## Legal Regulatory Guide Russia Q3-Q4 2023

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### Table of contents

INTRODUCTION
LIFE SCIENCES 4
An experiment on the traceability of the origin of pharmaceutical substances4
Harmonisation of Russian and EAEU legislation
Extension of the national registration of medical devices at the EAEU level until the end of 2025
Extension of counter-sanctions measures5
TMT
Significant increase in the state fee for obtaining a licence in the telecommunications sector7
Russian Parliament proposes limiting foreign research of the consumer market
Roskomnadzor's control over the website preventing circumvention and mass VPN blockings
Key changes in Russian Internet regulation in 2023: requirements for hosting providers and new rules for authorization10
CONSUMERS PRODUCTS
Significant changes in the regulation of tobacco products
Further development of the labelling system
GENERAL REGULATORY 15
Environmental ban on packaging and the development of the EMR system
Russia extends a number of regulatory counter-sanctions
Russian Government extends the simplified procedure for importing and assessing the conformity of products for a year 17

## Introduction

#### Dear Readers,

As the Russian market continues to adapt to the ever-changing economic landscape, it is crucial to stay abreast of the latest regulatory trends that shape the business environment. The second half of 2023 featured a confluence of regulatory developments that will significantly impact businesses operating within the country. This guide serves as an essential resource for navigating the nuanced regulatory landscape with valuable insights into the integration initiatives within the Eurasian Economic Union (EAEU), the extension of countersanctions measures to safeguard the national market, as well as changes in Technology, Media, and Telecommunications (TMT) and ESG regulations that are reshaping the legislative framework.

As part of international trade and economic collaboration, the integration efforts within the EAEU are a central focus of regulatory developments. As the EAEU continues to strengthen its economic ties, businesses must carefully assess and adapt to the evolving regulatory framework to capitalize on emerging market opportunities and mitigate potential challenges.

Furthermore, counter-sanctions measures that aim to protect the national market and enhance the competitiveness of domestic industries were prolonged in the second half of 2023. With a keen understanding of these measures and their implications, businesses can proactively adjust their strategies and operations to align with the evolving trade dynamics, thereby ensuring compliance, while also unlocking growth opportunities in the Russian market.

Moreover, as technology continues to reshape the business landscape, additional regulatory developments in TMT are set to come into effect. As they adapt to the ever-changing technologies, these regulations will introduce new compliance requirements and standards for businesses operating in these sectors. In parallel, the regulatory landscape in Russia is poised to take certain steps in line with ESG trends, such as amendments to ecological and packaging legislation. The integration of ESG considerations into the legislative framework reflects a broader global trend towards sustainable and responsible business practices.

This guide serves as an indispensable tool for staying ahead of the curve and harnessing opportunities amidst these transformative regulatory trends and technological advancements in Russia.



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## Life Sciences

## An experiment on the traceability of the origin of pharmaceutical substances

According to a <u>Decree of the Ministry of</u> <u>Industry and Trade of the Russian Federation</u>, the experiment will run from 15 October 2023 to 31 December 2024. The Decree established the list of pharmaceuticals subject to tracing, including insulin and its salts (EAEU HS code 2937 12 000 0), antibiotics (2941), lidocaine (2924 29 100 0), etc.

This experiment is being introduced as part of new mechanisms to support local production. Government bodies are proposing a new mechanism to support investment projects that aim to ensure the full production cycle of pharmaceutical substances. In addition, there is a government decree about the "third odd one out". There is a proposal to make it into the "second odd one out" for the state procurement of drugs produced in a full cycle on the territory of the EAEU. Thus, if a manufacturer offers a drug created using a full cycle for purchase, it will receive unconditional priority over all other offers.

The federal executive authorities in charge of the experiment are the Ministry of Industry and Trade, the Ministry of Health, the Ministry of Digitization, the Federal Security Service, the Federal Tax Service, the Federal Customs Service and the Federal Service for Surveillance in Healthcare (**"Roszdravnadzor**"). The operator of the information system for the experiment is the Centre for Advanced Technology Development (CATD). The Ministry of Industry and Trade is responsible for coordinating the actions of the participants in the experiment.

