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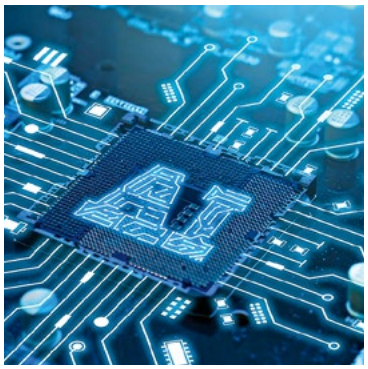
POSITION PAPER 2025

KEY ISSUES AND REGULATORY DEVELOPMENTS



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Dear readers,

In this special year of AEB's 30th anniversary, we are pleased to present to you the "AEB Position Paper 2025: Key Issues and Regulatory Developments".

The edition focuses on the most significant topics for our members and the Association, which experts from member companies addressed throughout the past year. The "Key Issues" part covers specific topics of relevance and outlines AEB's positions, recommendations and proposals in this regard, whereas the "Key Regulatory Developments" section comprises comments on the legislative changes and introduced novelties and reviews potential implications for foreign investors.

The articles presented in the publication deal with such issues as: taxation, regulation of marketplaces and the platform economy, recent customs trends, changes in parallel import rules, migration, trade and digital labeling of goods, pharmaceuticals industry and a medical devices market, insurance challenges and solutions, innovations in home appliances manufacturing, changes in conformity assessment of products, extended producer responsibility, imports of seeds and pesticides, specifics of veterinary market, AI perspectives, corporate and financial transactions, personal data, internet advertising, counteracting the spread of counterfeit products, consumer protection, sustainable development, real estate and construction.

We are immensely grateful to all the members who provided insightful contributions to the publication (in alphabetical order): Elena Agaeva (EPAM Law); Vladislav Arkhipov (Denuo); Alexey Aronov (Denuo); Anton Bankovskiy; Igor Bruevich (KWS RUS); Ilya Bulgakov (Denuo); Elena Chetverikova (Denuo); Veronika Emelianova (AstraZeneca); Darya Ermolina (Denuo); Ekaterina Erova (Melling, Voitishkin & Partners); Valeriya Eystrakh (Melling, Voitishkin & Partners); Alexey Filipenkov (Visa Delight); Roman Golovatsky (Denuo); Olga Gorokhova (ALRUD Law Firm); Nina Goulis (Kept); Alexey Grigoriev (METRO Russia); Roman Ishmukhametov (Melling, Voitishkin & Partners); Maria Kedrova (Thuricum); Maria Kelendzheridze (RB Life insurance); Denis Khabarov (Melling, Voitishkin & Partners); Andrey Kolesnikov (Teva); Irina Kosovskaya (EPAM); Yana Kotukhova (Servier); Elena Kvartnikova (EPAM Law); Shermet Kurbanov (SEAMLESS Legal); Maya Limonnikova (Servier); Ksenia Litvinova (Pepeliaev Group); Sergey Lomakin (Melling, Voitishkin & Partners); Dmitry Miklin (Herbalife); Nikita Nizkous (L'Oreal); Varvara Oglezneva (SumiAgro Russia); Maria Ostashenko (ALRUD Law Firm); Mikhail Pereverzev (Varian Medical Systems); Anastasia Petrova (ALRUD Law Firm); Galina Rezvan (GE Healthcare); Pavel Rudyakov (Samsung Electronics Rus); Alla Ryashentseva (SEAMLESS Legal); Gleb Samoilov (AVPHARM); Kazbek Sasiev (Nextons); Anna Savkunova (Nextons); Wilhelmina Shavshina (B1); Ludmila Shiryaeva (B1); Mikhail Sholokhov (Denuo); Mikhail Sinyavskiy (Nextons); Ksenia Sizova (B1); Andrey Slepov (ADVANT Beiten); Alexej Soldatow (BSHG); Ekaterina Sorokina (Melling, Voitishkin & Partners); Armen Tadevosyan; Zalina Tettsoeva (EPAM); Sergey Tikhov (Denuo); Capitolina Tourbina; Yulia Varlamova (Teva); Sergey Vasiliev (Denuo); Vera Volkova (B1); Yuri Yakhin (Melling, Voitishkin & Partners); Marina Zabalueva (Sanofi); Vadim Zakharenko (IRU); Andrey Zharskiy (ALRUD Law Firm); Semyon Zhavoronkov (AVPHARM); Leonid Zubarev (SEAMLESS Legal).

