

ekt.one — Electronic Patient Information Leaflet Management Platform

Used via Web / QR Code · License#: EKT-2026-02 / e-PIL Service Rev. 2.0 · April 2026

⚠ TİTCK e-PIL Mandatory: January 1, 2027

TİTCK IRD-KLVZ-07 Rev.17 Compliant

KVKK Compliant

WCAG 2.1 AA

AI Supported

Vertex AI TTS

COMPOSITION

Active substances: QR-Based Access · Version Control · AI Content Generation · AI Voice Instructions (Vertex AI TTS)

Excipients: Multi-Language Support · AI Chatbot (Multi-Layer Parameter Engine) · Usage Analytics (7 Action Types) · TİTCK Deadline Tracking · Pharmacovigilance Signal Detection · PIL Gap Reporting

Management components: Digital Leaflet · Language Contents · Version History · Service Packages (S/M/L/E) · Customer Subscriptions · Activity Management · Scheduled Alerts · QR Code Management · Product Category AI Settings · AI Analytics Panel

Added in v2.0: PDF → AI Content Conversion · Vertex AI TTS Voiceover · AI Chatbot + Multi-Layer Parameter Engine · 6 Product Group Templates · Pharmacovigilance Signal Automation (S2) · Subscription-Based Feature Management · Custom Domain QR Support · Real-Time Cost Visibility

Scan the code for informational media.

Keep this patient information leaflet for future reference. You may need to read it again. For additional questions, contact your system administrator or support@ekt.one.

Read this patient information leaflet carefully before starting to use ekt.one.

This platform is prescribed specifically for the company; do not transfer it to others. Do not exceed the subscription scope. Leaflet creation attempts that exceed the quota limit will be blocked by the system.

WHAT IS INCLUDED IN THIS PATIENT INFORMATION LEAFLET?

- 1.What is ekt.one and what is it used for?
- 2.Things to consider before using
- 3.How to use ekt.one? — Basic Workflows
- 4.Pricing and package features
- 5.Artificial intelligence (AI) features
- 6.What are the possible side effects?
- 7.Storage of ekt.one

What is ekt.one and what is it used for?

ekt.one is a TİTCK-compliant Electronic Patient Information Leaflet management platform designed for pharmaceutical and health product companies. While providing current, multilingual, and accessible digital patient information leaflets to

patients through QR codes on packaging, it allows Regulatory Affairs, Medical Marketing, and Legal departments to manage content approval, version tracking, and legal compliance processes under a single roof. With v2.0, the platform has been enhanced with **AI-powered content generation, voice instructions (TTS), patient adherence chatbot, and real-time pharmacovigilance signal detection.**

Mechanism of action

By eliminating the mandatory paper printing requirement and digitizing leaflet distribution

By keeping TITCK-approved content under version control; automatically archiving each update with the approver and date

By generating a unique QR code for each product and publishing it via a public URL — with custom domain support allowing the company to use its own branding

By converting TITCK-approved PDF text into 5-section compliant HTML using AI, shortening the preparation time for the regulatory team

By generating voice instructions in every language with Vertex AI TTS, providing full accessibility for visually impaired and literacy-challenged patients

By directing the AI chatbot to product-category-specific and company-policy-specific behavior through a multi-layer parameter engine, increasing patient adherence

Indications for use

E-01

TITCK e-PIL Legal Requirement

Meeting the electronic patient information leaflet obligation that becomes mandatory as of January 1, 2027 (TRANSITORY ARTICLE 3).

E-02

30-Day Update Management

Reflecting TITCK text changes in the digital environment within the legal deadline; automatic deadline tracking and responsible person notification.

E-03

Multi-Product Portfolio Management

Content, version, approval, and QR management for 10 to unlimited products from a single panel.

E-04

AI-Powered Fast Content Generation

Automatic creation of fully compliant digital content from TITCK PDF; one-click translation to multiple languages.

