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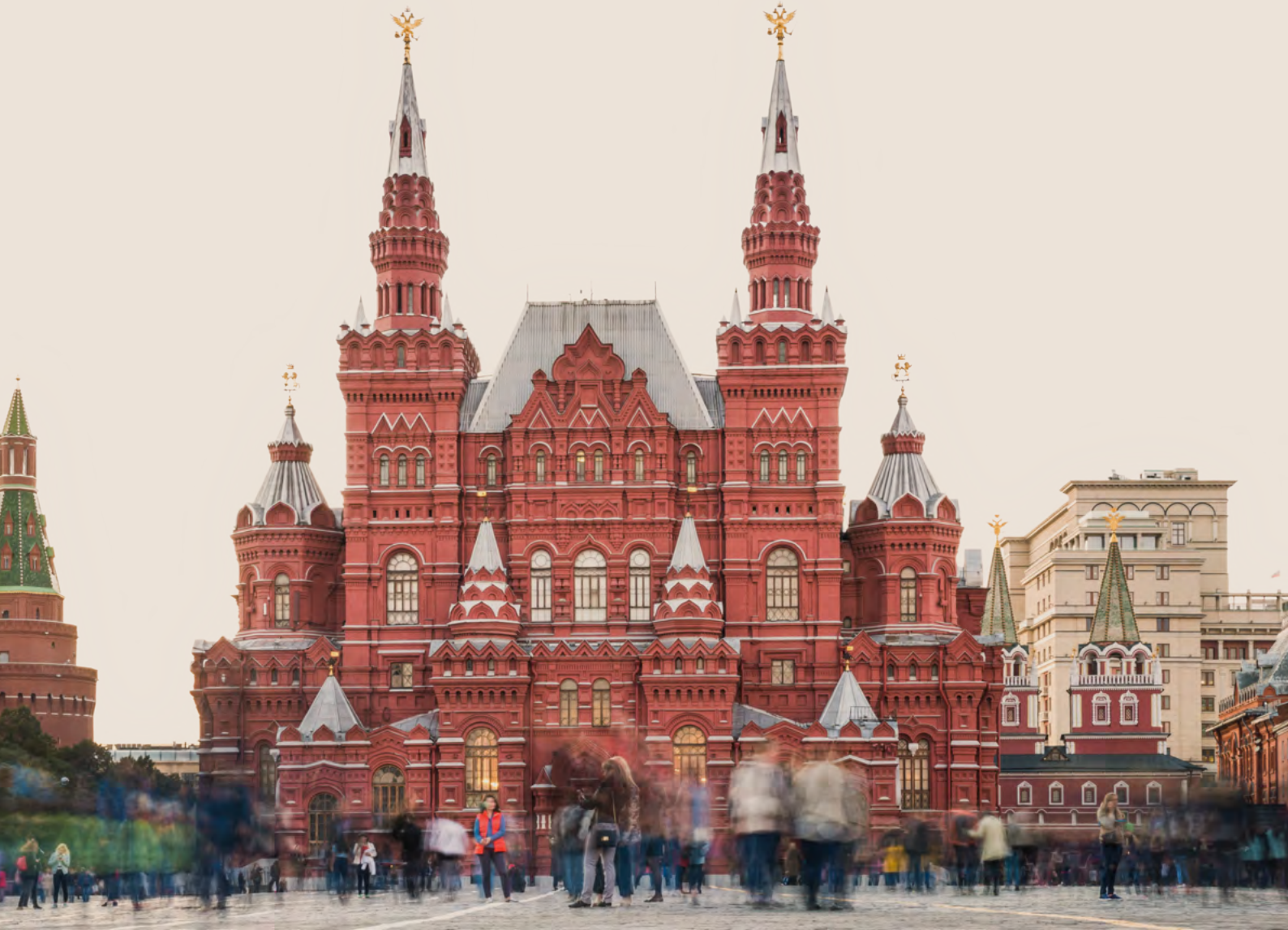
Key changes and trends 2022



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Introduction

Dear Readers,

After a long pause, we are pleased to release a new version of our regulatory Guides. To cover the gap since the last publication, we would like to devote this Guide to an overview of key changes and trends that took place in 2022.

2022 was a challenging year for many companies working on the Russian market as well as for the Russian market and economy as a whole. In response to challenges and threats, the Russian state authorities introduced a number of measures to ensure stability in turnover and mitigate negative consequences for different sectors of the Russian economy. Many of the legislative initiatives introduced over the last year were borne out of necessity (e.g., the Russian government banned the export of numerous goods from Russia and simplified the registration process for medical devices and medicines).

