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"This Newsletter as relevant December 13, 2023 has been written in general terms and should be seen as a broad guidance only. Nothing in this Newsletter is intended nor should be construed as a legal advice or guarantee from LTD "Nodia, Urumashvili & Partners" on the positive result of any legal proceeding with regard to the legal opinions provided herein."

1. Amendments to the Law of Georgia "On Entrepreneurs"

On November 30, 2023, the Parliament of Georgia adopted amendments to the Law "On Entrepreneurs" in the third reading. According to the amendments:

- Individual entrepreneurs and nonentrepreneurial (non-profit) legal entities are no longer obliged to bring constituent documents in line with the new Law on Entrepreneurs (including the obligation to register on the portal); in the latter case, they will still be given the right to do so voluntarily;
- 2. In addition, the deadline for businesses to bring their constituent documents in line with the new law will be postponed by one year and 3 months, until April 1, 2025. However, during the next year after the expiry of this deadline without any result, the powers of persons authorized to represent the enterprise will be restricted (which means restricting the possibility to dispose of property, participate in tax operations, management of bank accounts, open a new account, dispose of money in the account, take a loan).
- 3. The amendment also provides that if the documentation is not updated even before January 1, 2026, an additional period of 3 months will be set for the company, and only after its unsuccessful expiration the registration of the company will be canceled. If assets are available, liquidation procedures can be initiated.
- In addition, the amendments provide for an 4. exception, according to which the registration of an enterprise may be canceled on the basis of a voluntary application from May 1, 2024. In particular, the amendment provides that a partner/partners of an enterprise (other than a sole entrepreneur) whose ownership interest exceeds 50 percent shall have the right to apply to the registering authority with a request to cancel the registration of the enterprise. According to the amendment, at the time of such an application, cancelation of the registration of

the enterprise may be carried out if the following conditions are simultaneously present:

- (a) As of the date of the application and within the last 5 years prior to that date, the enterprise has not been registered:
- a.a) as the owner of an immovable included in the state register;
- a.b) as an owner of a share of another enterprise included in the register of entrepreneurs and entrepreneurial and non-entrepreneurial (non-profit) legal entities;
- b) as of the date of application and within the last 5 years prior to this date there is no vehicle registered in its balance in the registration database of the Service Agency of the Ministry of Internal Affairs of Georgia;

c) according to the data of the LEPL Revenue Service of the Ministry of Finance of Georgia, the enterprise has no tax debts, has not submitted a tax/customs return and has not paid the relevant tax declaration/fee in accordance with the legislation of Georgia as of the date of submission of the application and for the last 5 years prior to this date.

2. Law of Georgia "On Electronic Commerce"

The Parliament of Georgia enacted the "On Electronic Commerce" Law on June 13, 2023, set to be enforced 190 days after its publication on June 30, 2023. This groundbreaking legislation marks the initial regulation of activities pertaining to electronic commerce and information society services. It outlines the responsibilities of those offering these services, including intermediary service providers. The law also governs the concept of electronic contracts and their signing criteria within the realm of information society services, defining a service provider as a natural person or entity providing such services.

A crucial aspect highlighted in the law is that ecommerce and information society services do not require specific licenses or permits to commence. However, this exclusion doesn't apply when the Georgian law establishes a licensing regime for these services, necessitating licenses, permits, or authorizations for the principal activity, exempting it from this law.

To safeguard the rights of service recipients in ecommerce transactions, the law meticulously delineates the minimum information about the service provider that must be permanently available to the recipient. Additionally, it mandates the protection of personal data of involved parties and specifies liability rules for violations of this data protection obligation.

An important provision mandates that information outlined in Chapters II and III of the law must be provided in the official language of Georgia. Nonetheless, the law empowers service providers to furnish this information in other languages of their preference, supplementing the requirement.

Moreover, the law establishes the obligation of the Georgian National Competition Agency to address potential violations arising from the failure to provide requisite information upon the service recipient's complaint. It delineates the procedures and penalties for service providers in cases of noncompliance or inadequate adherence to the Agency's decisions.

