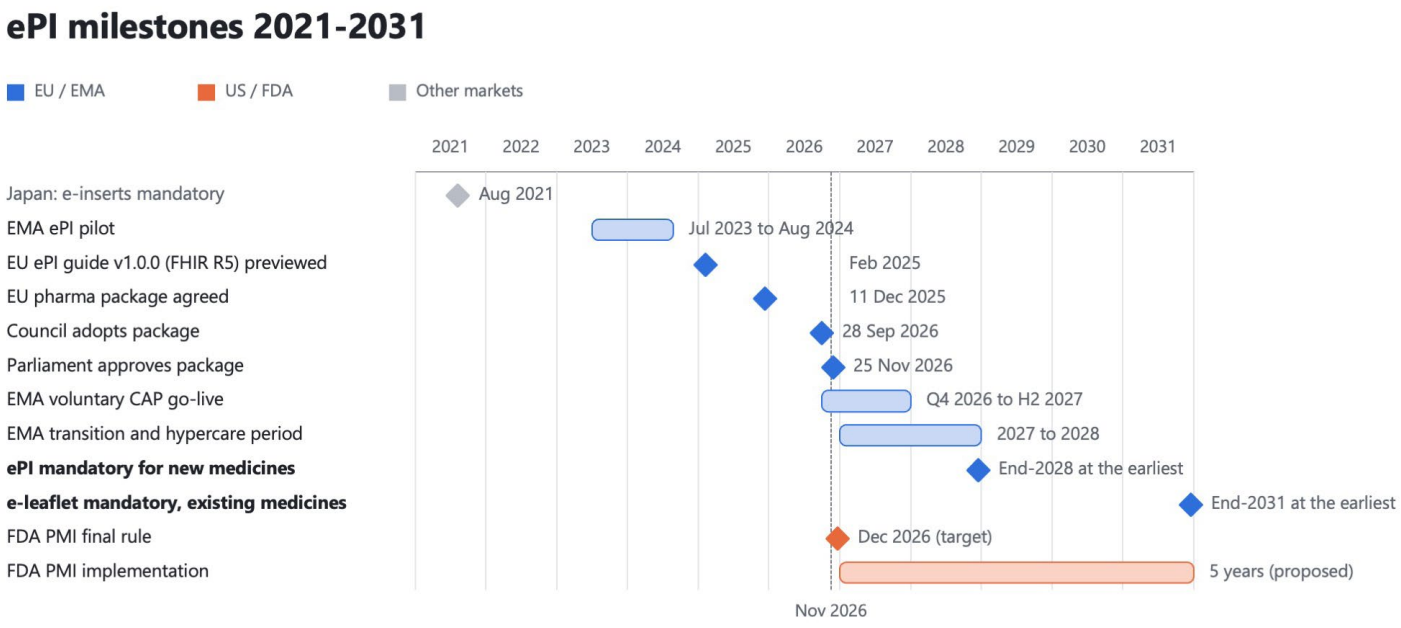


Figure 1: ePI milestones, EU and US, with selected other markets, 2021-2031. Dates after November 2026 are targets or estimates. Sources: EMA ePI roadmap and presentation (21 Oct 2026), EMA Management Board (Mar 2026), Council of the EU, European Parliament press release (25 Nov 2026), US Unified Agenda RIN 0910-AH68, PMDA. Existing-medicines date derived from expected entry into force plus five years.

In the EU, voluntary EMA phases are planned from late 2026, and ePI becomes mandatory for newly authorised medicines once the new legislation, adopted in November 2026, applies: from the end of 2028 at the earliest. In the US, the next binding change is PMI, with implementation running into the early 2030s if the rule is finalised as proposed.[12,13]

2.1. ePI versus ePIL

An ePIL (electronic Patient Information Leaflet) is a digital copy of the approved patient leaflet, usually a PDF or HTML page, and is used mainly in the UK and Ireland. ePI (electronic Product Information) covers the full authorised product information (Summary of Product Characteristics (SmPC), package leaflet and labelling) and holds it as structured data using the EU common standard based on HL7 FHIR.[20] Structured content can be authored once and published to both print artwork and digital channels. This reduces divergence between the pack and the screen, and can help approved changes reach patients faster.