In addition, despite all the turbulent circumstances of the previous year, we have seen that previous trends continue to unfold in different sectors as well (e.g., traceability labelling systems have been expanded to cover more and more products each year, green trends are getting more recognition and regulation and the Russian authorities continue to ensure the safety and autonomy of Russian telecom networks and infrastructure, while transitioning from blank supervision to a risk-based approach).

In summary, several important changes and initiatives took place in different regulatory spheres during the previous year and we have done our best to summarize them below.

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Pharma

Launch of an experiment on online sales of Rx medicines

In Russia, certain types of products could not be sold online, including medicines, until the global COVID-19 pandemic pushed the Russian government to allow the distribution of over-the-counter (OTC) medicines via e-commerce platforms in 2020. Discussions on the feasibility of safe online sales of Rx medicines continued until autumn last year when Russia adopted an experimental law on online sales of Rx medicines[1].

The law launched a pilot project, whereby online sales will be restricted both in terms of the geography, timeframe and variety of medicines. Rx medicines may be sold online only in Moscow, the Belgorod Region and the Moscow Region. The experiment will kick off on 1 March 2023 and continue until 1 March 2026.

The list of Rx medicines allowed for online purchase shall be approved by the Russian Ministry of Health. At present, the draft list has been published on the official portal of draft regulations. The list includes a total of more than 1,000 medicines, including drugs for the treatment of diabetes, HIV, Hepatitis C, cancer and oncohematological diseases, and musculoskeletal disorders. Remote sales of medicines containing narcotic, psychotropic or potent substances, alcohol-containing medicines with an ethyl alcohol fraction over 25 percent, immunobiological medicines stored below a temperature of 15 degrees Celsius, medicines produced in pharmacies and medicines dispensed free of charge or at a discount for citizens who have the right to receive them at the expense of the budget are prohibited.

The document also requires pharmacies and delivery services that sell Rx medicines online to ensure that the patient with the prescription for the medicine matches the identity of the customer to whom the medicine is to be delivered.

1 *Federal Law No. 405-FZ dated 20 October 2022 on Amendments to the Federal Law on the Circulation of Medicines.*

As prominent mass media outlets have noted, major Russian e-commerce platforms and the postal service, including Ozon, Yandex. Market and Russian Post, are ready to launch the delivery of prescription medicines to customers at the onset of the experiment.

Such IT companies will not only prepare technological capabilities in terms of medicine labelling and the verification of patients' prescriptions, but will also comply with other regulatory obligations, including licensing requirements for pharmaceutical sales.

New regulations for the circulation of medicines and medical devices in the event of a shortage in Russia

The ongoing epidemic as well as the economic and political situation have both made concerns about possible shortage of medicines and medical devices more acute than ever. As a partial response, the Russian government adopted Decree No. 593 on 5 April 2022, which provides for the specific regulation of medicines in the event of a shortage, including particular indulgences with respect to regulatory procedures. Such indulgences include an accelerated procedure for state registration and an accelerated procedure to amend documents in the registration dossier. Additionally, the deficient medicines may be imported in foreign packaging if an import permit is duly obtained, or without state registration in the event there is a temporary import permit and analogous medicinal products with the same taxpayer identification number (TIN) registered in Russia.

A special interdepartmental commission of the Russian Ministry of Health determines the list of medicine eligible for the simplified state registration and expert assessment procedure. The list of deficient medicines includes 86 TINs. The list can be viewed in the closed part of the State Register of Medicines. For these medicinal products, an import permit may be issued for foreign packaging and an accelerated registration procedure may be applied.

According to the latest available data, 36 of 86 drugs were permitted to undergo accelerated state registration in accordance with Decree No. 593. Permission was granted for 72 TINs to make amendments to the registration dossier using the accelerated procedure. For 10 drugs on the list, permits may be issued for the import of a series (batch) of the medicine to Russia in foreign packaging. Permits may be granted to 7 drugs for the temporary circulation of a series (batch) of a medicine unregistered in Russia under Decree No. 593. On the other hand, the commission has not yet granted any authorization to amend the documents in the registration dossier for a pharmaceutical substance produced for sale under a special procedure.

In addition, Decree No 552 of the Russian Government dated 4 April 2022 imposes a special regime on the circulation of medical devices under sanctions, including an accelerated market authorization procedure for the state registration of medical devices and an accelerated procedure to amend the registration dossier for domestically produced medical devices. The list of deficient medical devices is also determined by the special interdepartmental commission of the Russian Ministry of Health.