3. Law of Georgia "On Voluntary Private Pension"

On June 28, 2023, the Law "On Voluntary Private Pension" was published in the Legislative Herald of Georgia. The law regulates the rules and conditions for the organization and implementation of private pension voluntary schemes, their supervision and participation in schemes and the issues of guaranteeing the protection of the participants. With the adoption of the mentioned law, the Law of October 30, 1998 of Georgia "On the Provision of Non-state Pensions and Non-state Pensions Insurance" was declared invalid. This law aligns with obligations stemming from the Association Agreement and complies with European directives, prompting amendments to nearly 15 laws.

It is worth noting that the law applies to Georgiabased pension companies, Georgia-based asset management companies and insurers that carry out voluntary private pension activities; also, to voluntary private pension schemes registered in Georgia (hereinafter - pension scheme) and other individuals and legal entities involved in voluntary private pension activities. It is not allowed to carry out the voluntary private pension activity provided for in this law both in Georgia and outside of its scope without the license and registration and/or prior consent of the service provided for in this law.

Voluntary private pension activities include registration/establishment of a pension scheme, administration pension scheme, of the accumulation and accounting pension of contributions, formation of pension savings, investment of voluntary private pension assets and regular issuance of voluntary private pensions. This law does not apply to: state, autonomous republics and municipal bodies, national, regional and local bodies and institutions of foreign countries that manage social insurance or mandatory pension system funds; the pension scheme defined by the law of Georgia "On Cumulative Pension", the pension schemes based outside of Georgia offered international financial and diplomatic by institutions to their employees in Georgia. It is also noted that the pension schemes regulated by this law are the contribution pension schemes only. Within the framework of the same law, no pension scheme registered in Georgia can be offered as a defined benefit pension scheme, in which the payment of a voluntary private pension depends on the participant's earnings history, length of service and age and is not directly related to the pension contributions and related benefits made in his/her favor.

The law defines both group and individual pension schemes, allowing individuals (including the selfemployed) to join an individual pension scheme alongside existing state or accumulated pension schemes stipulated by the Law of Georgia "On Accumulated Pension". He/she can participate in an individual pension scheme established and registered by an asset management company or an insurer. Both an employed individual and any other individual (including the self-employed) can participate in the individual pension scheme.

The law determines when a person becomes a pension scheme participant. In the case of both individual and group schemes, it is important to sign the pension scheme agreement, the essential conditions of which are determined by the law itself. The law also provides for the unconditional rights of employees participating in group pension schemes established by the employer, employers' union and employees' union to the pension contributions made by the employer.

The law defines in detail the rules for establishing and licensing a pension company. In the same part, it establishes requirements for foreign pension organizations. In particular, a foreign pension organization is authorized to register a pension scheme in Georgia in accordance with this law only if it has the relevant permission of the appropriate foreign supervisory body and its activities are subject to prudential regulation taking into account the standards of reliability, security and transparency. A foreign pension organization is authorized to register a pension scheme in Georgia and to carry out voluntary private pension activities without additional licensing, based on recognition by the Service and through a branch established in accordance with the Law of Georgia "On Entrepreneurs". The Service determines the procedure and rules for recognizing foreign pension organizations and exempting them from fulfilling certain requirements.

The law also contains requirements for pension scheme registration. It is important to note that all registered pension schemes must use the services of duly authorized specialist depositories. In addition, the pension company should use the services of legally independent asset management companies and specialized depositories, which should not be owned or managed by the same entity or closely related entities. The functions of specialized depositories, norms of management of conflict of interest and cases of termination of authority are determined by law.

Beyond that the law provides for the merger of pension companies, the cancellation of the voluntary private pension activity license and the liquidation of the pension company. In addition, it is noted that the supervision of voluntary private pension activities is carried out by the Service, and within the framework of this law, the supervision and additional regulation of the specialized depository and asset management company is carried out by the National Bank of Georgia. The law also contains the rules concerning the breach of fiduciary duty and dispute resolution.

Lastly, founders of non-state pension schemes registered before January 1, 2025 are obliged to ensure compliance of their activities with the requirements of this law until January 1, 2026, otherwise, the service will carry out the procedures for canceling the registration of the pension scheme provided for by this law.

4. Amendments to the Law of Georgia "On Insurance"

The adjustments made to Georgia's Insurance Law are interconnected with the introduction of the Voluntary Private Pension Law. This new legislation oversees the operations of private pension entities. Starting January 1, 2025, oversight of insurance and voluntary private pension activities within the boundaries set by the Voluntary Private Pension Law will be managed by an independent regulatory body known as the Service, established by the state to govern the insurance sector. The Service's responsibilities, objectives, functions, and authorities are defined by both the Voluntary Private Pension Law and this Law. Further operational aspects are regulated by the Service's sanctioned Regulations by the Georgian Government.