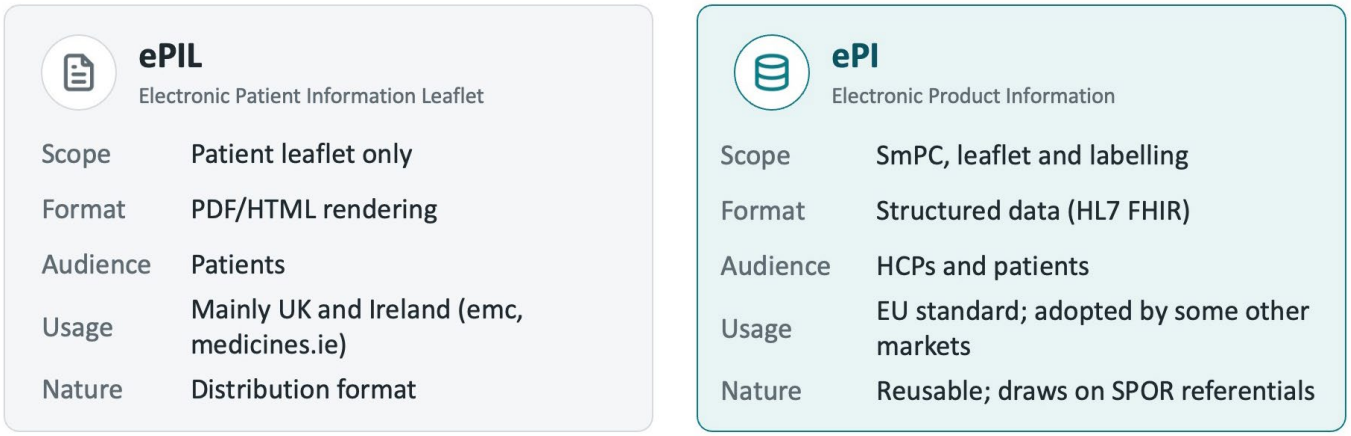


Figure 2: ePI vs ePIL at a glance. ePIL is one document. ePI covers the full product information and is structured data.

3.

EU / EMA: voluntary now, legislation adopted

Two tracks run in parallel. The EMA's operational ePI rollout is voluntary and is planned to start in Q4 2026. The new pharmaceutical legislation, adopted in November 2026, creates the legal basis for mandatory ePI for new authorisations and for electronic-only leaflets, but national choices will decide how the leaflet option is used.

3.1. Track 1: EMA ePI rollout (operational)

The operational track is led by the EMA and rests on the EU ePI Common Standard, an implementation of HL7 FHIR R5. The EMA has published version 1.0.0 of the implementation guide; the current release is dated September 2026.[18] The approach was proven in a pilot with Denmark, the Netherlands, Spain and Sweden, which reported in December 2024.[20]

The rules for submission are set out in the EMA's centralised-procedure guidance (EMA/199350/2026), which applies from go-live and covers both initial applications and post-authorisation procedures. Submission remains voluntary until the new Directive fully applies, although the guidance states that ePI in all languages is expected to become mandatory in future.[19] For now, ePI is an additional step rather than a replacement: applicants author or upload it in the EMA Product Lifecycle Management (PLM) portal and continue to submit Word and PDF documents. The initial scope is English, with other languages optional.[2,19] Points taken from the EMA's ePI web page are current as of its last update on 16 September 2026.[20]

Go-live for centrally authorised products is phased by therapeutic area. Vaccines (ATC J07) are planned first, in Q4 2026, followed by oncology (ATC L01, L04) in H1 2027 and all remaining CAPs in H2 2027.[1,3] Industry user acceptance testing for the vaccines phase concluded in Q3 2026, but at the time of writing (mid-November 2026) the EMA had not confirmed a start date, and it marks the two later phases "go-live TBC".[1]

The EMA roadmap shows a transition and hypercare period in 2027-2028.[2] Nationally authorised products (NAPs) follow a separate path: the EMA's October 2026 presentation states that compliance becomes mandatory under the new Directive, with implementation planned from 2027, but detailed national plans still depend on an assessment of national competent authority (NCA) readiness.[1] In parallel, the EMA consulted on a draft reflection paper on linking EU medicine packs to ePI (EMA/95076/2025; consultation closed 30 June 2025).[24] Its final form will shape how the printed pack connects to the electronic text.