We hope that the materials will be instrumental in achieving goals set by AEB members companies and businesses considering the possibility of joining the Association.

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Release date: February 25, 2025

KEY ISSUES

FOREIGN BUSINESS IN RUSSIA: MODERNIZATION OF TAX 'RULES OF THE GAME'

In 2024, a number of federal laws were adopted in the field of tax, significantly affecting the amount and procedure of taxation in 2025 and subsequent periods. The changes are mainly aimed at increasing the tax burden, and they affect companies with both Russian and foreign shareholders, as well as individuals. Thus, from 1 January 2025, the corporate income tax rate will increase from 20 to 25% as, accordingly, will the withholding tax rate (from 20 to 25%), except for certain types of income. Excise taxes and mineral extraction tax will be adjusted upwards, and a new tourist tax will be introduced. In addition, the income tax rate for companies engaged in IT activities is to rise from 0% to 5%, while insurance premiums are also being increased.

Significant changes also concern the taxation of individuals: a five-stage personal income tax scale is being introduced, with a maximum rate of 22% (at the level of income over 50 million roubles) as against the current 15% rate. A separate taxation procedure is established for certain types of income.

Thus, in 2024 the trend that gained momentum in past periods and is associated with an increase in the tax burden for almost all major taxes has crystallized more clearly.

Cross-border transactions, especially with related parties, also remain a focus of the legislature's attention. Thus, in 2024, the suspension of certain provisions of double tax agreements with European countries continued to apply. This led to a significant increase in the tax burden when dividends, interest and royalties are paid to foreign companies, which, together with the current procedure requiring permission for the payment of, primarily, dividends, significantly reduces the potential for the preservation and development of business in Russia. Unfortunately, the measures previously taken to mitigate the consequences of the suspension of double taxation are limited and do not apply to transactions with related parties.

In addition, significant changes to transfer pricing regulation, which came into effect from 2024, in many respects change the standards of documentation. They also significantly adjust approaches to the standards of proving that prices conform to the market level and that liability has been established along with its extent.

> In 2024, a number of federal laws were adopted in the field of taxation. The changes are mainly aimed at increasing the tax burden, and they affect companies with both Russian and foreign shareholders, as well as individuals.

Thus, in particular, when the RF Federal Tax Service adjusts prices (income) in controlled transactions between related parties, a party's income in the amount of such adjustment is equated to dividends only in relation to a foreign recipient regardless of whether the latter has corporate control over the Russian taxpayer. Similarly, the approach to liability for understating tax payable as a result of non-market prices being applied and the possibility of exemption from liability differs depending on whether the transaction has the nature of a domestic or cross-border transaction. If a taxpayer possesses documentation confirming that the prices of its transactions correspond to market prices, this will allow it to avoid liability only in the case of a domestic transaction. At the same time, the amount of the penalty for claims relating to a cross-border transaction is several times higher than the amount of the penalty for a similar offence relating to a domestic transaction.

Simultaneously, the tools of revising prices in the Tax Code of the Russian Federation for tax control, based on the median value of the interval, lead to an increased tax burden on the taxpayer (measured against comparable companies). This is because, in essence, additional charges for the difference between the median and the lower (upper) value of the interval will relate to the market price level (profitability).

It is also worth recalling that, from 1 January 2024, a 15% foreign income tax rate was introduced on payments under any service/work contracts concluded with a related foreign company. This also increases the burden on services that are often necessary for a Russian company's business to function normally, while the growth in the price of such services to offset the additional tax burden will lead to the risk of transfer pricing revisions.

The foregoing, namely, the changes in legislation introduced in 2024 and those expected to be introduced in 2025, indicate that the tax burden is increasing. This includes for foreign groups operating in Russia and having a large number of intra-group transactions, which may become restrictive for those companies that, despite the current situation, continue to be active in Russia or plan to enter the Russian market.

KEY ISSUES

LEGAL REGULATION OF MARKETPLACES

Marketplaces have transformed the interaction between sellers and buyers, bringing them closer than ever before. With goods now just a click away, marketplaces offer significant societal value.