Additionally, the rights of participants or beneficiaries, as outlined in the Voluntary Private Pension Law, are now assured. This includes the right to lodge a complaint with the asset management company, insurer, pension company, or the Service if any of these entities fail to fulfill their legal obligations.

The alterations also specify that the Service has the power to promptly implement sanctions, particularly those imposed through administrativelegal measures, based on enforcement orders issued in line with legally effective administrativelegal actions, as established by the Enforcement Proceedings Law of Georgia. The Service can enforce sanctions specified in the Voluntary Private Pension Law upon pension companies, insurers, and their administrators as per the conditions outlined in the same law.

Furthermore, the definition and entities covered by insurance were expanded to include the concept of annuity, a form of life insurance that can be for a fixed period or for the duration of one's life. Only insurers possessing a life insurance license are permitted to issue life annuities.

Lastly, amendments were made concerning insolvency proceedings. These revisions specify the requirements of creditors based on life insurance policies. The amount of life insurance liabilities for collectible and returnable life insurance types is determined by the life insurance reserve. In insolvency proceedings, these liabilities fall under third-order claims, while pension assets outlined in the Voluntary Private Pension Law are excluded from the insolvency/bankruptcy estate. outlined Enforcement measures in the Enforcement Proceedings Law of Georgia do not apply to these assets concerning actions against insurers.

5. New Law of Georgia "On Personal Data Protection"

On March 1, 2024, the new law on Personal Data Protection comes into effect, which, inter alia, approximates the legislation of Georgia with Regulation 2016/679(GDPR) of April 27, 2016 and the legislation of the European Union and imposes a number of new obligations and requirements for personal data processing.

Specifically, the law underwent changes that modified the definitions of "personal data" and "special category personal data," while also providing clearer guidelines on the principles governing the processing of personal data. Notably, significant alterations were made to the regulations concerning video surveillance, audio monitoring, and data processing for direct marketing purposes. For instance, in the context of video monitoring, the individual responsible for processing is now mandated to establish in written form the purpose and extent of video surveillance, its duration, the period for retaining video recordings, the protocols for accessing, storing, and erasing video recordings, as well as mechanisms ensuring the protection of data subject rights. This requirement, however, does not apply if an individual conducts video monitoring within a residential building.

Furthermore, under the new law, data processing for direct marketing purposes is permissible only upon obtaining explicit consent from the data subject. An obligation has been introduced wherein the data processor or authorized personnel must, before seeking the data subject's consent and during direct marketing activities, clearly and plainly explain the right of the data subject to withdraw consent at any time and elucidate the procedure for doing so.

In addition, in accordance with the GDPR, the following rights of data subjects were considered in the law:

- the right to receive information about data processing;
- the right to access and receive a copy of the data;

- the right to correct, update and complete data;
- the right to stop, delete or destroy data processing;
- the right to block data;
- the right to transfer data;
- the right to automated individual decisionmaking and related rights (right to refuse profiling)
- the right to withdraw consent;
- the right to appeal

Under the new legislation, specific obligations will be enforced starting November 1, 2024. This primarily concerns the requirement to designate a personal data protection officer and conduct a thorough data protection impact assessment.

According to the updated law, various entities such as public institutions, insurance organizations, commercial banks, microfinance institutions, credit bureaus, electronic communication companies, airlines, airports, medical institutions, and individuals responsible for processing or authorized for processing data-particularly those handling a substantial volume of data subjects' information or conducting systematic and extensive monitoring of their activities-are mandated to appoint or designate a personal data protection officer. This appointed individual must possess adequate expertise in data protection and is responsible for ensuring compliance with assigned legal obligations. Their duties encompass developing pertinent policies, internal regulations, documentation, and liaising with the personal data protection service.

It is important to note that, as per the law, the role of the personal data protection officer can be fulfilled either by an existing employee or by other individuals under a service contract, such as legal company employees operating via outsourcing agreements.