#### Harmonisation of Russian and EAEU legislation

Draft Law No. 416454-8 "On Amendments to the Federal Law "On the Circulation of Medicines" on the introduction of the unified regulation of the circulation of medicines within the EAEU (the "**Draft Law**") was adopted in the first reading by the State Duma.

The Draft Law contains proposals in the interests of drug importers and manufacturers to simplify or cancel certain documentation and registration requirements. It also contains amendments that make it possible to register generics before the patent for the original medicine expires.

The Draft Law aims to solve the problem of the data exclusivity period, which arose after the transition to EAEU legislation. Russian law previously envisaged a data exclusivity regime and prohibited applications for registration before the expiration of the exclusivity period. On the contrary, EAEU law did not regulate this period of data protection in any way. If the amendments are adopted, the Ministry of Health will have no grounds to reject applications submitted before the expiration of the exclusivity period.

Moreover, the Draft Law envisages the introduction of new definitions (namely "hightech medicines", "genotherapeutic medicines based on somatic cells") into the Federal Law "On the Circulation of Medicines" as well as the finalization of old definitions in order to bring it into compliance with the EAEU legal acts. Furthermore, the amendments expand the powers of Roszdravnadzor by providing access to data from the registration dossier of medicines.

## Extension of the national registration of medical devices at the EAEU level until the end of 2025

The State Duma has adopted <u>Federal Law No.</u> <u>394-FZ dated 31 July 2023</u> on the ratification of the protocol extending the national registration of medical devices until 31 December 2025 (the "**Protocol**").

The Protocol provides a possible extension for submitting an application for an expert examination or the registration of a medical device in accordance with the procedure envisaged by the legislation of an EEU member state, i.e. national legislation. The provisions of the Protocols aim to preserve national systems for the registration of medical devices to avoid a threat of shortages. The extension of the term established by the Protocol allows EEU member states to improve the system required for the transition to the unified single registration of medical devices, including clinical centres and testing laboratories.

#### Extension of counter-sanctions measures

Counter-sanctions measures have been extended. The details of key counter-sanctions measures currently in force are given below:

A) First, the simplified procedure for the registration and import of medicines has been extended until 31 December 2024 by Government Decree No. 824 dated 27 May 2023. This procedure is possible with or without a quality expert examination and is carried out within a shortened thirty-day period.

A special interdepartmental commission confirms whether there is a shortage or a risk thereof. In addition to the Ministry of Health, the commission includes representatives of the Ministry of Industry and Trade, the Customs Service, the Federal Service for Veterinary and Phytosanitary Supervision (Rosselkhoznadzor) and other state bodies. The simplified procedure is applied if it is determined that there is a risk or shortage of medicines due to the imposition of sanctions.

B) Second, Roszdravnadzor issued Order No. 2983 dated 16 May 2023 to approve the list of information on non-original spare parts for the maintenance of medical devices and the list of documents for registering such spare parts and their manufacturers.

The information includes documents on the analysis, assessment and risk management of the operation of spare parts, information on their repair, a warranty letter confirming the possibility of testing and information on the safety of joint use. In addition, there is an additional list of documents that manufacturers must submit for an expert examination, which includes technical documentation for non-original spare parts and an installation and dismantling manual.

C) Moreover, the ban on the export of medical devices from Russia has been extended until 31 December 2025 by Presidential Decree No. 540 dated 20 July 2023. Since 2022, the government has established the list of products and equipment banned for export, which contains more than 200 products, including pharmaceuticals. The list was subsequently expanded, and Roszdravnadzor approved the procedure for issuing permits for the export of medical devices from the country.



### TMT

## Significant increase in the state fee for obtaining a licence in the telecommunications sector

Starting from 1 January 2024, the state fee for obtaining a licence from the Federal Service for Supervision of Communications, Information Technology and Mass Media (**"Roskomnadzor"**) for the provision of telecommunication services will be substantially increased from RUB 7,500 (approx. USD 85) to RUB 1 million (approx. USD 11,000)<sup>1</sup>. The respective federal law amending the Tax Code of the Russian Federation was adopted on 21 September 2023.