3.2. Track 2: EU pharmaceutical legislation (legal)

The legal track determines when ePI stops being optional. Political agreement on the EU pharmaceutical legislation was reached on 11 December 2025, and the Council adopted its first-reading position on 28 September 2026.[8,25] The European Parliament approved the Council's position at second reading on 25 November 2026, which completes adoption.[34] At the time of writing, the acts had not been published in the Official Journal.[7]

Publication starts the clock. Both acts enter into force 20 days after publication.[4,5] The Regulation then generally applies after 24 months, and Member States have 24 months to transpose and apply the Directive.[4,5] The earliest hard deadline for ePI adoption is therefore the end of 2028 or early 2029, depending on the publication date.

For new medicines, the obligation is set at EU level. The EMA has stated that once the new legislation applies, ePI will become mandatory for all newly authorised medicines (EMA Management Board, March 2026).[6] Its October 2026 presentation sets out the legal timelines: an electronic package leaflet for new medicines 24 months after the Directive enters into force, and for existing medicines five years after.[1] The presentation refers specifically to the electronic package leaflet, which may be narrower than full ePI covering the SmPC and labelling.

Whether paper continues to be supplied is a separate question, and one left to Member States. In the Commission proposal, Article 63 of the Directive allowed Member States to permit electronic-only leaflets, with paper available on request.[26] The adopted text, which is the Council's first-reading position approved without amendment, keeps both this discretion and the paper-on-request safeguard, and expects the marketing authorisation holder to place a digitally readable code, such as a QR code, on the outer packaging.[5] For antimicrobials, the text adds a further safeguard: where a Member State opts for electronic-only leaflets, the antimicrobial resistance information is still provided to patients in paper form, as an 'awareness card', unless that Member State decides otherwise in duly justified cases.[5]

3.3. What this means for EU operations

- New authorisations: the EMA's centralised-procedure guidance covers ePI for initial marketing authorisation applications and post-authorisation procedures.[19] Once the legislation applies, ePI becomes a required part of the application for new medicines rather than an optional extra step.
- Lifecycle: every variation that changes product information will need a matching ePI update. Workload therefore follows label-change volume, not only the number of new products.
- Languages: initial ePI is in English. National-language ePI will depend on the NAP rollout and NCA readiness, so multilingual demand is likely to rise in stages.[1,19]
- Paper and packs: national transposition, due within 24 months of entry into force, will decide where electronic-only leaflets are allowed. Where they are, the Council text expects a digitally readable code on the outer pack, and the EMA's reflection paper will shape how that code links to ePI.[5,24] Both affect artwork, so labelling teams should track them by Member State. For antimicrobials in those markets, the paper awareness card is a further printed item to design, approve and control.[5]

4.

US / FDA: electronic format mandatory, paper retained

The US already requires structured electronic labelling. What it has not done is remove paper. The next change is to patient-facing information, not to the prescribing-information format.

- SPL (in force): FDA regulations require content of labelling to be submitted electronically, in Structured Product Labeling (SPL), an HL7 XML standard. The US National Library of Medicine publishes the labels through DailyMed.[9,10]
- Paper prescribing information (retained): In December 2014, the FDA proposed electronic-only distribution of prescribing information to healthcare professionals.[21] The FY2016 omnibus appropriations act, enacted in December 2015, barred the FDA from finalising it.[11]
- Patient Medication Information (pending): This is a one-page, FDA-approved patient document that would replace Medication Guides and Patient Package Inserts. The FDA published the proposed rule on 31 May 2023. It is at final-rule stage, with a December 2026 target in the Unified Agenda; that date is a projection, not a commitment.[12] The proposal sets a five-year implementation period. Paper is the default, and patients can request an electronic version.[13] No final rule had been published by November 2026. In July 2026 the FDA sought reinstatement of its information collection for Medication Guides, which indicates that Medication Guides remain in use for now.[27]
- FHIR: There is no FDA requirement to submit FHIR-based labelling. The FDA's data standards staff has explored a transition from SPL to FHIR, and a draft HL7 SPL-to-FHIR mapping guide exists.[28] An FDA presentation (June 2023) describes the work as exploratory, with no compliance date.[29]

PMI is the near-term US workload: new content, new templates and FDA approval for each product over about five years. Authored as structured content, it can be reused for EU ePI.