6. Labor Code of Georgia

The changes introduced in the Defense Code of Georgia have led to specific additions in the Labor

Code of Georgia. These amendments outline additional provisions for employee leave:

- A) State of War or State of Emergency Participation Leave: Employees are entitled to an extra paid leave once, for a maximum of 15 calendar days, following their participation in a state of war and/or state of emergency.
- B) Peace Operation Rotation Completion Leave: After the conclusion of the rotation period in a peace operation and upon return to Georgia, employees are granted a paid leave of 30 calendar days.

Importantly, additional these paid leave entitlements do not require an 11-month waiting period for activation, unlike other leave Additionally, entitlements. employers are prohibited from dictating the order or manner in which employees must utilize this particular leave.

7. Law of Georgia on "Copyright and Related Rights"

The amendments introduced to the Law of Georgia on Copyright and Related Rights, effective from September 1, 2023, focus primarily on refining the system for managing property rights associated with copyright and related rights. These changes primarily address collective management issues and aim to ensure robust protection of intellectual property rights.

Article 63 of the Law, which addresses the creation of collective management organizations for property rights, underwent substantial revision. The revised article specifies that authors of scientific, literary, and artistic works, performers, producers of phonograms and videograms, and other holders of copyright and related rights have the authority to establish collective management organizations. Notably, the management of property rights for a specific right or category of rights is designated to a single collective management organization. To engage in such activities, these organizations must obtain accreditation from a commission comprising representatives from the Georgian government, parliament, and the chairman of Sakpatenti. The criteria and process for accreditation, as detailed in Article 64, include requirements such as confirming representation of right holders, allowing any right holder to join the organization in accordance with its charter, possessing necessary resources for royalty collection, and implementing effective mechanisms for royalty collection, distribution, and payment.

Additionally, Article 66, a newly added section, defines the functions, rights, and obligations of these collective management organizations, emphasizing that their activities must align with the interests of the rights owners they represent. The law also stipulates that the maximum rights management fee cannot exceed 20 percent of the collected royalties by the collective management organization. Furthermore, the organization must inform the rights holder about the rights management fee and any deductions from the collected royalties before acquiring the management permit.

The Law establishes rules for the collection and distribution of royalties, requiring these organizations to distribute income diligently and fairly among the rights owners whose rights they manage, based on agreed-upon principles detailed in Article 66⁴. Moreover, Article 66⁴ outlines guarantees to the management organization on property rights and specifies the rights holder's authority to terminate contracts regarding rights transfer to the organization.

Additionally, procedures for setting tariffs and rights holders receiving appropriate royalties before their rights' use are outlined. The collective management organization is mandated to publish tariff plans on its website and collaborate with "Sakpatenti" to make them publicly available. These amendments enforce several obligations on the collective management organizations. For instance, Article 66⁷ mandates these organizations to provide annual information to each rights holder regarding royalties received, amounts paid to rights holders by category of rights and type of use, and deductions implemented as rights management fees. Article 66⁸ defines obligations to other collective management organizations based on representative agreements.

In pursuit of transparency, the amended Law mandates these organizations to publish certain information, including their charter, membership rules, termination of rights management permits, rights management fee details, and general rules for royalty distribution, on their website. Annual reports must also be produced and made publicly available to ensure transparency in their activities.

Furthermore, Sakpatenti is designated as the supervisory body for activities related to collective management of property rights of rights holders, tasked with ensuring compliance with Georgian legislation and decisions pertaining to copyright and related rights. It holds the authority to request reports on the organization's activities at any time and can instruct audit firms to conduct investigations if necessary, with the organization bearing the costs if any violations are found.

Notably, the amendments allow for the possibility of terminating accreditation if organizations fail to meet their obligations, with Sakpatenti having the authority to make such decisions in accordance with the General Administrative Code of Georgia.

8. Waste Management Code

Starting September 1, 2026, revisions to the Waste Management Code will take effect, driven by the need to align it with the fresh legal guidelines outlined in Georgia's draft law on "Industrial Emissions." These amendments introduce a novel permit category, namely the integrated environmental permit, which becomes obligatory for activities specified under Georgia's "Industrial Emissions" legislation. Specifically, any individual conducting activities outlined in the "Industrial Emissions" law must acquire this particular permit. The legislation also outlines the specific documentation necessary to secure an integrated environmental permit.