#### This increase will only affect

telecommunications services that are subject to a mandatory licence requirement to ensure compliance with the requirements for networks and means of communication for conducting operational and investigative activities, i.e., they are subject to the implementation of SORM<sup>2</sup>, however from a practical perspective it covers the vast majority of telecommunications services licenced by Roskomnadzor, excluding local telephone services using collective access facilities, cable broadcasting services, terrestrial broadcasting services, wire radio broadcasting services and mail services (the state fee will remain at RUB 7,500 (approx. USD 85) for these type of telecommunications services).

By doing this, legislators intended to increase the amount of the state duty to a level comparable to that of a fine for an administrative offence related to the introduction of SORM and the cost of connecting or renting the relevant equipment.

1 Federal Law No. 497-FZ dated 28 September 2023 on Amendments to Articles 333-33 and 333-40 of Part Two of the Tax Code of the Russian Federation.

<sup>2</sup> Telecom providers in Russia bear a general obligation to deploy the System for Operative Investigative Activities ("SORM"), which consists of a set of equipment and software meant for the lawful interception of information in telecommunications networks operating in Russia. It includes the installation of special equipment allowing the Federal Security Service to get remote access to the traffic of the telecom provider (when needed), perform testing of such equipment, arrange coordination with the Federal Security Service in this regard, store users' data for a certain period of time in the territory of the Russian Federation, etc. Prior to the deployment of SORM, the action plan for such measures must be approved with the Federal Security Service.

In addition, the move is intended to prevent telecom providers in Russia that violate the introduction of SORM from applying to Roskomnadzor for the termination of a licence for the provision of telecommunication services and immediately applying for a similar new licence. In such a case, Roskomnadzor has no grounds to refuse to terminate a licence and issue a new one, so this scheme was being commonly used by small telecom providers to postpone the introduction of SORM. carefully consider the decision to revoke telecommunications licences in Russia taking into account the increased state fee for repeated application. However, if the provider decides to not revoke a licence, it would also seem reasonable for all Russian telecom providers (including subsidiaries of international telecom operators) to double check their compliance with SORM requirements and initiate the necessary actions beforehand, if needed, since liability for violations in this regard was also substantially enhanced in 2023.

For this reason, it is recommended to

## Russian Parliament proposes limiting foreign research of the consumer market

In 2023, the State Duma (the lower chamber of the Russian Parliament) introduced a draft law imposing restrictions on foreign companies that conduct research on the product market in Russia and the consumer behaviour of Russian nationals<sup>3</sup>. The draft law supplements Federal Law No. 381-FZ dated 28 December 2009 on the Fundamentals of the State Regulation of Trade Activities in the Russian Federation with a new article, which establishes the procedure for the activities of an entity that organizes research on the structure of the consumer market (**"Market Research Organizer**").

Market Research Organizers are defined as Russian legal entities that provide services for the collection, processing and analysis of data on the structure of the market in the Russian Federation and whose total revenue for the last calendar year amounts to at least RUB 30 million (approx. USD 330,000).

According to the bill, Market Research Organizers must comply with the following key obligations: A) The Market Research Organizer must be owned and controlled (both directly and indirectly) by Russian citizens/entities. Foreign entities may control no more than a 20% stake (shares) in the company's capital.

Increases in such foreign control (more than 20%) may be subject to approval by the Governmental Commission for Control over Foreign Investments in the Russian Federation (the **"Commission**"), however such a decision is taken at the Commission's discretion.

B) General compliance with data protection, countersanction information and other confidential information regimes in Russia, as well as other laws of the Russian Federation must be ensured, and unreliable data about market research cannot be used or published online.

C) Information received as a result of market research must be localized in databases on the territory of the Russian Federation as well as in other technical means for conducting such market research<sup>4</sup>.