The marketing authorization certificates for medical devices obtained under the accelerated procedure for state registration are valid until 1 January 2025. For some medical devices, the state registration period has been reduced from 50 to 22 business days, while for others this period was reduced to 5 business days. Medical devices with a low class of potential risk (excluding sterile ones) can now obtain marketing authorization using the notification procedure if the medical device is submitted for testing within five business days and a document is submitted within 150 days.

New Good Pharmacovigilance Practices of the Eurasian Economic Union

The Council of the Eurasian Economic Commission approved a new version of the Good Pharmacovigilance Practices of the Eurasian Economic Union ("GVP") in May 2022[2]. These rules constitute the basic regulatory document that defines the requirements for the proper implementation of pharmacovigilance in the EEU member states. The new version details the pharmacovigilance processes for which the drug manufacturer is responsible, expands options for interaction between the manufacturer and authorised bodies, and extends the lists of capabilities to use active safety monitoring methods, as well as the use of labelling with special warning signs about unsafe drugs. There is a strong emphasis on a risk-based approach (which is an ongoing trend in compliance confirmation) to process continuity.

As part of pharmacovigilance quality management, the need to document personnel data has been clarified. In addition to the requirement to document the organizational structure, the responsibilities and functions of staff within the pharmacovigilance system must now be documented.

The updated GVP explicitly mentions the need for the regular evaluation of the performance of the pharmacovigilance system. System review programmes must be developed, including the evaluation of standard operating procedures, work instructions, process performance indicators and system performance deviation criteria.

The new version of the GVP has significantly revised the section describing the tasks for handling the risk management plan. In particular, a paragraph has been added highlighting the need to take into account the links between the sections of the risk management plan and their corresponding modules in the registration dossier.

For each type of medicine, the requirements have been extended for submitting a risk management plan when applying for marketing authorization or aligning the registration dossier with the requirements of the EEU.

Significant changes have been made to the rules for mandatory post-registration safety studies. The changes affect both the design of the study protocol and the procedure for conducting the study.

Additionally, amendments have been made to the requirements for drug instructions (leaflets). It is expected to include a warning about the safety of medicines obtained by processing human blood plasma. The amendments outline the unified approaches that the pharmaceutical manufacturers of EEU countries must take to the indication of special warnings about safety measures with respect to the transmission of viral agents with blood preparations. This will avoid possible discrepancies when examining the text of the general characteristics of the medicinal product and the leaflet for such medicines in EEU countries.

Off-label use of medicine to treat children

In any jurisdiction, the off-label use of medicines is a controversial issue, and Russia is no different in this regard. The ability to use medicine "off-label" has been discussed for quite a long time now, but never really implemented in law or in practice. At present, the prescription and use of off-label medicines by healthcare professionals may lead to

2 *Decision of the Council of the Eurasian Economic Commission as of 19 May 2022 on Amendments to the Good Pharmacovigilance Practices of the Eurasian Economic Union.*

certain risks related to medical organizations failing to comply with licensing requirements, possible fines, the refusal by insurance companies to cover an insured event and even administrative and criminal prosecution for healthcare professionals themselves.

However, to meet actual demand and keep up with global trends, the Russian Ministry of Health has developed a draft regulation regarding the inclusion in medical care standards of medicines that may be used outside the instructions (off-label use). The draft version of the document was published on 7 November 2022.

The draft document establishes two conditions for the off-label use of medicines with respect to children. Such medicines may be included in paediatric care standards and clinical guidelines if their efficacy and safety is confirmed by clinical trials and/or scientific studies published in scientific journals indexed in international databases. Additionally, such off-label medicines must have greater efficacy while maintaining safety, or greater safety while maintaining efficacy, than usually prescribed medicines.

As a reminder, Federal Law No. 482-FZ on amendments to the Russian Law on the Fundamentals of Healthcare in the Russian Federation was adopted on 30 December 2021, and it became effective in June 2022.

The law allows for the inclusion of medicinal products to be used outside the instructions i.e., medicines for off-label use, in the medical care standards. The Russian government approves the list of medical conditions when it is permissible to include the off-label use of medicines in the medical care standards.

Hopefully, the state authorities and healthcare professionals will be able to find a tentative balance between regulating the use of off-label drugs and provide patients with better treatment without additional risks.

TMT

New reporting obligations of telecom providers in Russia

The reporting obligations of telecommunication services providers in Russia were supplemented with new rules on the submission of general annual reports, which have been in force since 1 December 2022[3].

Telecommunication service providers must submit an annual report on their activities to the Federal Service for Supervision of Communications, Information Technology and Mass Media ("Roskomnadzor") in electronic format, which, inter alia, must contain information about the communications network, the communications equipment used by the respective telecom licensee as part of the communications network, and the communication services provided.