5.

Rest of the world: a balancing perspective

While this paper focuses on the EU and US, other global markets are also heavily engaged in the ePI adoption process – some to a significant level of maturity – and offer useful lessons and perspectives.

- **Japan:** Under the amended PMD Act, electronic package inserts for prescription medicines have been required since 1 August 2021, with paper inserts phased out by the end of July 2023. They use a national PMDA XML format rather than FHIR. Healthcare professionals reach the current insert by scanning a GS1 barcode on the pack. Products bought directly by consumers, such as OTC medicines, keep paper inserts.[14,22]
- **Jordan:** The JFDA requires an electronic leaflet in HL7 FHIR for registered products, reported as mandatory by the end of 2025.[16] Industry sources describe it as linked from a 2D code and supplied in addition to the printed leaflet, with reported deadlines ranging from January to December 2025.[15]
- **Canada**: Health Canada has required an XML Product Monograph for new drug submissions since 18 July 2025, with other submission types to follow.[17] The format is based on SPL, extending the US approach rather than adopting FHIR.

5.1. Points to note

Japan's experience offers three lessons for EU and US planning. Paper removal depended on a pack-level barcode linking to one authoritative source. Patient-purchased products were exempt. And full removal of paper took a two-year transition.[14,22]

6.

Standards explained

The EU and US use different structured formats, and other regulators add national variants. All are machine-readable and come from the same idea: label product content as structured data rather than as a formatted document. Of all the choices a company makes, the output format is the one most likely to change across markets and standard releases.

Standard	Used by	Origin	Status	What it structures
EU ePI Common Standard (HL7 FHIR R5)	EMA and EU network	HL7 FHIR resources, EU implementation guide	Voluntary for CAPs from Q4 2026; implementation guide v1.0.0	SmPC, package leaflet and labelling sections, linked to product master data
Structured Product Labeling (HL7 v3 XML)	FDA	HL7, adopted by the FDA	Mandatory for labelling submissions; stable	Prescribing information, patient labelling, product listing data
PMDA package insert XML	PMDA, Japan	National schema	Mandatory since August 2021; paper phased out by July 2023	Package insert content for HCP access
JFDA ePI (HL7 FHIR)	Jordan FDA	HL7 FHIR	Reported mandatory from 2025; printed leaflet retained	Leaflet content, linked from a 2D code
XML Product Monograph (SPL-based)	Health Canada	HL7 SPL with controlled vocabularies	Mandatory for new drug submissions from 18 July 2025; scope widening	Canadian product monograph
PharmaLedger ePI	PharmaLedger Association (industry consortium)	Industry-led platform, outside regulatory submission	In production since April 2023 (self-reported)[30,31]	Leaflet content in HL7 FHIR, accessed from the pack

Table 2: Structured label formats by regulator. The rows below the EU and US are included for broader context. PharmaLedger differs from the others: it is an industry channel that sits alongside regulatory submission, not a regulator's format.

6.1. What this means in practice

- If a company manages SmPC and US Prescribing Information (USPI) content as separate documents, it typically carries a conversion cost for each, and every further market adds another. Each regulatory change multiplies them.
- One source can generate each format if it manages labelling as governed, component-level content.
- FHIR is the most likely point of convergence, given the EU commitment and HL7 activity, but there is no confirmed US commitment and other markets are split. Even within FHIR, outputs are portable only between markets using the same release; the EU implementation guide uses R5.[18]

7.

Options available

Companies have six broad routes to ePI readiness. They are not exclusive. Many will combine a short-term route for early EMA submissions with a longer-term content model. The categories are vendor-neutral, and examples within each should be assessed on their own merits.