<sup>3</sup> Draft Law No. 412669-8 on the Introduction of Amendments to Chapter 4 of the Federal Law on the Fundamentals of the State Regulation of Trade Activities in the Russian Federation (regarding research on the structure of the consumer market) (available <u>here</u> in Russian only)

<sup>4</sup> The rules for collecting and processing information during market research are supposed to be developed by the Federal Service for Supervision of Communications, Information Technology and Mass Media (**"Roskomnadzor"**) together with the Federal Security Service.

D) The Market Research Organizer must submit information demonstrating its compliance with foreign control and the revenue threshold, as well as annual reports on the market research it conducted in the reporting year to the Federal Antimonopoly Service (the **"FAS**"). Annual reports are subject to publication on the Market Research Organizer's official website.

The FAS may also request information about the methods, techniques and technologies used in the market research, as well as the software used to conduct the market research, and the Market Research Organizer is obliged to disclose such information.

E) The Market Research Organizer must prevent the execution of the decisions of foreign states and/or associations (unions) of foreign states on the imposition of restrictive measures (sanctions) in relation to the Russian Federation, Russian entities and Russian legal entities.

According to the draft law, a register of Market Research Organizers will be created and maintained by the FAS. Companies will apply for inclusion into the register if they collect data on the structure of the consumer market in more than half of Russia's regions or if they have received a notice from the FAS. The application to be included to the register is submitted by the company to the FAS, and afterwards the application is forwarded to the Commission for a subsequent decision. The draft law describes particular cases when a company may be excluded from the register (e.g., gross regulatory violation, compliance with foreign sanctions against Russia etc.). Companies that are excluded from the register (or denied inclusion thereto) cannot continue their activities related to market research in Russia.

Under the draft law, counterparties may not conclude contracts for research on the structure of the consumer market in Russia with companies that do not meet the regulatory requirements specified in the draft law. Such contracts shall be considered null and void.

The draft law is being considered by the State Duma. It passed the first reading on 16 January 2024, and some amendments may be expected in the second reading. As such, major foreign players that conduct consumer research on the Russian market are advised to closely monitor the further status of the draft law to ensure timely compliance and make any necessary fillings with the Commission and the FAS, if needed.

## Roskomnadzor's control over the website preventing circumvention and mass VPN blockings

In recent years, the Federal Service for Supervision of Communications, Information Technology and Mass Media ("**Roskomnadzor**") has focused on controlling the distribution of prohibited information and access to restricted resources.

In this regard, in an effort to prevent the dissemination of prohibited information online, the regulator pays close attention to and is attempting to restrict the use of VPN services in Russia. Although the general use of the VPN network for internal business processes such as cybersecurity is not prohibited in Russia, the Russian VPN Law<sup>5</sup> prohibits telecommunication and information networks/information resources that enable access to information networks that are prohibited in Russia. The owners of such networks/resources are not allowed to offer their networks/resources for the purposes of gaining access to blocked content and thereby circumventing blockage procedures.

5 Article 15.8 of Federal Law on Information, Information Technologies and Information Protection No. 149-FZ dated 27 July 2006 (the "Information Law"). Additionally, in July 2023, the list of prohibited information under the Information Law was supplemented with "information on ways and methods of providing access to information resources and/or information and telecommunications networks, access to which is restricted on the territory of the Russian Federation"<sup>6</sup>. From 1 March 2024, Roskomnadzor will be empowered to block websites that contain such information by sending notifications to information resource owners and hosting providers.

At the same time, since 1 September 2019, telecommunications providers have specific obligations to introduce technical means to counter threats (i.e., software and hardware systems that restrict access to information whose distribution is prohibited while filtering such traffic via DPI ) ("TMCT") under the socalled Sovereign Runet Law. Roskomnadzor recently resumed mass testing of TMCT, which led to the mass blockage of VPN resources. Some VPN resources were accidentally blocked, although they can be dually used both internally in a corporate network as well as for gaining access to blocked content. This concerned many companies that use VPN services in their work for the remote access

of employees or the consolidation of servers into a single network, including information security services providers.