This report is submitted in electronic format by completing electronic forms or posting information in XML format in the telecom provider's personal account on the official website of Roskomnadzor. The report is drafted with respect to each type of telecommunication services provided by the operator, and it confirms that the telecommunication services provider is rendering telecommunication services. Reports containing knowingly unreliable or incomplete information on the telecommunication services provided must not be submitted.

The procedure and the form for telecommunication services providers to submit the general annual report are specified in Governmental Decree No. 1984 dated 3 November 2022 on the approval of the procedure for reporting on the activities of a telecommunication operator and the report form on the activities of a telecommunication operator. A telecommunication services provider that engaged in activities to provide telecommunication services during a partial reporting period must report information about activities took place during that this period.

The telecommunication services provider must annually submit the general annual report by 1 March of the year following the reporting year.

3 *Federal Law No. 546-FZ dated 30 December 2021 on Amendments to Articles 46 and 51.1 of the Federal Law on Communications.*

Failure to provide such a report or the inclusion of knowingly unreliable information therein serves as legal grounds for Roskomnadzor to suspend the provider's telecom licence under Article 39 (2) of Federal Law No. 126-FZ dated 7 July 2003 on communications ("Communications Law"). Additionally, the telecommunication services provider may be fined up to 5,000 RUB (approx. 70 USD) for the failure to provide information to the relevant authorities under Article 19.7 of the Code of Administrative Offences of the Russian Federation.

As Roskomnadzor representatives have emphasized, the latest changes aim to improve the quality and reliability of telecommunication services as the new reporting obligations make it possible to update the data contained in the register of telecom licences and provide users of telecommunication services with reliable information about providers that actually provide telecommunication services within Russia.

The first annual reports must be submitted by the telecommunication services providers that obtained telecom licence(s) before the effective date of the amendments to the Communications Law (i.e. before 1 December2022) until 1 March 2023.

Public liability for failure to ensure the autonomous operation of the Russian segment of the Internet

Starting from 1 November 2019, telecommunications service providers in Russia must introduce specific equipment (technical means for countering threats or "TMCT"), which is necessary to block the possible disconnection of the Internet in Russia and to ensure the autonomous operation of its Russian segment ("Sovereign Internet Law")[4]. The Sovereign Internet Law creates independent infrastructure in Russia that makes it possible to reroute data through domestic lines when it is impossible to connect to foreign root servers. In other words, the law creates a legal framework for the centralized state management of the Internet within Russian borders by imposing obligations on telecommunication services providers to comply with special traffic routing rules and instal specific hardware allowing Roskomnadzor to reroute or block the traffic directly.

The Russian government approves the procedure for installing, operating and upgrading such technical means, as well as the types of threats and the regulations for identifying them. TMCT are provided by Roskomnadzor gratuitously. Additionally, Roskomnadzor approves technical conditions for the introduction of TMCT and particular technical requirements with respect to communication networks when introducing TMCT.

Even though this obligation was introduced several years ago, there was no liability for the failure to comply with the requirements, which made its implementation more problematic for the state authorities. The situation has changed recently since a law imposing sanctions on Russian telecommunication services providers for the failure to reroute traffic through TMCT came into force on 1 January 2023[5]. The Code of Administrative Offences was supplemented with Article 13.421, which envisages administrative liability for the failure to ensure the autonomous operation of the Russian segment of the Internet.

4 *Federal Law No. 90-FZ dated 1 May 2019 on Amendments to the Federal Law on Communications and the Federal Law on Information, Information Technologies and Information Protection.*

5 *Federal Law No. 259-FZ dated 14 July 2022 on Amendments to the Code of the Administrative Offences of the Russian Federation.*

This article imposes administrative fines on telecommunication services providers of up to 1,000,000 RUB (approx. 14,000 USD) for such a violation and up to 5,000,000 RUB (approx. 70,000 USD) for a repeat offence. Additionally, the officials of the telecommunication services providers may be fined up to 50,000 RUB (approx. 700 USD) for the first time and up to 200,000 RUB (approx. 2,800 USD) for a repeat offence.

Furthermore, criminal liability for the same offence was also introduced, and the respective norms took effect on 1 January 2023. The systematic violation of obligations to reroute traffic through TMCT (i.e. more than 2 times) may lead to criminal liability for the officials of such telecommunication services provider under Article 274.2 of the Russian Criminal Code. Criminal sanctions include criminal fines, correctional work, forced labour or imprisonment for up to 3 years. In accordance with Russian criminal legislation, legal entities may not be held criminally liable, and in such cases criminal liability is usually imposed on a general manager (CEO) or other managing officers who were responsible for adopting the relevant decisions at the company.

