



## LEGAL ALERT

October 24, 2023

**This notice contains notices related to Laws and by-laws that have come into force during the last months, the period April-October 2023, relevant to businesses. This alert should not be construed as legal advice or a legal opinion on any specific facts or circumstances. This alert is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. The contents are intended for general informational purposes only.**

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### 1. Laws

#### 1.1. Law no. 08/L-172 On General Product Safety

This Law has been enacted to ensure the safety of products introduced to the market. It outlines general safety standards for products, lays down the responsibilities of producers and distributors, mandates public information dissemination, promotes voluntary measures, and facilitates inspection surveillance to meet specific requirements.

**Safe Product Definition:** A safe product is defined as any item that, under ordinary or foreseeable use conditions, encompassing installation, operation, and maintenance requirements, poses minimal to no risk consistent with its intended use. This risk level must adhere to stringent standards aimed at ensuring the health and safety of consumers and other users.

**Producer's Liability:** The act of placing, withdrawing, or recalling products from the market does not absolve producers or distributors from criminal liability under relevant criminal laws. Complying with obligations outlined in this Law does not exempt producers from civil liability concerning damages resulting from defective products, as governed by applicable laws on obligations. Decisions to limit market placement, withdrawal, or recall, as per this Law, do not compromise the manufacturer's criminal responsibility.

**Distributor Responsibility:** Distributors are obligated to exercise professional diligence to guarantee that products meet safety requirements. Distributors are prohibited from making products available if they are aware or should reasonably presume, based on their professional knowledge, that the products are hazardous.



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**Public Access to Risk Information:** Information about risks associated with products affecting consumer and user health and safety, including product identification, nature of risks, and actions taken, must be accessible to the public. Transparency principles guide the sharing of this information, despite any constraints imposed by monitoring and research activities. Details about product identification, risk nature, and actions taken must be particularly accessible to the public.

**Inspection Surveillance:** Competent inspectorates are tasked with enforcing this Law and related sub-legal measures. They carry out inspection surveillance within the scope of their defined responsibilities and obligations outlined in this Law, along with relevant market surveillance laws and regulations pertaining to groups of products subject to inspection surveillance.

**Fines for Non-compliance:** Legal entities may incur fines ranging from four thousand (4,000) Euros up to twelve thousand (12,000) Euros for violations.

In summary, this Law is designed to ensure the safety of products entering the market by establishing safety standards, outlining producer and distributor responsibilities, promoting transparency, facilitating inspection, and enforcing compliance through penalties.

## **1.2. Law no. 08/L-220 on the Price of Medicinal Products**

The recently implemented law in the Republic of Kosovo focuses on governing the production, quality control, marketing authorization, registration, import, trade, clinical trials, and supervision of medicinal products and medical devices. Its primary objective is to ensure the availability of safe, effective, and high-quality medicinal products for the citizens of Kosovo.

The law applies to a broad range of entities, including public authorities, public and private enterprises, and individuals engaged in activities related to medicinal products and medical devices. It encompasses various product categories, such as those containing radioactive substances, immunologic preparations, blood products, medical gases, vitamins, herbal and mineral preparations, cosmetic preparations with therapeutic attributes, and more.

The law comprehensively addresses several key areas, including:

- Manufacturing standards and procedures for medicinal products and medical devices.
- Quality control measures and classifications for products.
- Authorization processes for marketing, registration, and importation.
- Ongoing supervision and pharmacovigilance to ensure product safety.



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- Oversight of clinical trials and research involving medicinal products.
- Regulations governing veterinary medicinal products.
- Wholesale trade of medicinal products.
- Establishment of fees and related matters.

The pricing of medicinal products and the determination of margins for both medicinal products and medical devices fall under the authority of the Kosovo Medicines Agency (KMA) and the Ministry of Health. These regulatory bodies collaborate with other relevant ministries to establish pricing frameworks in accordance with specific sub-legal acts.

### **3. Law no. 08/L-191 for Judicial Experts**

The publication outlines the scope of a law that focuses on licensing procedures for experts and entities engaged in expertise activities. It covers the conditions, methods, rights, and responsibilities associated with licensing. The document also explains the fundamental principles that guide expert work and defines the prerequisites for obtaining an expert license.

The law also governs the conditions for licensing experts affiliated with legal entities, which encompasses the establishment of the Expert Registry.

The Ministry is mandated to create an official registry exclusively for experts. This Registry is mandated to be made public on the official websites of the Ministry of Justice, the Kosovo Judicial Council (KJC), and the Kosovo Prosecutorial Council (KPC). Furthermore, the Ministry reserves the right to commence disciplinary procedures against an expert, particularly when prompted by a formal proposal from a pertinent institution.

It is important to note that relevant institutions are exclusively authorized to designate experts for appointments. These appointments are to be drawn from the Expert Registry issued by the Ministry. The selection process is executed in a sequential manner as dictated by the registry's order. This selection can be made either ex officio or in response to a request submitted by involved parties.

### **4. Law no. 08/L-201 on Amending and Supplementing Law no. 05/L-081 on Energy**

The law aims to amend and complement the existing Energy Law (Law No.05/L-081) to establish energy conservation measures during times of emergency, oversee the enforcement of these measures, and outline penalties for non-compliance.

