

WEEKLY NEWSLETTER

Metin & Cicek Attorney Partnership Weekly Newsletter



IN THIS ISSUE

Regulation Amending the Trade Inspection
Regulation Published

Regulation on Medical Laboratory Services and
Advanced Technology Medical Laboratory
Applications Published

Regulation on Amendments to the Private Health
Insurance Regulation

Presidential Decree Establishing Procedures and
Principles for Drought-Resistant Landscape
Applications Published

KVKK, Mango T.R. Tekstil Tic. Ltd. Şti.
Data Breach Notification

Regulation Amending the Trade Inspection Regulation Published

The Regulation Amending the Trade Inspectorate Regulation, published in the Official Gazette dated October 23, 2025, and numbered 32352, aims to strengthen product safety and commercial quality inspections, streamline inspection processes, and update the institutional structure of the inspectorate profession.

- Main Innovations Introduced:
- With the new regulation, Product Safety Inspection Group Presidencies have been established. These presidencies will be tasked with distributing the duties of inspectors, coordinating inspection plans, conducting training activities, and ensuring uniformity of application.
- A requirement to assign at least two inspectors to domestic market inspections has been introduced.

If multiple opinions arise during the audit process, the differing opinions will be recorded in the minutes, and the final decision will be made by the Head of the Product Safety Audits Group.

- The entrance exam system for Trade Inspector Assistant positions has been reorganized. The scope of the written and oral exams has been differentiated according to disciplines such as law, economics, finance, engineering, international trade, statistics, and biology. Exam announcements must be published in the Official Gazette at least 30 days in advance. In the qualification exam, a minimum score of 70 must be obtained separately in both the written and oral sections; two exam attempts will be allowed, and those who fail will lose their "Inspector Assistant" title.
- In the event of inspectors leaving their positions or taking extended leave, it has been made mandatory for them to return the seals entrusted to them to the relevant director.

With these changes, it is expected that the Ministry of Trade's institutional capacity in product safety inspections will be increased, the professional competence of inspectors will be strengthened, and higher standards will be achieved in the inspection processes.

In particular, the establishment of Group Presidencies is an important structural reform that will ensure the coordination of inspections in the field.



Regulation on Medical Laboratory Services and Advanced Technology Medical Laboratory Applications Published

The new regulation reorganizes the establishment, classification, licensing, operation, and supervision principles of all medical laboratories with the aim of protecting human health, preventing diseases, and effectively conducting diagnosis and treatment processes. Going beyond traditional laboratory services, the regulation also covers artificial intelligence-supported clinical decision systems, advanced technology laboratory applications, and the fields of genetic and cellular therapy. Thus, the "era of digitization and transition to high technology" in laboratory services has officially begun.

Key innovations introduced:

- Laboratories are divided into units such as biochemistry, microbiology, pathology, genetics, and tissue typing according to their service scope and technical equipment; additionally, definitions for regional laboratories, national reference laboratories, and test-based authorized laboratories have been introduced. This classification will directly affect authorization, inspection frequency, and reporting obligations.
- A legal framework has been established for the use of artificial intelligence and KDS. These systems will support laboratory specialists in their decision-making processes; the medical laboratory specialist is responsible for the accuracy of the final results and report approval. Procedures regarding the verification/validation of the systems and their usage limits are outlined in the regulation.
- Laboratory licensing criteria have been updated; special ethical, technical, and quality standards and licensing requirements have been introduced for advanced technology (gene/cell/RNA/DNA-based therapy, etc.) laboratories. Inspections will be differentiated according to classification; the role of national reference and regional laboratories has been strengthened.
- A requirement to have at least one responsible medical laboratory specialist in each laboratory has been introduced; the job descriptions of technical personnel, technicians, and specialists have been detailed. Device calibration, test validation, and quality control processes must be recorded and reported.

- Separate licensing, ethical oversight, and technical standards requirements have been introduced for laboratories in fields such as gene therapy, cell therapy, RNA/DNA-based therapy, stem cell therapy, regenerative medicine, and nanomedicine; principles for the research, storage, and data management of human tissue/cells/genetic material have been established.
- Test-based authorized laboratories and a national reference/regional network aim to ensure test reliability and standardization. Authorization for critical tests may be granted to central structures.

Legal Assessment and Compliance Requirements:

- Even if artificial intelligence systems produce results, the ultimate responsibility lies with the laboratory specialist. This means that in cases of medical malpractice and service failure, the responsibility remains with the human.
- The regulation stipulates that in cases of unlicensed activity, ethical violations, or failure to meet quality standards, activities may be suspended, licenses revoked, and administrative fines imposed.