However, this convenience often hides the identity of the actual seller. Consumers frequently engage directly with the platform, relying on its reputation and infrastructure, often unaware of the true seller's existence.

A pressing concern is the sale of products requiring *declaration, certification, state registration, licensing, or inclusion in special catalogs* that do not meet these requirements or are accompanied by fraudulent documentation. Particularly sensitive categories include pharmaceuticals, medical devices, pesticides, food products, cosmetics, and household chemicals, all of which pose potential risks to consumer health and environmental safety.

Manufacturers of medicines are faced with cases of illegal sale of medicines without authorization documents (license, online trading permit) by unscrupulous sellers on marketplaces, sale of counterfeit and unregistered medical devices is observed.

The turnover of pesticides requires that the substance undergoes state registration, within the framework of which it is thoroughly tested, receives the appropriate certificate for 10 years and is included in the State Catalog of pesticides and agrochemicals allowed for use in the territory of the Russian Federation. Special requirements apply to transportation and storage of pesticides. However, there are sellers who on marketplaces sell pesticides that have long since expired Certificate of State Registration, as well as pesticides that have been discontinued and are not available in the offered packages (i.e. knowingly counterfeit).

Similar cases occur in the segment of food products, primarily in the segment of biologically active food supplements, when sellers sell dietary supplements that have not passed state registration, have exceeded the permissible dosages of active substances, and contain substances not authorized for use, including toxic ones.

In addition, there are cases of selling goods on marketplaces that *violate the legislation on trademarks, protection of exclusive rights and interests of right holders*. These are goods imported into Russia as part of unauthorized parallel imports, and in addition, there are cases of sales of goods that violate trademark legislation, protection of exclusive rights and interests of right holders.

As a result of such sales, the consumer not only bears the risks associated with the quality and safety of such goods, but may also be deprived of the opportunity to protect their rights in relations with the legal representatives of right holders, who may not be liable for products, the sale of which they did not control.

This practice is fraught with damage to the investment climate and to the interests of bona fide right holders who, while complying with all legal requirements, bear additional costs, as well as ensure brand recognition at the cost of marketing investments, the lack of which allows unscrupulous players to dump prices.

Marketplaces have cases of *violation of legislation on mandatory labeling* with means of identification and traceability in sales of relevant goods.

Some sellers resell labeled goods purchased by them as end consumers, for example, under a promotion, and withdrawn by the retailer from circulation in the "Honest Mark" system. There are also cases of sales of unlabeled goods in categories for which it is mandatory.

The legal framework governing the relationships among marketplaces, sellers, and buyers is still developing in Russia, leaving many rights, responsibilities, and liabilities undefined. Effective state regulation is essential for sustainable growth, equitable competition, and consumer safety.

To ensure balanced development and protection for all stakeholders — from big corporations to SMEs — state regulation should foster cooperation rather than conflict between market participants and regulators.

Sellers and producers of goods, trademark right holders and marketplaces united by AEB consider the main goal of the regulation to be the protection of consumers' interests and share responsibility towards them. The key regulatory objectives include:

- ensuring the safety of goods sold on marketplaces;
- enforcing intellectual property rights and compliance with exclusive rights laws;
- promoting traceability through adherence to mandatory labeling requirements;
- encouraging fair competition among various e-commerce models.

Drawing from international best practices (notably in China, the EU, and the US), AEB proposes the following principles as a basis for the regulation to be created:

- shared accountability: marketplaces should bear joint administrative responsibility with sellers for unsafe goods, intellectual property violations, or non-compliance with labeling laws;
- liability exemptions: platforms that implement sufficient preventive measures against these violations should be exempt from liability;
- exhaustive measures: clearly define and limit the measures marketplaces must undertake to mitigate risks;
- unchanged seller responsibility: the responsibilities of sellers and manufacturers should remain consistent and clearly defined;
- pre-administrative resolution: marketplaces should facilitate collaboration among producers, right holders, and sellers through standardized, mandatory procedures to address issues before administrative actions are taken;
- equitable regulation: legal frameworks should avoid creating undue advantages for any party;
- by aligning marketplace practices with robust regulatory standards, all participants can thrive while ensuring consumer safety and trust.