9. Law of Georgia "On Radiation Safety, Nuclear Security and Protectiveness"

On June 16 of 2023, the Law on Radiation Safety, Nuclear Security, and Protectiveness was enacted, rendering the previous Law of Georgia on Nuclear and Radiation Safety obsolete, excluding its fourth chapter, which governs the authorization system for nuclear and radiation activities and the protocol for issuing licenses and permits. This segment of the prior law will become void starting in 2026.

The primary objective of this new law is to address identified regulatory issues and bring conformity with international standards, implementing recommendations outlined by experts from the International Atomic Energy Agency (IAEA).

While the general jurisdiction of state agencies concerning radiation safety, nuclear security, and protectiveness remains unchanged, the law consolidates their competencies into a single chapter, categorized by different thematic directions, aiming to enhance the effectiveness of the regulatory framework.

The law imposes strict prohibitions on activities associated with nuclear weapons, explosive devices containing nuclear material, controlling or cooperating in their development, and the nonpeaceful use of nuclear or radioactive materials.

In addition, it was specified and additionally prohibited:

- Deliberately adding radioactive substances to food, toys, jewelry, cosmetics, and consumer products, as well as importing, exporting, and/or placing these items on the market.
- Use of living or working space contaminated with radionuclides, if the level of pollution exceeds the permissible level of pollution established by the legislation of Georgia.
- Importing, exporting and/or placing on the market a consumer product contaminated with radionuclides, if the level of contamination exceeds the permissible level of contamination established by the legislation of Georgia.
- Transit of radioactive waste on the territory of Georgia, import of radioactive waste generated outside Georgia and re-export of radioactive waste.

The law specified and expanded the rights of natural persons, in particular, a natural person has the right to:

- a) receive complete, objective and timely information about the radiological situation in his/her work and living spaces, including the nuclear or radiological emergency, in accordance with the procedure established by the legislation of Georgia;
- b) live and work in a radiation safe environment;
- c) participate in consideration and adoption of important decisions related to issues regulated by this law;
- apply to the court for the protection of his/her right in relation to the issues regulated by this law.
- *10. Resolution of the Government of Georgia "On Procedure for Issuing Construction Permits and Permit Conditions for Facilities of Special*

Importance (including Radiation or Nuclear Facilities)"

Regarding the energy efficiency of buildings, the specific document to be presented to the agency for approval of architectural designs, construction, and/or technological schemes has been defined. To comply with the regulations, the customer is required to submit, before June 30, 2025, either an expert report or evidence demonstrating adherence to the national program outlined in the Government of Georgia's resolution efficiency minimum energy concerning standards for buildings, sections of buildings, or building components. Post-June 30, 2025, the customer must provide an expert report prepared by authorized experts, aligning with the minimum energy efficiency requirements for buildings, sections of buildings, or building elements determined by the Government of Georgia's decree based on the national program (with exceptions as specified in the law).

11. Order #78/m (November 2, 2023) of the Minister of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia on the Procedure for Issuing a Certificate of Pharmaceutical Product (CPP) and Approval of the Form of the Certificate

The Minister of Internally Displaced Persons from the Occupied Territories, Labor, Health, and Social Affairs of Georgia has endorsed the protocol governing the issuance of a certificate of pharmaceutical product (CPP).

The LEPL Regulation Agency for Medical and Pharmaceutical Activities (referred to as the Agency henceforth) oversees the issuance of the certificate of pharmaceutical product (CPP) under the state supervision of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health, and Social Affairs of Georgia.

Each certificate of pharmaceutical product (CPP) is designated for a singular dosage, a specific dosage form, and a particular quantity of a pharmaceutical product with a distinct name.

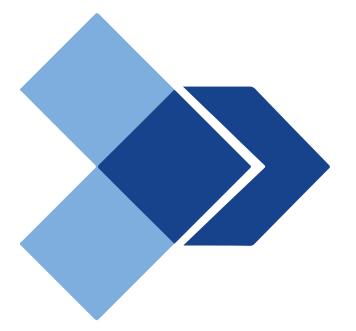
Issuance of a certificate of pharmaceutical product (CPP) is solely granted to a pharmaceutical product manufactured by a company holding certification validating compliance with the Georgian national GMP (good manufacturing practice) standard, and the said pharmaceutical product must be registered within the Georgian market.

To ensure transparency, information regarding the issuance or denial of a certificate of pharmaceutical product (CPP) is made publicly available on the Agency's official website: www.rama.moh.gov.ge.



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