Option	How it works	Best fit	Main limitation
1. EMA PLM portal authoring	Author or upload ePI directly in the EMA's portal alongside Word/PDF	Small CAP portfolios; early voluntary participation	EU only; manual re-keying; no reuse across markets
2. Outsourced conversion	A service provider converts approved PI to FHIR or national XML; regulatory submission may or may not be included	Fast start without internal tooling	Ongoing per-document cost; content stays document-centric; dependence on the provider
3. RIM platform extension	ePI generated from, or tracked within, the regulatory information management system	Companies with a mature RIM and EMA submission focus	Content depth varies; weak link to pack artwork
4. Structured content authoring (SCA)	Labelling authored as reusable components in a component content management system, with ePI as one output	Large portfolios, many markets, frequent label changes	Highest change-management effort; authoring model changes
5. Labelling and artwork platform with ePI output	Label text, artwork and ePI managed in one governed workflow, with change impact traced from the Company Core Data Sheet (CCDS) to pack	Companies where label changes drive artwork volume and errors	Value depends on integration with RIM, ERP and DAM
6. In-house build on FHIR tooling	Internal team builds conversion and validation using open FHIR libraries	Companies with strong internal IT and unusual requirements	Maintenance of evolving standards; validation burden under GAMP 5

Table 3: Routes to ePI readiness

Any route that holds GxP-relevant label content must meet computerised-system expectations: 21 CFR Part 11, EU GMP Annex 11 (itself under revision) and a GAMP 5 risk-based validation approach. Where AI assists with structure recognition, section mapping, text comparison or impact analysis, it should be scoped as decision support. Validation against the standard should remain deterministic and rule-based, with human review and approval at each regulated step. Draft EU GMP Annex 22, consulted on alongside the revised Annex 11 (consultation closed 7 October 2025; not adopted at the time of writing), and ISO/IEC 23894 are also relevant.[32]

8.

Decision matrix

No single option leads on every dimension. Low-cost routes meet the voluntary EMA phase but carry little value into future markets or mandates. Content-centric routes cost more up front and get cheaper with each label change and each market added.

Option	Upfront cost	Time to first EMA ePI	Multi-market reuse	Compliance risk	Scalability	Integration (RIM, ERP, PLM, DAM)
1. EMA PLM portal authoring	Low	Fast	Low	Medium (manual re-keying)	Low	Low
2. Outsourced conversion	Low-Medium	Fast	Low-Medium	Medium (oversight of the provider)	Medium	Low
3. RIM platform extension	Medium	Medium	Medium	Low-Medium	Medium	High with RIM; low with artwork
4. Structured content authoring	High	Slow	High	Low once validated	High	Medium-High
5. Labelling and artwork platform with ePI output	Medium-High	Medium	High	Low (traceable change control)	High	High where integrated
6. In-house build on FHIR tooling	Medium-High	Slow	Medium	High (validation and maintenance)	Medium	Variable

Table 4: Decision matrix for ePI routes. Ratings are the author's qualitative assessment, based on how each model works. They are not benchmarked data, and should be tested against each company's own portfolio size, change volume and systems estate. Perigord operates in options 2 and 5 (see Section 13).

Rule of thumb:

- A small CAP portfolio, few markets and infrequent label changes: start with option 1 or 2, and build the content model in parallel.
- A large multi-market portfolio with high label-change volume: options 4 or 5 give the best long-term position. Option 1 or 2 can serve as a bridge for early EMA phases.

9.

The case for waiting

The strongest argument against early investment is that, although the legislation is adopted, much of the detail of the EU obligation is still undefined.

- National rollout has no dates. The EMA's roadmap ties the NAP phase to an NCA readiness assessment, with go-live to be confirmed.[1,2]
- The detail of the obligation is not settled. The EMA's October 2026 presentation points to new medicines at 24 months and existing medicines at five years after the Directive enters into force. The legislation is now adopted, but the implementing acts that will set out the detail are not yet published.[1,7]
- Structured content changes how labelling teams author, review and approve. That cost is certain; the regulatory benefit before 2028 is not.

For a company with few CAPs, few markets, infrequent label changes and no pipeline products due after 2028, this case holds. PLM portal authoring meets the voluntary phase at low direct cost, and the EMA's guidance attaches no consequence to non-participation.