E-05

Patient Adherence Chatbot

AI assistant customized according to product and company policy through a comprehensive parameter engine; adherence coaching and patient journey tracking.

E-06

Pharmacovigilance Signal Detection

Automatic adverse event signal from chatbot interactions; TITCK 24-hour notification support — Module requiring Medical Approval (S2).

QR-Based Patient Access (active substance)

When the patient scans the QR code on the packaging, they access the current patient information leaflet within seconds. Each leaflet is assigned a unique identifier when created and published via a public URL. If the company prefers, QR codes can be printed with their own domain (e.g., <https://company.com/...>) instead of <https://ekt.one/...>. Response time remains unaffected even under simultaneous high traffic; audio files are delivered via instant streaming.

Version Control and Audit Trail (active substance)

With each **Commit and Publish** operation, all language contents, audio files, and PDF attachments are automatically stored as a complete archive. In TITCK audits, retrospective traceability is provided immediately; the option to revert to previous versions is available.

Multi-Language Support (excipient)

Content management in Turkish, English, Arabic, and all languages defined in the system. With the AI translation feature, the Turkish-approved text can be translated to target languages with a single click; no additional workflow is required for foreign patients.

Voice Instructions — Vertex AI TTS (excipient)

Automatic audio generation per language using Google Vertex AI Gemini TTS technology. Provides full accessibility for visually impaired and literacy-challenged patients. Compliant with WCAG 2.1 AA accessibility standards. Manual audio upload is also supported for companies preferring studio recording.

Things to consider before using

Contraindications — Do not use ekt.one

The platform cannot be activated without the following conditions:

If there is no active subscription: Leaflet cannot be created. A subscription package must first be selected for the company name.

If product quota is full: New leaflet cannot be opened without exceeding the product limit in the selected package. Package upgrade or cancellation of an existing leaflet is required.

If content commitment is not approved: Content cannot be published without the Responsible Pharmacist approval.

If technical infrastructure is not set up: Service cannot be provided without completing the platform setup. (Consult the IT team for details.)

Legal warning — these methods do not meet TITCK standards

Paper-only patient information leaflet: After January 1, 2027, paper leaflet alone is not sufficient.

Static file link (PDF link): QR code pointing to a non-updatable file does not meet TITCK's dynamic content requirement.

Visual (JPG/PNG) QR content: Does not meet accessibility and updatability standards.

Conditions requiring careful use

Notify regulatory affairs or system administrator in the following situations:

If you know the TITCK text change date — always enter this date in the system; otherwise, the 30-day legal deadline cannot be automatically calculated and tracked.

If AI chatbot will be activated — determine the monthly AI usage budget in advance; when set to zero, no limit is applied.

If pharmacovigilance automation will be activated — define the email address of the PV responsible who will receive the reports.

If the product is under e-PIL exemption — record the exemption reason (Small Packaging, Radiopharmaceutical, Hospital Use, Vaccine, etc.); exempted products can be tracked separately in reporting and analytics.

If QR will be printed with custom domain — do not proceed to printing until the domain DNS record is completed; otherwise, QR codes will not work.

Automated checks (daily scheduled tasks)

TITCK Deadline Tracking	Daily	Creates task for responsible user 5 days before update date; sends warning to administrator if deadline is exceeded.
Leaflet Expiry Check	Daily	Automatically changes expired leaflets to <i>Expired</i> status.
Subscription Check	Daily	Changes expired subscriptions to <i>Inactive</i> status; sends warning to commercial team for renewal.
KVKK Data Deletion	Daily	Automatically deletes analytics records that exceed the defined retention period.
PIL Gap Report	Weekly (S2)	Notifies regulatory/medical team by email when unanswered question categories exceed the defined threshold.

KVKK and data privacy

Zero personal data policy

No patient location, identity, or any personal data is collected when QR is scanned. Connection information is stored with one-way encryption; geographic location data is automatically deleted after one hour. Chatbot conversations do not contain personal data. KVKK scope, consent requirements, and data retention periods can be configured separately for each product category.