In October 2023, the Ministry of Digital Development acknowledged this problem, as VPN protocols may be subject to Roskomnadzor's restrictions, but the blocking can be lifted if the service is needed for business purposes<sup>7</sup>. If a company encounters difficulties with a VPN, it must contact Roskomnadzor. As a rule, lists of companies are submitted to Roskomnadzor through the relevant industry authority. If the relevant industry authority has not notified Roskomnadzor about a company, the company may submit information independently to the Russian authorities for the expansion of the "white list" of VPNs.

As such, companies using VPNs for their internal business purposes may encounter accidental technical restrictions due to the use of TMCT by Roskomnadzor or its restrictions based on Roskomnadzor's decision in accordance with Russian information laws. Such issues may be resolved via communication with the Russian authorities.

#### Key changes in Russian Internet regulation in 2023: requirements for hosting providers and new rules for authorization

Numerous significant changes were made to Russian Internet regulation in 2023, including the introduction of a regulatory framework for hosting providers and the limitation of authorization methods on Russian websites<sup>8</sup>.

Since 1 December 2023, hosting providers (i.e., companies that offer services for the provision

of computing power to post information in information systems permanently connected to the Internet) are subject to new requirements in Russia. They are now obliged to send a notification on the commencement of hosting services to the Federal Service for Supervision of Communications, Information Technology and Mass Media (**"Roskomnadzor**"),

- 7 More about VPN protocols for business purposes <u>here</u>
- 8 Federal Law No. 406-FZ dated 31 July 2023 on Introduction of Amendments to the Federal Law on Information, Information Technologies and the Protection of Information and the Federal Law on Communications.

<sup>6</sup> Federal Law No. 406-FZ dated 31 July 2023 on the Introduction of Amendments to the Federal Law on Information, Information Technologies and the Protection of Information and the Federal Law on Communications. From 1 March 2024, Roskomnadzor will be empowered to block websites containing such information by sending notifications to information resource owners and hosting providers.

ensure the introduction of specific information security requirements, ensure the introduction of requirements for conducting operational and investigative activities, prevent the disclosure of organizational and tactical methods for conducting such activities, comply with certain requirements established by the Sovereign Runet Law and verify the identification or authentication of its customers<sup>9</sup>.

Based on a notification from a hosting provider, it is included in a special register that will be maintained by Roskomnadzor. As of 1 February 2024, the absence of information in the register will be an obstacle for the provision of hosting services. Hosting providers currently submit their applications via Roskomnadzor's portal<sup>10</sup>.

Roskomnadzor will monitor the activities of hosting providers in Russia. If the hosting provider fails to eliminate violations identified by Roskomnadzor within 10 business days from the date of the request (unless earlier deadlines are set out in the notification itself), the hosting provider will be removed from the register and prohibited from conducting its activities.

In addition to the new requirements for hosting providers, Russian legislators introduced new rules on authorization for users on Russian websites, which took effect on 1 December 2023. As a general rule, owners of websites, mobile applications or other information systems that are Russian legal entities or citizens of the Russian Federation are now limited to the following possible options for the authorization of users located in Russia: via phone number in accordance with the procedure established by the Russian government based on an identification agreement concluded by the owner with a telecom provider, via 'Gosuslugi' (a Russian state services platform), via the Unified Biometric System, and via another information system that meets information protection requirements. The owner of such a system may only be a citizen of the Russian Federation who does not have citizenship of another state, or a Russian legal entity. This restricts the use of various foreign authorization systems on Russian websites or applications, such as Apple ID or Google.

However, due to numerous concerns from the business community and the lack of any grace period, Russian legislators adopted another law that provides for a transitional period until 1 January 2025, during which a number of derogations to the authorization rules for users of Internet resources will be in force<sup>11</sup>.

During the grace period, the Russian owner of a website, mobile application or other Internet resource with visitor authorization may also conduct it through a separate information system in relation to Russian users. The system must meet information protection requirements and belong, for example, to the owner of the resource (despite foreign control), an economically significant organization, etc.