The case weakens as portfolio size, change volume and pipeline exposure grow:

- Format risk has fallen. The EMA has published version 1.0.0 of the implementation guide and submission guidance.[18,19]
- Pipeline products are exposed. Any medicine authorised after the legislation applies needs ePI from first approval, and existing medicines follow within five years of entry into force.[1]
- Master data is a lighter dependency than often assumed. Version 1.0.0 profiles the document itself (Composition, Bundle and List resources) and draws value sets from the EMA's SPOR (Substance, Product, Organisation and Referential) data. It does not profile IDMP (Identification of Medicinal Products) product resources, so full Product Management Service (PMS) readiness does not appear to be a precondition for a first submission.[33]
- The content model is format-independent. Work done for EU ePI also serves US PMI and any national electronic-only leaflet decision.

10.

Evaluating providers across the ePI lifecycle

Options 2, 3 and 5 outlined in the decision matrix in Section 8 depend on an external provider, and whichever is chosen, conversion is only part of the work. The 13-stage lifecycle below is a working framework developed by Perigord, not an industry standard. Conversion to FHIR XML is one of its 13 stages. Providers and internal teams vary most at the two ends: source content and metadata at the start, and dissemination, lifecycle maintenance and system integration at the end. Asking about each stage shows where a buyer still carries the work.

Stage	What it involves	Question to ask
1. Source content authoring	Approved SmPC, prescribing information and package leaflet text	Is source authoring in scope, or does the company supply approved Word files?
2. Metadata capture	Product, procedure and regulatory reference data, plus country, language, document type, version, pack and identifiers such as GTIN and the FMD unique identifier	How is metadata checked against the source and master data? Are pack identifiers captured so ePI can later be linked from a 2D code?
3. Pre-conversion assessment	Structure, missing sections and encoding issues flagged	Are source defects found before conversion or after?
4. Conversion	Word to FHIR, SPL or national XML	How much is automated and how much is manual post-processing, for each standard?
5. Technical validation	Schema and FHIR validation using tools such as the HAPI FHIR validator and XSD schemas; regulator test portals; QRD and business-rule conformance	Which validators are used, and who holds regulator portal access? Does validation cover QRD section structure, or only schema conformance?
6. Content QC	Text comparison against the approved source; SME review	Is the comparison tool-supported, and is evidence retained?
7. Review and approval	Formal sign-off under change control	Is approval recorded in a Part 11 / Annex 11 compliant workflow?
8. Link to artwork	ePI tied to the pack components it describes	Does a change to ePI trigger an artwork impact assessment?
9. Storage and audit trail	Validated output, reports and sign-off kept together	Can an inspector trace each ePI version to its source and approval?
10. Regulatory submission	PLM portal or national gateway	Who submits, and under whose account?
11. Dissemination and 2D codes	Hosting, pack QR or 2D codes	Is this in scope, or does it sit with the company or a third party?
12. Lifecycle maintenance	Re-conversion after variations and safety updates; reconciliation of the authority-published ePI against the submitted version	Is re-conversion a defined process with turnaround commitments? How is the published version retrieved and compared?
13. System integration	Links to RIM, PLM, ERP and product master data	What is integrated today, and what is only on the roadmap?

Table 5: ePI lifecycle stages and buyer questions

Three practitioner observations, based on Perigord delivery experience rather than public evidence:

- Semi-automated conversion still needs significant manual post-processing while implementation guides are new and national variants continue to change. Buyers should expect human-in-the-loop validation for now.
- Technical validation often depends on the company's own regulator portal access. A provider cannot always validate end to end without it.
- Stages 11–13 are where buyers are most likely to keep work in-house or with other providers. Ask each provider, Perigord included, which of these it covers today.

The same delivery experience points to recurring practical problems: legacy Word and PDF sources, tables and images that break in conversion, inconsistent metadata, uncertain FHIR mapping, risk at PLM import, and the effort of scaling across languages and countries.

11.

Recommendations

Invest now in structured, governed label content, and keep spending on submission mechanics to the minimum the voluntary EMA phase needs. The format will change before the content model does.

1. Map your obligations by market and product. List which products are CAPs, NAPs, US New Drug Applications (NDAs) and Biologics License Applications (BLAs), and approvals in other markets where relevant. Note which falls in which EMA phase: vaccines first, then oncology, then all CAPs. Include the development pipeline: any product expected to be authorised after the new EU legislation applies will need ePI from first approval.