Use with other systems (dependencies)

Odoo Core Platform	User management, approval workflows, email notifications
Web Infrastructure	Public URLs and page templates
Customer Portal	Company representatives' access via portal
Stock Module	Product and portfolio connection (added with v2.0)
ak_ai Service	AI content generation, TTS voiceover, chatbot LLM engine

How to use ekt.one? — Basic Workflows

Always use ekt.one as described in this patient information leaflet. Consult the system administrator for any unclear points.

Setup (single dose)

Step 01 — Company registration and subscription activation

Follow **ekt.one** → **Subscriptions** → **New** to select the company, package type (S/M/L/E), and contract date range. Upon completion, the subscription automatically becomes *Active*. Package features are transferred to the subscription; additional features agreed upon commercially can be separately enabled on the subscription.

Step 02 — Product category and AI behavior template

Category template is selected based on product group such as medicine, nutritional supplement, vitamin, or medical device. The system automatically populates all parameters of the AI chatbot and content generation engine with default values suitable for the selected category. Each parameter can also be customized separately with the approval of Medical and Legal departments. (See Section 5)

Step 03 — Content upload and AI conversion

The TITCK-approved patient information leaflet is uploaded to the system as PDF. When the **"Generate Content with AI"** button is pressed, the AI reads the text, prepares 5-section HTML content compliant with TITCK IRD-KLVZ-07 (Rev.17) format, and sends a notification upon completion. For different languages, the **"Translate from Turkish"** button translates the approved Turkish text as source to target languages.

Step 04 — Voice instruction generation

After HTML content is approved, the **"Generate Audio"** button is pressed for each language. The AI voiceover service works in the background; notification is sent when the audio file is ready. Companies preferring studio recording can also upload audio manually.

Step 05 — Responsible Pharmacist approval and publishing

After the regulatory affairs department reviews the content, they give the **"Content Commitment"** approval and press the **"Commit and Publish"** button. All language contents, audio files, and attachments are automatically archived to version history; QR code is ready for packaging printing.

Approval workflow (recommended treatment regimen)

Draft

→

Review

→

Approved

→

Commitment

→

Published

→

New Version

1. Create Draft	New Leaflet form	Active subscription and product quota	Regulatory Affairs / Product Management
2. Send for Review	<i>Send for Review</i>	Product and company selected	Regulatory Affairs
3. Approve	<i>Approve</i>	e-PIL Administrator authorization	Medical / Regulatory Affairs Manager
4. Content Commitment	<i>Content Commitment</i> checkbox	Content compliant with TITCK text	Responsible Pharmacist
5. Publish	<i>Commit and Publish</i>	Content Commitment approved	Responsible Pharmacist
6. Automatic Archive	— (done by system)	—	All language contents, audio, and PDF are archived

TITCK update tracking

The date when TITCK officially updates the text is entered in the **TITCK Approval/Change Date** field. After that, everything is automatic:

Legal update deadline is automatically calculated (TITCK Date + 30 days)

Task notification is created for responsible user 5 days before the date

If deadline is exceeded and content is still published, warning is sent to administrator and leaflet is marked as *update delayed*

Legal risk of update delay

Leaflets still published with old content 30 days after TITCK change are automatically flagged. As this carries the risk of non-compliance with TITCK regulations, immediately inform the Legal and Regulatory Affairs departments.

Common situations and solutions

e-PIL Exemption	The relevant product record is marked with <i>e-PIL Exemption</i> , reason is selected (Small Packaging, Radiopharmaceutical, Hospital Use, Vaccine, etc.). Exempted products can be tracked separately in reporting and analytics.
Custom Domain QR	Verified domain is entered in the subscription record. All QR codes belonging to that company are automatically generated with the custom domain.
Products with expiry date	Expiry date is entered in the leaflet record. When this date passes, the system automatically changes the leaflet to <i>Expired</i> status.
Usage analytics	Page views, downloads, audio listening, printing, chatbot opening, and message sending data can be accessed from the <i>ekt.one</i> → <i>Analytics</i> menu.
Terminating a leaflet	The leaflet is closed with the <i>Cancel</i> button and removed from product quota.
AI Chatbot budget management	Monthly AI usage budget can be defined in TL for each leaflet. When budget is exceeded, the chatbot stops responding. Cumulative AI expense per subscription can be monitored in real time.