Taking this into account, we think it would be advisable for all telecommunication services providers to double check how the Sovereign Internet Law requirements apply to their business and pay careful attention to compliance with its obligations (if applicable) during their further operations.

Food & beverages

Introduction of a legal framework for "green" products

"Green" products are becoming more and more popular these days, and to observe this trend, manufacturers are keen to market their products as "organic", "eco" or "green" on local markets. However, there is no mutual recognition for product certification in matters concerning the manufacturing of "organic", "eco" and "green" products, while safety and labelling requirements for such products vary considerably.

Recently, Russia has begun actively developing a legal framework for the production and sale of "organic" products[6] and products "with improved characteristics"[7] (or "green" products). A major improvement was introduced on 1 March 2022, when Federal Law No. 159-FZ dated 11 June 2021 "On Agricultural Products, Raw Materials and Foodstuffs with Improved Characteristics" ("Green Law") took effect.

In general, the Green Law provisions cover only the production and packaging stages which, in our view, does not preclude the law from being supplemented by requirements for the storage, transport and disposal of goods. The Green Law stipulates some basic rules, which are very similar to the ones established for "organic" products[8] and sets out some more detailed requirements, such as the obligation to use recyclable and/or biodegradable packaging. All in all, manufacturers who wish to obtain official "green" labelling should ensure the products meet less stringent requirements than "organic" ones. The specific technical requirements are now contained in national standards that cite European and international standards[9].

6 *On 1 January 2020, Federal Law No. 280-FZ dated 3 August 2018 "On Organic Products and on Amendments to Certain Legislative Acts of the Russian Federation" came into force.*

7 *Includes agricultural products, foodstuffs, industrial and other products.*

8 *E.g. an obligation to isolate production, to use "green" raw materials and technologies that have a minimal negative impact on the environment, not to use genetic engineering methods and ionising radiation, etc.*

9 *The existing standards are approved by Order of the Russian Government No. 330-p dated 26 February 2022.*

The procedure for obtaining "green" certification is as follows:

I. Obtaining a certificate of conformity to national standarts

II. Registration in the state register of the Russian Ministry of Agriculture for "green" producers

III. Labelling with the "green" mark

Notably, the "green" labelling may be used for a period not exceeding the period of validity of the certificate of conformity.

As of today, there are 3 possible designs of "green" labelling in Russia:

Among other things, it is important for manufacturers wishing to operate on the Russian market with the "green" label to bear in mind that:

- The Green Law is in full force since it has no transitional period unlike the law for "organic" products. There are already 4 Russian mineral fertiliser producers registered in the state register[10]

- Greenwashing will not work: according to media reports, the state authorities monitor actual compliance of products that are labelled as "green"

- The current regulation does not prohibit the use of words "organic", "green", "bio" or their derivatives without respective labelling; however, unscrupulous producers may be held administratively liable for deceiving consumers

Having said all that, we believe that active development of "green" legislation in Russia should help to improve the competitiveness of agricultural, raw materials and foodstuffs on the local market, make "green" claims more reliable and products, and make them more attractive to end users.

Development of a traceability system in 2022 and 2023

The National System of the Traceability of Goods is a state information system that was created to automate the collection and processing of information on the turnover of goods that are subject to mandatory labelling. The system aims to prevent the use

10 *The register is available in Russian*

of customs and tax evasion schemes, ensure the quality of goods and combat the turnover of counterfeit products. The obligation to provide traceability labelling is imposed on parties involved in the turnover of goods that are subject to mandatory labelling through identification, including legal entities and individual entrepreneurs that are engaged in the import of such goods, their production, wholesale or retail.

Labelling must be provided for goods from the list approved by Order No. 792-r of the Russian Government dated 28 April 2018, as well as goods for which the Russian government has approved special traceability labelling rules. Different deadlines have been set for the introduction of mandatory traceability labelling and the termination of the turnover of unlabelled products turnover for different types of goods.

The mandatory traceability labelling of goods is carried out by applying two-dimensional barcodes on the goods, their packaging or label, which outwardly resemble QR codes. In order to obtain the traceability labelling codes, manufacturers must register in the Honest Sign system, contact its operator and conclude a number of contacts with it. As a general rule, the traceability labelling of goods must be reported through the Honest Sign system to be considered properly executed.

The traceability labelling practice is constantly evolving and the state authorities intend to expand the existing system to the maximum practical extent at the current stage of the market's development.