2. Decide whether to join the voluntary EMA phases. Early participation builds experience while the stakes are low. Joining with a manual process creates habits that do not scale. EMA user acceptance testing calls for later phases offer a low-risk way to start.

3. Fix ownership. Assign one accountable owner for ePI across Regulatory Affairs, Labelling and IT. Without one, ePI ends up as a submission task with no content governance.

4. Build the content model before the tooling. Define label components, CCDS-to-local traceability and change control. Then choose the tool that fits.

5. Plan for PMI in the US. Treat the five-year PMI rollout as a parallel structured-content programme, not a separate document project.

6. Link ePI to pack change. Any 2D code on packs, and any national electronic-only leaflet decision, will connect ePI to artwork. Change impact must run from label text through to printed components. Hold pack identifiers such as GTIN and the FMD unique identifier as ePI metadata, so that a 2D code resolves to the correct version.

7. Validate proportionately. Apply GAMP 5 risk-based validation, and keep any AI-assisted steps under human review and approval.

8. Review again at Official Journal publication. Confirm the final article text and application dates, and reset the plan against them.

12.

ePI readiness checklist

A “no” to any item marks a gap to close before EMA phases scale up in 2027-2028.

12.1. Regulatory

- ◯ We have mapped every product to its ePI regime (EMA CAP phase, NAP, FDA SPL and PMI, and other national regimes where relevant).
- ◯ We know which EMA go-live phase each CAP falls into.
- ◯ We have identified pipeline products likely to be authorised after the new EU legislation applies.
- ◯ We track national decisions on electronic-only leaflets in each EU market.
- ◯ We have a plan for US PMI content within the proposed five-year window.
- ◯ We have dated our ePI plan from the Official Journal publication and application dates.

12.2. Content and process

- ◯ Each local label traces back to its CCDS or core reference.
- ◯ One change to label text triggers a traceable impact assessment on ePI, leaflets and artwork.
- ◯ QRD template conformance is checked before submission.
- ◯ Validation covers QRD structure and business rules as well as schema conformance.
- ◯ Pack identifiers (GTIN, FMD unique identifier) are held as ePI metadata.

12.3. Organisation

- ◯ One owner is accountable for ePI across Regulatory, Labelling and IT.
- ◯ We have registered roles in EMA Account Management for ePI.
- ◯ We have assigned budget for the transition period (2027-2028).

12.4. Technology and compliance

- ◯ We can produce valid FHIR ePI conforming to the EU implementation guide.
- ◯ We have validated systems (Part 11, Annex 11, GAMP 5) holding label content.
- ◯ We have identified integration points with RIM, ERP, PLM and DAM.
- ◯ Any AI-assisted step is defined as decision support, with human approval.

13.

About Perigord

Perigord provides ePI conversion as a managed service. Conversion from approved Word source to structured XML is semi-automated, and each output goes through human-in-the-loop validation and SME sign-off before delivery. Among the options above, the service sits closest to option 2 (outsourced conversion), connected to a labelling and artwork platform (option 5) through GLAMS AMS. Health authority submission is not part of the confirmed service scope.

