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Digital Transformation in Packaging: Compliance Deadlines for E-Leaflets, QR Codes, and Anti-Tampering

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I. Introduction and Scope of the Updated Guideline

The Turkish Medicines and Medical Devices Agency ("TİTCK") has updated its Guideline on Packaging Information and Patient Information Leaflets for Medicinal Products for Human Use ("Guideline"), with its latest revision dated August 11, 2026. Issued under the Regulation on Packaging Information, Patient Information Leaflets and Tracking of Medicinal Products for Human Use ("Regulation"), the Guideline sets out requirements concerning pharmaceutical packaging, patient information, and product safety.

A significant development concerns the mandatory introduction of electronic patient information leaflets ("e-KT") for most medicinal products as of January 1, 2027. Alongside this transition, the Guideline addresses anti-tampering measures, risk warning symbols, and optional multimedia QR codes. Marketing authorization holders must assess these requirements against their existing packaging arrangements and regulatory obligations.

II. Physical Packaging Requirements: Anti-Tampering Measures and Risk Pictograms

The Guideline establishes specific measures to preserve packaging integrity and improve patient safety.

Under Chapter I, Paragraph 21, medicines subject to red and green prescriptions, as well as ordinarily prescribed medicines subject to special monitoring, must incorporate anti-tampering measures. These may include security seals, transparent outer coverings, adhesive side flaps, or perforated packaging that makes opening detectable. Importantly, this obligation does not extend to all medicinal products.

The Guideline also requires warning symbols on the outer packaging of medicines that may impair driving or machinery operation. These symbols comprise yellow, orange, and red warning triangles, reflecting different risk levels. Medicines containing relevant active substances outside the designated categories must display a separate warning pictogram without a specified risk level.

These measures must not compromise the readability of mandatory packaging information, including applicable Braille labeling requirements.

III. Digitalization: Electronic Patient Information Leaflets and Multimedia QR Codes

The transition to e-KT represents a significant regulatory development. Under Chapter II, Paragraph 2.11/A, electronic leaflets will become mandatory for most medicinal products from January 1, 2027.

However, the Guideline excludes products intended exclusively for administration by healthcare professionals, qualifying small packages, and products without outer packaging.

For products within the mandatory regime, printed leaflets will become optional, although marketing authorization holders may continue providing them alongside electronic versions. Every medicinal product must nevertheless have at least one patient information leaflet available in printed or electronic form.

Patients must be able to access e-KT through a QR code on the outer packaging without installing additional software. The code must not obstruct other packaging information and must be accompanied by the statement "Bilgilendirme medyası için kodu okutunuz" ("Scan the code for informational media").

Electronic leaflets may be provided in PDF or HTML format but cannot consist entirely of a single image file. The relevant website must also be operational before the marketing authorization holder submits its application to TİTCK.

Crucially, e-KT content must correspond to the approved patient information leaflet. Following approval of an updated leaflet, the electronic version must be updated within 30 days. Digitalization therefore facilitates access to updated information without eliminating regulatory approval requirements.

Separately, the Guideline permits optional multimedia QR codes linking to audio or audiovisual materials. Such content must remain consistent with approved patient information, although TİTCK-approved additional risk minimization materials may also be included. Marketing authorization holders must submit the prescribed commitment regarding the content.

IV. Data Protection and Digital Governance

The introduction of digital patient information also raises considerations under Türkiye's Law No. 6698 on the Protection of Personal Data ("KVKK").

While scanning a QR code does not automatically involve processing sensitive health data, websites providing access to e-KT may process personal data through IP addresses, cookies, device identifiers, or analytics tools.

Where personal data processing occurs, marketing authorization holders and relevant service providers must identify an appropriate legal basis, comply with applicable transparency and data minimization requirements, and assess any international data transfers.

The Guideline further provides that accessing e-KT must not require additional permissions beyond those arising under the KVKK. Digital platforms should also maintain the accessibility and integrity of approved medical information.

V. Compliance Deadlines and Regulatory Obligations

The Guideline establishes different implementation dates for its principal requirements.

Warning symbols concerning driving and machinery operation became applicable on **July 1, 2025**. Anti-tampering measures became mandatory for red- and green-prescription medicines on the same date, while the corresponding deadline for ordinarily prescribed medicines subject to special monitoring was **July 1, 2026**.

The principal upcoming deadline is **January 1, 2027**, when the mandatory e-KT requirements will take effect for products within their scope.

Marketing authorization holders must review their product portfolios, packaging designs, digital access systems, and regulatory submissions accordingly.

Importantly, not every packaging modification automatically requires a separate variation application. Under the applicable variation framework, changes forming part of an existing variation are addressed through that procedure, while other modifications must follow the relevant submission requirements.

For e-KT implementation, marketing authorization holders must also submit a commitment confirming that electronic content is identical to the currently approved patient information leaflet.

VI. Regulatory Enforcement and Administrative Consequences

Non-compliance with mandatory packaging or patient information requirements may expose marketing authorization holders to regulatory scrutiny and enforcement measures under the applicable pharmaceutical legislation.

Article 22 of the Regulation refers to the relevant statutory provisions governing violations and sanctions. Depending on the circumstances, regulatory measures or administrative penalties may arise where their legal conditions are satisfied.

However, the Guideline does not establish automatic suspension of batch releases, marketing authorization revocation, or fixed monetary penalties for every packaging or QR-code-related deficiency. Enforcement consequences must therefore be assessed according to the nature of the violation and the applicable legislation.

VII. Conclusion

The updated Guideline marks an important development in Türkiye's pharmaceutical packaging framework, combining physical product safeguards with increased digital accessibility.

With the mandatory e-KT deadline approaching on January 1, 2027, marketing authorization holders should prioritize reviewing their packaging compliance, digital infrastructure, and regulatory procedures.

Timely implementation will be essential to maintain regulatory compliance while ensuring patients have reliable access to accurate and up-to-date medicinal product information.

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