There are several obligations imposed within the traceability system:

- Registration in the Honest Sign system
- Applying the traceability labelling to the product
- Reporting certain information on turnover to the Honest Sign system

The obligation to undergo each of the stages is imposed separately by the state authorities.

In 2022, the following categories of products became subject to the traceability mandatory labelling and/or actions, while the following categories of products became subject to mandatory reporting: dairy products, packaged drinking water, nicotine containing products and electronic nicotine delivery systems, imported perfume sets and imported sets of photographic goods.

Meanwhile, the list of products that must be labelled, registered in the Honest Sign system and supervised during their turnover in the territory of Russia will be supplemented in 2023 by the following categories:

- Bicycles and bicycle frames (in terms of mandatory traceability labelling)
- Nicotine containing products and electronic nicotine delivery systems (in terms of both registration and reporting in the Honest Sign system on turnover for wholesale and retail sellers)
- Dairy products (in terms of mandatory traceability labelling for farmers)
- Malt beer and beverages made from beer (beer drinks), cider and pear cider, and other fermented sparkling and non-sparkling drinks with an actual alcohol concentration of no more than 7% volume (in terms of mandatory traceability labelling)
- Packaged drinking water (in terms of reporting in the Honest Sign system on sales)

In addition, several traceability labelling experiments are being conducted until 28 February 2023:

- Voluntary traceability labelling of biologically active supplements
- Voluntary traceability labelling of beer, beverages made from beer and certain types of low-alcohol beverages
- Voluntary traceability labelling of antiseptics
- Voluntary traceability labelling of medical devices

To take part in the experiment, manufacturers must follow the link https://markirovka.crpt.ru/register and contact the operator of the Honest Sign system. In practice, the experiment consists of the testing of the traceability system and is usually followed by introduction of mandatory traceability labelling, so in the event an experiment is started, it could be advisable to take part in it to ensure the smooth operation of all systems after mandatory traceability labelling is introduced.

There are different opinions on the need for a traceability labelling system in Russia since, apart from positive consequences, there are negative results as well (traceability labelling leads to additional work and expenses for manufacturers, importers, wholesalers and retailers, which ultimately leads to increased prices for goods). Nevertheless, we see a clear trend on the extension of traceability labelling and it is highly probable that more and more goods will be subject to this labelling and reporting each year. Thus, we believe it would be advisable for all manufacturers and importers of goods to Russia to keep an eye on how the system develops and be prepared for its introduction with regard to their products.

General regulatory issues

Sanctions-related restrictions on exports from Russia

As a part of the counter-sanctions policy in 2022, the Russian government has introduced several export restrictions that vary depending on the type of exported goods.

Please see below for the main restrictions imposed on exports from Russia, which have been extended for 2023 as well:

A) **General export ban**

Certain categories are subject to a general ban on exports from Russia (e.g., agricultural machinery, vehicles, certain types of industrial products, telecommunication equipment, medical goods, etc.). There are certain exceptions to this general ban:

- This ban does not apply to exports to the EAEU and other selected territories. Exports of these goods to the EAEU is subject to the export permit set out in point C below.
- The export of the listed goods originating from Russia is allowed, but only if a special certificate of Russian origin (form CT-1 or other) is obtained. Thus, it does not automatically mean that goods manufactured in Russia are free for export.

In addition, in exceptional cases, even if the case is not covered by the exceptions provided by law, exports may be authorised by a decision of the Russian prime minister or a deputy prime minister.

Applicable regulations: Decree of the Russian Government No. 311 dated 9 March 2022; Decree of the Russian Government No. 361 dated 14 March 2022

B) **Targeted export ban**

Certain timber and steel items are banned for export from Russia in the event: a) the goods are exported to the listed foreign states (those

that imposed sanctions against Russia), or b) the exports are made under foreign trade contracts concluded with persons/entities from the abovementioned countries or the payments under the contract handled through the banks registered in such a foreign state (even if the goods are not sent to the listed states directly).

Please note that the targeted ban also covers certain dual-use goods listed separately in the same Decree.

Applicable regulation: Decree of the Russian Government No. 313 dated 9 March 2022

C) **Export permits**

A permissive regime is in place for the export of the listed goods to the EAEU and selected territories (the general export ban is imposed on exports to other countries, as mentioned in point A above).

The restrictions apply to the following types of goods depending on the listed HS Code: a) agricultural machinery (authorised body – Ministry of Agriculture); b) vehicles, parts and components (authorised body – Ministry of Transport); c) certain types of industrial products (authorised body – Ministry of Industry and Trade); d) telecommunication equipment (authorised body – Ministry of Science and Technology); e) certain types of laboratory, mining, exploration and geophysical equipment (authorised body – Ministry of Natural Resources); f) medical goods (authorised body – Ministry of Health).