Based on the above, hosting providers in Russia must duly ensure compliance with the new regulatory framework, including registration with Roskomnadzor and the implementation of technical and information security measures together with the user authentication system. It would be advisable for customers of such services to check their hosting providers in order to avoid the risk of their hosting service being suspended. As regards owners of Russian websites, it would be advisable for them to review the new rules for the authorization of users and implement their own compliance strategy in 2024.

<sup>9</sup> A set of amendments to Russian telecommunications laws provided by Federal Law No. 90-FZ dated 1 May 2019 on Amendments to the Federal Law on Communications and the Federal Law on Information, Information Technology and Information Protection.

<sup>10</sup> More about providers applications on Roskomnadzor's portal <u>here</u>.

<sup>11</sup> Federal Law No. 588-FZ dated 12 December 2023 on Amendments to Article 8 of the Federal Law on Information, Information Technologies and Protection of Information.



### **Consumers** products

#### Significant changes in the regulation of tobacco products

On 1 September 2023, Federal Law No. 203-FZ dated June 13, 2023 "On the State Regulation of the Production and Circulation of Tobacco Products, Nicotine-Containing Products and Raw Materials for Their Production" (**'Federal Law No. 203-FZ**") came into force. Federal Law No. 203-FZ introduced a regulatory framework similar to that of alcohol regulation:

A) The licensing of the production and import/export of tobacco products, nicotine-containing products and raw materials for their production<sup>12</sup>

Since 1 September 2023, a register of licences has been in effect on the basis of the GovTech Unified Digital Platform<sup>13</sup>. There is no licensing for retail sales of tobacco products, nicotinecontaining products and raw materials.

B) Requirements for the main technological equipment

The manufacturer must own the main technological equipment by right of ownership or economic or operational management<sup>14</sup>.

If the manufacturer does not have a licence to produce tobacco products, the equipment may be mothballed under the control of the authorized body<sup>15</sup>. The equipment may be removed from circulation or confiscated from the manufacturer if the requirements for its use are violated.

C) The obligation of manufacturers to register the main production equipment in the unified state register, which is managed by the Federal Service for the Control of Alcohol and Tobacco Markets

D) State regulation of prices for tobacco and nicotine-containing products<sup>16</sup>

E) Requirements for recording the volume of production and turnover of tobacco products, raw materials, nicotine-containing products and nicotine raw materials<sup>17</sup>

- 12 Applicable from 1 March 2024
- 13 Please see the link https://platform.gov.ru/. According to Decree No. 1138 of the Russian Government dated 12 July 2023 "On the Approval of the Rules for Maintaining the State Register of Issued, Suspended and Canceled licences for the Production and Circulation of Tobacco Products, Nicotine-Containing Products and Raw Materials for Their Production"
- 14 Applicable from 1 July 2025

15-17 Applicable from 1 March 2024

F) A number of direct restrictions in order to prevent the illegal production and circulation of products<sup>18</sup>, including for example:

G) A ban on retail sales of tobacco and nicotine-containing products not in consumer packaging

H) A ban on concluding purchase and sale agreements that require obligations to be fulfilled as part of the transaction in favour of

a third party (except for monetary obligations), exchange agreements, agreements on the assignment of claims (except for monetary claims) and for the transfer of debt (except for monetary debt) if these transactions are made in relation to tobacco and nicotine-containing products.

The Federal Service for the Control of Alcohol and Tobacco Markets will act as a controlling body.

#### Further development of the labelling system

In recent years, the Russian government has devoted special attention to mechanisms for maintaining control of products that are often counterfeited. A national track and trace digital-labelling system called "Honest Sign" ("**Honest Sign**") was created to supervise the transportation of products over Russian territory to eliminate counterfeits. A general overview of the system can be found in our newsletter <u>"The Russian Government has</u> <u>adopted rules for the digital labelling of new</u> <u>products and the procedure for accessing</u> <u>labelling information</u>" or on the <u>official</u> <u>website of Honest Sign</u> (the latter is also available in English and Chinese).