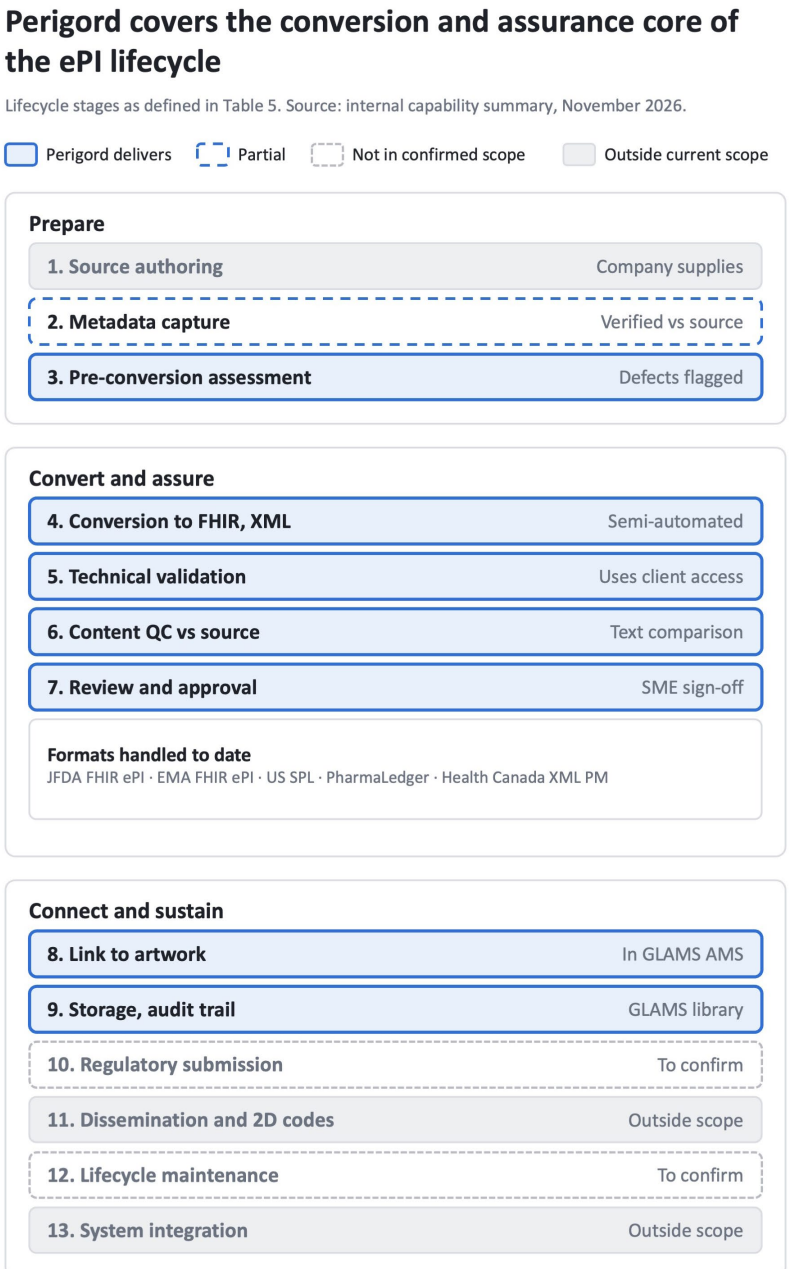


Figure 3: ePI lifecycle stages and Perigord service coverage

The service covers stages 2 to 9 of the lifecycle in Table 5, with stage 2 limited to verifying company-supplied metadata:

- Metadata verification against the source.
- Pre-conversion assessment.
- Conversion.
- Technical validation, using the HAPI FHIR validator, Lorenz eValidator and XSD schemas.
- Text comparison against source.
- Formal review and approval.
- Linking each ePI to its artwork in GLAMS AMS.
- A validated library with a full job record.

The service works alongside a company's own systems. Approved source authoring, pack 2D code hosting and full RIM or master-data integration are outside its current scope; regulatory submission and lifecycle maintenance are not in the confirmed scope.

Standards delivered or prepared to date: JFDA FHIR ePI, EMA FHIR ePI, US SPL, PharmaLedger and Health Canada XML PM. Companies can use the service in three ways: approval workflow only, conversion only, or a combined GLAMS workflow covering job intake, conversion, review and approval, and an XML editor.

14.

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Disclaimer

This white paper has been produced by Perigord for strategic and informational purposes only. It does not constitute legal or regulatory advice. Regulatory requirements described here reflect published sources available as at 25 November 2026. EU pharmaceutical legislation, EMA ePI guidance and the FDA Patient Medication Information rule remain subject to change. Readers should consult current published standards and qualified regulatory counsel before making compliance-related decisions.

The options review and decision matrix reflect the author's qualitative assessment and are not benchmarked data. The 13-stage ePI lifecycle is a working framework developed by Perigord, and the practitioner observations draw on Perigord delivery experience. The About Perigord section describes Perigord's own services.

Large language models were used to support structural outlining, background research and the evaluation of research materials. All outputs were reviewed critically and modified where necessary. Every source relied on has been verified against the original and cited.


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