Each authorised body establishes its own procedure for obtaining the relevant export permit without which customs will not confirm the export of the goods. One of the grounds for denying a permit is a shortage of exported goods in Russia.

Similar to the exception from the general ban (item A above), permits are not required for the export of the listed goods originating from Russia, but only if a special certificate of Russian origin (form CT-1 or other) is obtained.

Applicable regulation: Decree of the Russian Government No. 312 dated 9 March 2022 and ministerial regulations on the procedure for obtaining permits

The exact list of goods with respect to each of the regimes is periodically updated and structured according to the HS Codes, so changes should be reviewed.

In addition, the applicable regulations specify a number of exceptions for each list of goods (e.g., goods originating in Russia and exported for private use). Consequently, a full and detailed analysis is required in each case to make a final conclusion on the ability to export the exact goods from Russia and the applicable procedure.

"Clean up your mess": new obligations to remedy environmental damage

Starting from 1 September 2023, the key provisions of Federal Law No. 446-FZ dated 30 December 2021 "On Amendments to the Federal Law "On Environmental Protection" and Certain Legislative Acts of the Russian Federation" will come into force (the so-called "Usolsky Law", which was unofficially named after a chemical plant that went bankrupt and left behind a lot of hazardous waste to be dealt with by state bodies).

The main purpose of the Usolsky Law is to require owners of hazardous industrial facilities and waste disposal facilities of hazard classes I and II, as well as coal mines (together "HIF") to be responsible

for environmental damage during the decommissioning stage and remedy damage, if any, using the following instruments.

Action plan

- HIF owners will be obliged to develop an action plan to prevent and eliminate environmental pollution no later than 5 years before the end of the HIF operation time.

- All costs on preparing an action plan will be borne by the HIF owners. An independent guarantee, suretyship or reserve fund must provide evidence of sufficient funds for the plan's implementation.

- Within 2 months from the date of the plan's implementation, the owners of HIF must submit to Rosprirodnadzor an action plan implementation report.

Compensation payment as a kind of liability

- If an action plan is not prepared, HIF owners may be required to pay compensation to the state budget. The compensation payment is a result of the failure to submit an action plan and accompanying documents for the mitigation of a decommissioned HIF.

- The compensation payment is calculated by Federal Service for the Supervision of Natural Resources based on the degree of environmental pollution resulting from the operation of HIF. The methodology for calculating the compensation payment will be approved by the Russian government soon, but is expected to help cover all costs incurred for the measures to be implemented to prevent and eliminate environmental pollution.

Related restrictions for non-compliance

- If a company owing a HIF fails to comply with a court order to make a compensation payment, it may not decide on the payment of dividends and may not pay the declared dividends on the shares.

- In the event of a transaction to dispose of HIF or the reorganization of its owner within 5 years or less prior to the expiry of HIF operation, the buyer/successor must provide documents on an action plan, after which the Federal Service for the Supervision of Natural Resources shall issue an opinion on the financial security of the HIF owner. Otherwise, provided that the owner has already made the compensation payment, the evidence of payment will be sufficient to conclude a transaction or engage in reorganization.

- If said transaction or reorganization is planned within more than 5 years prior to the expiry of HIF operation term, the buyer/successor must provide documents on their financial security.

In conclusion, there is a tendency towards stricter environmental legislation with the newly introduced compensation payment that should reflect the real costs on environmental remediation. The HIF owners should take into account the forthcoming requirements at least when planning their budget and updating their compliance policy.

Limitation of state and municipal control

Limitations on state and municipal control were introduced in 2022 and prolonged for 2023. The implementation of such limitations varies in terms of scheduled and unscheduled inspections:

- **Scheduled inspections.** Scheduled inspections may be carried out only with respect to:

  - Monitored sites that are classified as extremely high-risk and extremely high-

risk facilities, hazardous production facilities of hazard class II and hydraulic structures of class II. This means that inspections related to other non-risk facilities (e.g., offices and shops) should not be conducted.