The Honest Sign system continues to expand and plans to encompass the following categories:

 A) Beer and low-alcohol beverages in aluminium cans and other types of packaging (since 15 January 2024)

B) Soft drinks, excluding juices, nectars, fruit drinks and beverages based on vegetable raw materials, in an aluminium and polymer jar (since 1 March 2024)

C) Hearing aids, except for parts and accessories, coronary stents, computed tomographs, sanitary and hygienic products used for incontinence (since 1 March 2024)

D) New groups of light industry products (since 1 April 2024)

E) All types of soft drinks, including juices, nectars, fruit drinks and beverages based on vegetable raw materials, in kegs, Tetra Pak and other types of packages (since 1 June 2024)

F) Bicycles and bicycle frames (since 1 September 2024)

A number of products are undergoing labelling experiments:

A) Fibre-optic products (1 December 2023 – 1 December 2024)

B) Radio-electronic products (1 December 2023 – 28 February 2025)

C) Technical means of rehabilitation (15 October 2023 – 31 August 2024)

D) Caviar of sturgeon and salmon fish (15 April 2023 – 31 March 2024)

E) Titanium metal products (1 September 2023 – 31 March 2024)

F) Certain types of products for children(20 December 2023 – 1 December 2024)

18 Applicable from 1 March 2024

Considering all the previous legislative practices concerning labelling, we assume that the experiments will conclude with the adoption of obligatory labelling. In addition, discussions are now being held about labelling cosmetics, canned food, grocery products and pet food (except agricultural) packaged in consumer packaging.

On 21 November 2023, the Russian Government introduced a ban on the sale of products subject to mandatory labelling based on the information contained in the Honest Sign system or in the event such information is absent in the system.

Furthermore, the State Duma is now considering a legislative initiative that would check the database on excise taxes on tobacco products based on the data of the Honest Sign system. Moreover, the Plan for the Implementation of the Strategy to Combat the Illegal Trafficking of Industrial Products in the Russian Federation until 2025 provides for the development of a draft law that would impose criminal liability on importers for importing unmarked products subject to labelling to the territory of the Russian Federation. All in all, the Honest Sign system is still being developed and is intended to become a universal tracing mechanism that would allow for combatting counterfeits on the market. As such, we think it would be reasonable for all players on the Russian market to follow its development and be prepared that the tracing system may cover their products as well (if not currently covered).





### **General Regulatory**

## Environmental ban on packaging and the development of the EMR system

On 15 November 2023 the Ministry of Industry and Trade submitted to the authorized departments for approval a draft governmental decree (the "Decree") banning the use of polymer product packaging waste from which cannot be recycled or is inefficiently extracted. If the draft Decree receives positive feedback, it will undergo further consideration by the Russian government and be subsequently adopted.

The list was not publicly available as of the end of 2023, and it is not clear when it will be finally adopted, but media reports indicate the document includes a list of 23 types of packaging, six of which are proposed to be limited as of 2024, and the remaining 17 items — as of 2030.

According to publicly available information, the authorities are considering banning the following packaging in 2024:

A) Translucent PET bottles of all colours, except blue, green, brown, and black (these colours preserve the consumer properties of products and increase the shelf life)

B) Opaque PET bottles, except for white containers for dairy products (where the colour has a functional purpose), as well as PET packaging made using PVC labels that interfere with recycling

C) Multilayer PET bottles, coffee capsules made of multicomponent materials and plastic containers for canned food with a rolled metal lid

A ban is also being considered on the following items as of 2030:

A) Multicomponent Bag-in-Box packaging

B) Flexible vacuum packaging doypacks, flowpacks and multilayer toothpaste tubes

- C) Multicomponent bags in jug form
- D) Polymer sachet bags up to 80 mm

E) Nets for vegetables and fruits, food packaging made of expanded polystyrene, etc.