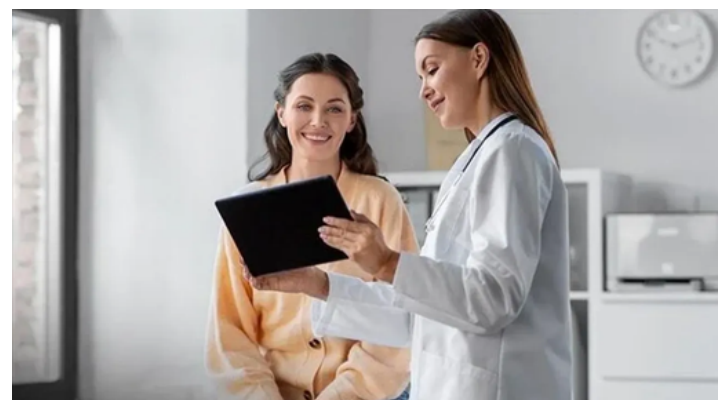
Regulation on Amendments to the Private Health Insurance Regulation

The regulation published in the Official Gazette dated October 20, 2025 introduces significant amendments to the Private Health Insurance Regulation. These amendments aim to establish new standards in the insurance sector regarding issues such as lifetime renewal guarantees, insured transfer rights, waiting periods, and age limit applications.

The amendments will come into effect on January 1, 2026; transition provisions will apply to existing policies.

Key Changes Introduced:

- Insurance companies are now required to offer policies with lifetime renewal guarantees to insured persons under the age of 60. To qualify for this guarantee, the policy must have been in continuous force for three years, and the ratio of premiums paid during this period to claims paid by the insurance company must not exceed 80%.
- Once the guarantee is provided, the insurer cannot demand extra premiums on the grounds of advancing age or changes in health status, nor can it impose restrictions on coverage.
- If policyholders meet the guarantee conditions, they will have the right to continue under the same guarantee when switching to a new insurance company.
- The waiting period will only apply during the initial policy period. The waiting period will not be reapplied in renewals under the same plan or when changing companies.
- Policyholders' health information and insurance records will be kept on an individual basis in accordance with the Personal Data Protection Law No. 6698. This information will not be shared with third parties without the policyholder's consent.



Presidential Decree Establishing Procedures and Principles for Drought-Resistant Landscape Applications Published

This Presidential Decree aims to ensure the efficient and effective use of water resources, adapt to climate change, consider local ecological conditions, and create resilient and sustainable urban landscape areas, particularly in public open-green spaces and semi-private open-green spaces located in residential areas.

- **Definition of Drought-Resistant Landscape:** These are multifunctional, sustainable landscape applications designed with plants that are resistant to drought, salinity, and heat, have low water requirements, are compatible with the local climate and natural vegetation, and take into account environmental, aesthetic, and cultural values, based on the efficient use of water.
- **Plant Selection and Use:** The use of plant landscape elements that are resistant to drought, salinity, and heat, have low water requirements, and are suitable for the local climate and natural vegetation is encouraged in landscaping. Reducing the use of turf in areas where it is not essential is recommended, and selecting drought-resistant turf types suitable for the region's climate conditions is advised in areas where turf will be used.
- **Irrigation Methods:** The use of pressurized irrigation systems and methods that provide water efficiency is encouraged. It is recommended that irrigation needs be met primarily from non-traditional water sources.
- **Zoning and Mulching:** In landscape design, zoning based on plant water requirements and usage intensity is recommended. The use of methods that increase efficiency, such as soil analysis, mulching, and zoning, is encouraged.



KVKK, Mango T.R. Tekstil Tic. Ltd. Şti. Data Breach Notification

In the data breach notification submitted to the Board by Mango T.R. Tekstil Tic. Ltd. Şti., acting as the data controller, it is summarized that:

- The breach occurred between October 6, 2025, and October 10, 2025, and was detected on October 10, 2025.
- The breach occurred as a result of unauthorized access to customer data due to the leakage of administrator credentials used to access the API of the digital marketing email system platform used by the data controller.
- The cyberattack was carried out against Mango's headquarters in Spain, and unauthorized access was gained to the personal data of all customers globally, including Turkish citizens.
- The breach affected customers' first name (no breach occurred for last name data), country, postal code, phone number, and email address information.
- The breach affected 4,349,620 individuals related to Mango Turkey,
- Affected individuals can obtain information about the data breach via email, call center, and chatbot communication tools,
- information is provided.