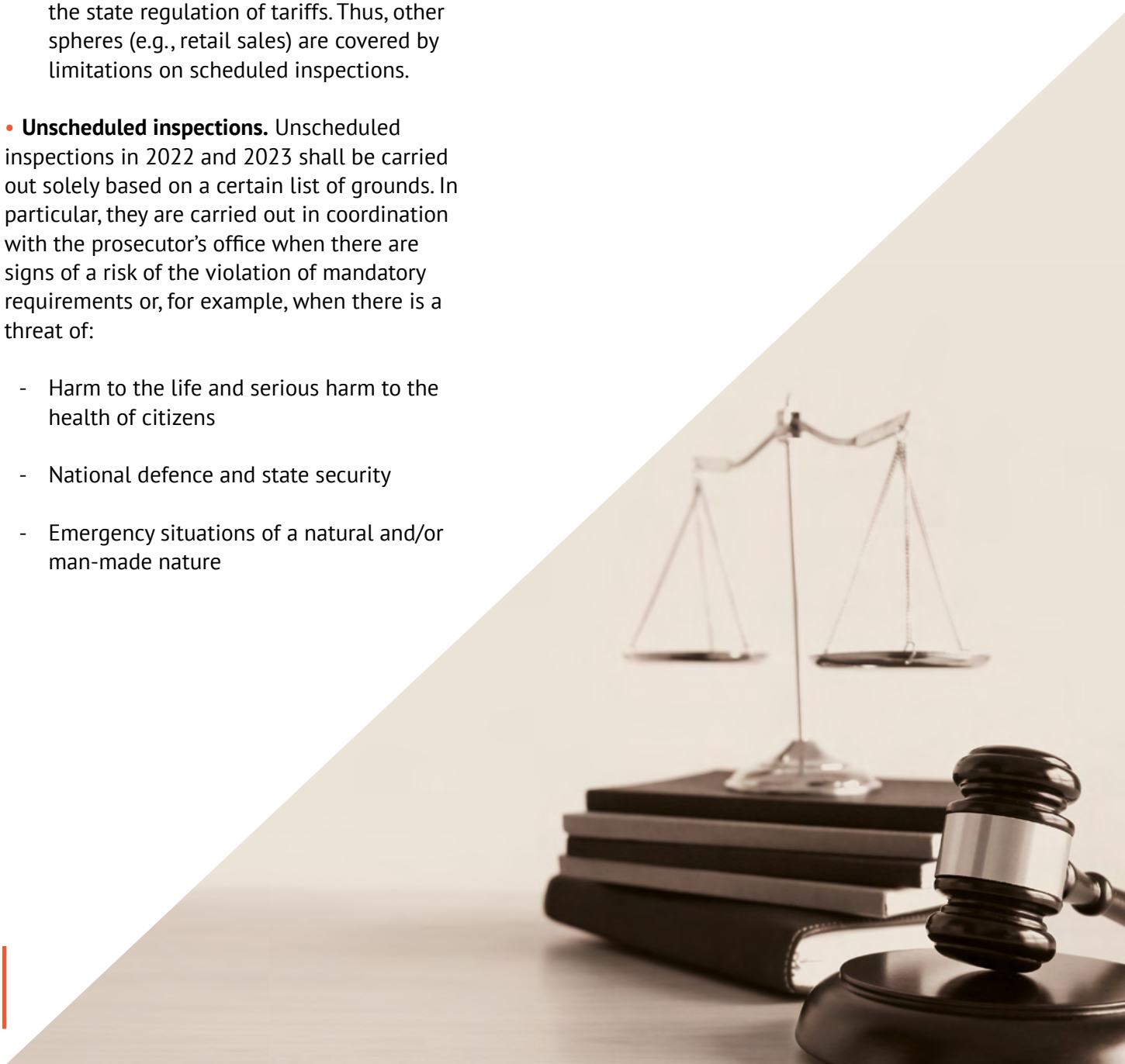
- In the spheres specifically indicated in Decree of the Russian Government No. 336 dated 10 March 2022 "On the Specifics of the Organization and Implementation of State Control (Supervision) and Municipal Control". In particular, this includes inspections that are carried out with respect to federal state supervision in the use of atomic energy, as well as regional supervision in natural monopolies and the state regulation of tariffs. Thus, other spheres (e.g., retail sales) are covered by limitations on scheduled inspections.

• **Unscheduled inspections.** Unscheduled inspections in 2022 and 2023 shall be carried out solely based on a certain list of grounds. In particular, they are carried out in coordination with the prosecutor's office when there are signs of a risk of the violation of mandatory requirements or, for example, when there is a threat of:

- Harm to the life and serious harm to the health of citizens
- National defence and state security
- Emergency situations of a natural and/or man-made nature

It should be noted that preventive and control (supervisory) measures may be carried out without any interaction with the entities that are subject to such control. The latter do not require coordination with the prosecutor's office.

Taking this into account, in the event that a company's officials see that it has become subject to a state inspection, it would be advisable to double check the grounds for such an inspection and the applicability of the general limitations described above. Should an inspection be unsubstantiated (violates the limitations), there is a good chance to invalidate the inspection and challenge its results.



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