Common mistake — Attempting to publish without Content Commitment approval

When the "Commit and Publish" button is pressed, if Responsible Pharmacist approval has not been obtained, the system blocks the action and issues a warning. First, the *Content Commitment* checkbox must be checked, then publishing can be done.

Pricing and package features

Select a package based on the size of your product portfolio. **Multi-language, AI content generation, AI translation, and AI voice instructions are standard in all packages.** Other features can be added as optional add-ons in each package. All packages include technical support and automatic TITCK deadline tracking.

Standard features included in all packages

Multi-Language Support	AI Content Generation (PDF → HTML)		AI Translation	AI Voice Instructions (TTS)	
TITCK Deadline Tracking	Version Archive	QR Code Management	Usage Analytics	Technical Support	

Package comparison — product limit and scale

S	Up to 10 products	☐	☐	☐	☐	☐	☐	☐	☐
M ☐	Up to 50 products	☐	☐	☐	☐	☐	☐	☐	☐
L	Up to 100 products	☐	☐	☐	☐	☐	☐	☐	☐
E	Unlimited	☐	☐	☐	☐	☐	☐	☐	☐

☐ Optional features can be enabled when creating a subscription or added later. The unit price of each feature multiplied by the number of active products calculates the monthly cost in real time.

Monthly cost visibility

Actual Cost and **Budget Estimate** fields in the subscription record are automatically calculated; no additional reporting request or processing is required.

Base PIL fee	Sum of unit prices of enabled features × number of active products
Additional user fee	Monthly unit price for each user exceeding the included user count in the package
Additional storage fee	Monthly unit price per GB exceeding the storage space included in the package
Fixed fees	Account manager, API access, white label, training, setup fee
AI usage expense	Chatbot and content generation LLM cost — monitored separately monthly and per product

Automatic package upgrade

When the number of active products approaches the current package limit, the system automatically suggests upgrading to the next package. When the upgrade is approved, unit prices are updated and additional features become available.

SLA Levels

Bronze	Standard technical support	24 hours
Silver	Priority support, upgrade management	4 hours
Gold	Dedicated account manager, 99.9% uptime guarantee, proactive monitoring	1 hour

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Artificial intelligence (AI) features

About AI features

Content generation, translation, and TTS are standard in all packages. AI Chatbot, AI Analytics Panel, and Pharmacovigilance Automation can be enabled as optional add-ons in any package. Approval from Medical and Legal departments must be obtained before activating the chatbot and PV automation.

PDF → TITCK Compliant Digital Content

The regulatory affairs team uploads the TITCK-approved patient information leaflet PDF to the system and presses the **"Generate Content with AI"** button. The AI:

1. Reads the PDF text and automatically detects the medicine name
2. Prepares 5-section HTML content compliant with TITCK IRD-KLVZ-07 (Rev.17) format rules
3. Produces output compliant with WCAG 2.1 AA accessibility standards
4. Sends a notification upon completion and reports the processing cost used

Content is reviewed and approved by a regulatory affairs specialist before publishing; AI output does not go directly to publication.

5-Section Standard Format (TR/EN/AR/DE/FR)

- Section 1: What is [medicine name] and what is it used for?
- Section 2: Things to consider before using
- Section 3: How to use
- Section 4: What are the possible side effects?
- Section 5: Storage of [medicine name]

Vertex AI TTS — Voice Instruction Generation

When the **"Generate Audio"** button is pressed for each language, the AI converts the text to near-human-quality voice. Platform usage continues uninterrupted during generation; notification is sent when audio is ready.