**Energy Targets:** The government is responsible for defining yearly and long-term objectives for the use of renewable energy sources in electricity consumption, thermal energy generation through renewables and cogeneration, and renewable energy use in



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transportation. The long-term targets, spanning ten years, are established through sub-legal regulations approved by the Ministry.

**Emergency Measures:** In cases of emergencies declared as per Article 25 of the Basic Energy Law, the Minister has the authority to introduce energy-saving measures applicable to public institutions, individuals, and legal entities.

**Supervision and Enforcement:** The implementation of energy-saving measures, specified under Article 25A, is overseen by various entities including the Energy Inspectorate, Market Inspectorate, and Municipal Inspectors. Additionally, the Kosovo Police can offer support as requested by relevant bodies.

**Penalties:** Anyone found in violation of the energy-saving measures outlined in Article 25A faces fines, as follows:

Legal persons: €300 to €900

Natural persons conducting individual businesses: €100 to €300

Natural persons or individuals responsible for legal entities: €50 to €150

This law's purpose is to extend the Energy Law to include provisions for energy conservation during emergencies, ensuring adherence through supervision and penalties.

### **5. Law no. 08/L-102 on Amending and Supplementing the Law no. 04/L-139 on Enforcement Procedure, Amended and Supplementing by the Law no. 05/L-118**

The amendment to the law encompasses various significant aspects. Firstly, it explicitly defines what constitutes a "public institution." Secondly, the amendment grants exclusive authority to the private enforcement agent for determining the execution procedure and application of enforcement related to court decisions, specifically those related to competences arising from employment relationships. Additionally, the law establishes that revenues originating from emergency packages or specific measures sanctioned by the Government for extraordinary or urgent scenarios, like pandemics or natural disasters, are safeguarded from enforcement actions.

Regarding enforcement cases where a public institution serves as the creditor, these cases will be directed to the Chamber. The scope of these cases, as stipulated in section 4a.2, incorporates both the enforcement proposal and the enforcement document or an authenticated document.

A noteworthy provision within the amendment designates the Chamber with the responsibility of equitably allocating the cases received from public institutions among the private enforcement agents. These agents, in turn, bear the responsibility of managing the enforcement process, including scheduling, implementation, case administration, and the exchange of data via applicable public and other legally accessible registers. This includes

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compliance with provisions allowing access to specific registers. Furthermore, private enforcement agents are obligated to report on their activities via the central electronic system established by the Ministry of Justice.

To summarize, this amendment brings clarity to the definition of public institutions, confers authority upon private enforcement agents for execution and enforcement decisions linked to employment-related competences, protects specific funds from enforcement in extraordinary situations, and outlines the procedural framework for enforcement cases involving public institutions and the roles of private enforcement agents.

## 2. Administrative Instructions and Regulations

### 2.1. Administrative Instruction no. 08/2023 on the Procedure for Registration of Trademarks

This Administrative Instruction serves as a comprehensive guide governing the processes related to trademark registration at the Agency for Industrial Property. It plays a crucial role in bringing clarity and structure to the trademark registration procedure. The instruction meticulously outlines various aspects, including the content requirements for trademark applications, establishing the procedure for the formal examination of applications. Additionally, it delves into the specifics of the Internal Regulation, which governs the use of collective and certificate marks by regulating owners. By defining these procedures and requirements, the Administrative Instruction ensures a transparent and standardized approach to trademark registration, promoting fairness, consistency, and adherence to legal standards in the realm of industrial property.

### 2.2. Regulation no. 07/2023 on the Procedure for Determining and Verifying Reciprocity, Conditions, Content and Manner of Maintaining the Database for Acquiring the Property Right over immovable property by foreigners in Kosovo

This regulation is designed to oversee the process of establishing and confirming reciprocity, specifying the designated authority responsible for reciprocity assessment, outlining the prerequisites, defining the information and protocols for maintaining a database regarding reciprocity status with specific nations, and addressing the acquisition of property rights by non-citizens within the Republic of Kosovo.

The determination and verification of reciprocity are initiated upon the request of a foreign individual seeking to acquire ownership rights of specific immovable property or the person intending to sell said real estate. Throughout the reciprocity verification process, the Ministry gathers information about how property rights are governed by the legislation of



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the foreign citizen's home country. This includes the methods employed for the acquisition of property rights by natural or legal persons in the Republic of Kosovo, particularly in properties of similar type and located in the same area. Upon receiving data from the foreign legislation, the Ministry initially confirms whether, according to that state's laws, a citizen or legal entity from the Republic of Kosovo can indeed attain ownership rights over a similar property in the same area, following the procedures and conditions required by the foreign citizen.

If the Ministry determines that a citizen or legal entity from the Republic of Kosovo has the potential to acquire ownership rights over immovable property of the same type situated in the same area in the foreigner's country, it proceeds to assess whether the legislation of that state outlines comparable conditions for foreigners to obtain property rights over similar types of immovable property in the same area. Following these evaluations, if it is established that, according to the foreign legislation, a citizen or legal entity from the Republic of Kosovo cannot acquire ownership rights over the same property situated in the same area under the conditions requested by the foreign citizen, the Ministry issues a decision declaring the absence of reciprocity, and consequently, the rejection of the foreign citizen's request.

Furthermore, it is important to note that a foreign person, whose request for consent to acquire ownership rights has been rejected, is prohibited from reapplying for consent for the same property until a period of five (5) years has elapsed from the date of the initial rejected submission.

## About Our Practice

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