These amendments may have a material effect on both:

A) Russian manufacturers of products

B) Foreign manufacturers and importers of their products to Russia both from EAEU member and non-member states

These measures should stimulate the transition from opaque PET containers to transparent ones, from multilayer materials to single-layer ones, and from multicomponent to mono-material ones, which will facilitate the processing of these materials. Public discussions indicate that further reforms in this regard are underway as well.

The planned reform is being conducted as part of the development of the extended manufacturer's responsibility (**"EMR**") system, which was adopted on 4 August 2023 by amendments ("Amendments") to Federal Law No. 89-FZ dated 24 June 1998 "On Production and Consumption Waste". Russia introduced the EMR system in 2015 in order to create an incentive for manufacturers and importers to recycle waste from the use of products and packaging that they market in the Russian Federation. Among other things, the Amendments implied the imposition of liability for the disposal of the packaging of products made in the Russian Federation on packaging manufacturers, the introduction of a recycling standard for packaging equal to 100% and the creation of a register of authorized recyclers.

All the amendments that have already been adopted and the ones being considered by the Russian state authorities may require substantial changes in manufacturing processes and the re-equipment of production lines, as well as the development of new production methods. In this regard, we would recommend keeping an eye on the further development of this Decree and other requirements related to the EMR.

#### Russia extends a number of regulatory counter-sanctions

Decree No. 560 of the President of the Russian Federation dated 6 August 2014 prohibited or limited the conclusion of foreign economic transactions involving the import into the Russian Federation of certain types of agricultural products, raw materials and food that originate from a country that decided to impose economic sanctions against Russian legal entities or individuals or acceded to this decision. Decree No. 693 of the President of the Russian Federation dated 18 September 2023 extended the effect of the countersanctions until 31 December 2024.

The following special economic measures put in place under Decree No. 11 of the President

of the Russian Federation dated 8 March 2022 "On the Use of Special Economic Measures in Foreign Economic Activity To Ensure the Security of the Russian Federation" have been extended until 31 December 2025<sup>19</sup>:

A) A ban on the export of products and raw materials outside the territory of the Russian Federation according to the lists determined by Decrees No. 311 and No. 313 of the Government of the Russian Federation dated 9 March 2022

B) Restrictions on the export outside of and the import into the territory of the Russian Federation of products and raw materials

<sup>19</sup> By Decree No. 540 of the President of the Russian Federation dated 20 July 2023 "On Amendments to Decree No. 100 of the President of the Russian Federation dated 8 March 2022 "On the Use of Special Economic Measures in Foreign Economic Activity To Ensure the Security of the Russian Federation".



according to the lists determined by Decrees No. 312 of the Government of the Russian Federation dated 9 March 2022 and No. 1034 dated 26 June 2023 C) Increased export and import customs duties on products and raw materials according to the lists determined by the Russian government

#### Russian Government extends the simplified procedure for importing and assessing the conformity of products for a year

Until 1 September 2024, products intended for circulation exclusively in the territory of the Russian Federation may be imported into the territory of the Russian Federation without the labelling required by Federal Law No. 184-FZ dated 27 December 2002 "On Technical Regulation" <sup>20</sup>.

Until the same date, the government has allowed for the assessment of the conformity of a number of products with mandatory requirements in a simplified manner<sup>21</sup> - in the form of a declaration based on evidence from the applicant. Information about such a declaration must be posted based on the applicant's decision on the website of the

- 20 Decree No. 1133 of the Government of the Russian Federation dated 10 July 2023 "On Amendments to Appendix No. 18 to Decree No. 353 of the Government of the Russian Federation dated 12 March 2022".
- 21 In accordance with Decree No. 353 of the Government of the Russian Federation dated 12 March 2022 "On Specific Aspects of Licensing Activities in the Russian Federation".

accreditation body. If the applicant fails to do so, the products will not be allowed to be sold only for personal, family, household and other needs that are not related to business, including retail. Please be aware that all information provided in this brochure was taken from open sources. Neither ALRUD Law Firm, nor the authors of this brochure, bear any liability for consequences of any decisions made in reliance upon this information.

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