Language	Voice Used	Output Format
Turkish	Charon (Vertex AI)	MP3 / AAC

Language	Voice Used	Output Format
English	Kore (Vertex AI)	MP3 / AAC
Arabic	Aoede (Vertex AI)	MP3 / AAC
Other languages	Default Gemini TTS	MP3 / AAC

AI Patient Adherence Chatbot — Multi-Layer Parameter Engine

Chatbot behavior is managed through a comprehensive parameter set defined for each product category. These parameters are configured **without requiring code changes** through consensus among Medical Marketing, Regulatory Affairs, and Legal departments; can be customized independently according to product group, therapeutic area, and company policy.

Product Group Templates — Quick Start

When a category template is selected, all parameters are automatically populated with default values appropriate for that group:

Template	Product Group	Key Behavioral Difference
Medicine	Prescription / OTC Medicine	Therapeutic claim prohibited · FV signal automation enabled · Full TITCK compliance
Nutritional Supplement	Dietary Supplement	Cross-selling enabled · TGDF regulations · Therapeutic claim prohibited
Vitamin & Mineral	Vitamin / Mineral	Low medical warning threshold · High educational content ratio
Medical Nutrition	Food for Special Medical Purposes	Dietitian referral · HCP bridge enabled
Gluten-Free Product	Special Diet	Celiac sensitivity protocol · Cross-contamination warning
Medical Device	Medical Device / eIFU	Technical instruction format · CE certificate link · eIFU mode (S5)

Parameter Groups

Regulatory Compliance

Therapeutic claim limits · advertising class (A/B/C/D) · competent authority (TITCK / TGDF) · ...

Safety Protocol

Escalation threshold · emergency routing · contraindication rigidity · ...

Pharmacovigilance Signal

Adverse event signal detection · reporting mode (disabled / patient-approved / automatic) · TITCK 24-hour notification · ...

KVKK & Consent Management

Special category data scope · granular consent · pre-chat consent screen · ...

PIL Gap Reporting

Unanswerable question threshold tracking · automatic notification to regulatory/medical team · proactive regulatory warning · ...

Marketing Permissions

Cross-selling target categories · competitor policy (silent / neutral / positive) · brand tone · ...

Patient Adherence & Compliance

Treatment discontinuation intent detection · barrier analysis · reminders and self-management support · ...

Target Audience & Response Style

Healthcare professional mode (HCP) · literacy level · formal / friendly tone · ...

Chatbot Interaction Analytics (May 2026)

Each chatbot response is automatically classified and recorded in the analytics database. This data is visualized in the AI Analytics Panel and can be used for regulatory decisions:

Analytics Dimension	What It Measures	Use Case
Question Category	Efficacy, dosage, side effects, contraindication, pregnancy, storage, price, compliance, etc.	PIL gap detection · Content improvement priorities
Safety Flag	Questions containing low / medium / high / critical safety risk	Automatic escalation to PV team
Adherence Risk	Signs of treatment discontinuation tendency or compliance difficulty	Medical marketing support content
PIL Coverage	Whether the question is addressed in current PIL content	Regulatory update priorities
Patient Journey Stage	New user / experienced / reconsidering / caregiver	Targeted communication and education design
PV Signal	Interactions containing adverse event reports	Pharmacovigilance automation

AI Analytics Panel

From the *ekt.one* → *AI Analytics* menu, AI-powered analysis is initiated by selecting date range and product. The panel interprets usage trends, patient adherence signals, PIL gaps, and regulatory risk areas; produces summary and recommendations ready for management reports.

What are the possible side effects?

Like all platforms, *ekt.one* may cause side effects; however, not all of these may occur in every user.

If any side effect becomes severe, contact our support team.
support@ekt.one · Your side effect reports contribute to platform development.

Very common — seen in more than 1 in 10 users

- Budget savings:** Elimination of printed patient information leaflet printing, distribution, and update costs.
- Quota limit warning:** System warns when the number of active leaflets reaches the package limit. Upgrade to a higher package or cancel an existing leaflet is required.

No active subscription found warning: A subscription must first be created for the company name.

AI content generation waiting notification: Content generation runs in the background; notification is sent upon completion (usually 15–60 seconds).

Common — seen in 1 in 10 users

Reduced Responsible Pharmacist workload: TITCK deadline warnings, version archiving, and approval workflows run automatically.

Shortened audit preparation time: All versions are immediately accessible in the archive with date and approver information.

Missing content commitment warning: Publishing cannot be done without Responsible Pharmacist approval.

Voice content quality expectation: AI TTS is sufficient for general quality; companies wanting to highlight brand voice may prefer the studio recording add-on.

AI chatbot monthly budget exceeded: Chatbot usage budget must be determined in advance; setting to zero results in unlimited usage.

Uncommon — seen in 1 in 100 users

Increased patient satisfaction: Instant access, voice reading, multi-language, and personalized chatbot support.

Unexpected version number increase: Each time "Commit and Publish" is run, the version number increases by one — this is a feature, not a bug.

Custom domain QR not working: QR codes printed without DNS configuration cannot reach their target; technical verification should be done before printing.

PV misclassification (false positive): A verification step can be added by selecting the module requiring patient approval.

Rare — seen in 1 in 1000 users

Elimination of TITCK audit anxiety: Complete audit trail, all versions archived, chatbot interaction classification.

QR update delay (max. 5 minutes): Cached content updates within 5 minutes at most; consult the system administrator if instant publishing is critical.

Storage of ekt.one

Run only in production (live) environment; do not mix test data with the live system.

Never transmit API keys (Anthropic, Vertex AI) via email, messaging applications, or shared documents; use only secure secret management systems.

Take regular database backups and perform restore tests.

Track module version: **19.0.2.2.0** — consult the IT team for compatibility check when migrating to the new platform.

Close cancelled or expired leaflets; this action releases both quota and storage space.

Regularly review AI chatbot monthly usage budgets; cumulative AI expense per subscription can be monitored live.

Configure KVKK data retention periods by product category and periodically verify that the automatic deletion task runs regularly.

Compliance commitments

- ✓ **TİTCK IRD-KLVZ-07 (Rev. 17, March 18, 2026)** — 30-day update deadline automatically tracked.
- ✓ **KVKK — Zero Personal Data Policy** — Connection information encrypted, location data deleted in 1 hour, health data is session-based.
- ✓ **WCAG 2.1 Level AA** — Screen reader compatibility, TTS voice instructions, keyboard navigation.
- ✓ **99.9% Uptime SLA (Gold package)** — QR code on packaging works anytime, from anywhere.

Roadmap — Time remaining until January 1, 2027 target

(April–May 2026): Chatbot question categorization engine — live deployment.

(May 2026): Interaction analytics, PV signal automation, PIL gap reporting.

(End of May): Cross-selling chatbot flow for nutritional supplement category.

(June–July): Medical device eIFU mode and CE certificate integration.

(July–Q4 2026): High-scale chatbot service, comprehensive analytics dashboard, big data analytics infrastructure.

Target: January 1, 2027 TİTCK e-PIL mandatory — fully prepared.

Marketing Authorization Holder

Kardan.Digital Software Inc.

Web: ekt.one · kardan.digital

Email: support@ekt.one

License: Other Proprietary

Technical requirements (IT reference)

eKT.one · Python 3.11+ · PostgreSQL 15+

ffmpeg 4.0+ (for TTS AAC conversion)

Module version: 19.0.2.2.0

Dependencies: qrcode, pdfplumber

AI: ak_ai module + Vertex AI / Anthropic API

This patient information leaflet was approved in **April 2026** (Rev. 2.0 — v19.0.2.2.0).

*This patient information leaflet is for demonstration and demo purposes only. It does not belong to a pharmaceutical product registered with TİTCK.
ekt.one is a software platform.*