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KEY ISSUES

CUSTOMS TRENDS: REGULATION AND PRACTICE

CURRENT ISSUES OF DETERMINING THE COUNTRY OF ORIGIN OF GOODS

Proving the country of origin of goods is becoming an increasingly salient issue for companies that import goods into Russia. Not only does the origin of goods directly affect eligibility for tariff preferences, but it also determines whether certain categories of goods are subject to higher import duty rates and anti-dumping measures.

A particularly acute issue at present is proof of origin for non-preference purposes. In particular, Government Decrees No. 788 of 06.07.2018 and No. 2240 of 07.12.2022 set duty rates of up to 50% for certain types of goods (tools, specialized road-building machinery, flowers, confectionery, perfumes, cosmetics, articles of apparel, and others) originating in states and territories which take measures that are detrimental to the economic interests of the Russian Federation.

Furthermore, businesses are finding it increasingly difficult to obtain certificates of origin for goods originating in "unfriendly" states, which results in additional financial burdens.

At a recent conference hosted by the Ministry of Finance of Russia (in November 2024), businesses proposed an option whereby the Chamber of Commerce and Industry of Russia would be granted powers to issue certificates of origin for foreign goods. It was also suggested that adjustments could be made at the level of the risk management system so that the customs authorities would require the provision of certificates only in those cases where they have reasonable grounds to believe that a good originated in a country against which measures have been introduced.

A further proposal was for random checks of information on a foreign trade partner to be carried out (at the preliminary decision stage or the post-clearance stage) via Russian trade missions in foreign states (for example, to determine whether the partner imports goods from countries on which Russia has imposed measures). Businesses also called for simplified of proof of origin procedures for companies that have received the status of authorized economic operators.

The dialogue between businesses and the status regarding the proof of origin rules is ongoing, and importers are ready to propose technical adjustments to the current legal framework and assist in the development of compromise solutions.

PROBLEM OF INCLUSION OF DIVIDENDS IN THE CUSTOMS VALUE

As mentioned in the previous report for 2023 concerning the inclusion of dividends in the customs value, the trend towards controlling importers that pay dividends to foreign founders is getting stronger in 2024.

When conducting audits, customs authorities presume that dividends must be included in the customs value of goods supplied by the founder, without establishing the fact of the goods being under-priced. In most cases courts would take the side of customs authorities. However, in the current practice, there are precedents[1] where the inclusion of dividends in the customs value is found illegal due to the supplier's public offer enabling other companies to buy goods at the same prices.

In its recent clarifications, the Ministry of Finance[2] states that dividends should not be included in the customs value on condition of confirmation of the purchase of goods on competing market conditions and their accessibility to other independent market actors. It should be noted that this position applies only to a limited number of situations where the same goods are supplied by different importers at the same price.

[1] Case of SCHOTT PHARMACEUTICAL PACKAGING (A09-1177/2024).

[2] Letter of the Ministry of Finance No. 27-01-21/59650 dd 27 June 2024.

> As practice shows, not in all cases dividends actually refer to the goods checked by customs. Therefore, it is important that companies properly formulate a position that will help them to exclude or substantially reduce potential surcharges, including documentation on the arm's-length level of prices.

The law enforcement practice continues to expand cases where dividends are included in the customs value. Customs and courts recognize dividends paid to the founder who is not a supplier as being "indirectly payable" to the supplier via a group of companies and, accordingly, as being subject to inclusion in the customs value[3].

It can be concluded that since the publication of the position of the Supreme Court of the Russian Federation[4], consistent law enforcement practice in relation to this category of disputes has not evolved yet. As of now, there is no specific legislative regulation on the matter. Clarifications of government bodies, including clarifications of the Ministry of Finance, are ad hoc regulations in nature and do not suggest a single solution to the problem. To our knowledge, EEC is to draft an act concerning the treatment of dividends for customs valuation purposes.

RECOMMENDATIONS

As practice shows, not in all cases dividends actually refer to the goods checked by customs. Therefore, it is important that companies properly formulate a position that will help them to exclude or substantially reduce potential surcharges, including documentation on the arm's-length level of prices.

SUPPLY RESTRUCTURING AND INCLUSION OF THE AGENCY FEE IN THE CUSTOMS VALUE

Supply restructuring in today's environment is a dynamic process which requires constant monitoring. Channels that work today may not be available tomorrow. The main challenges remain the expansion of sanctions, increased compliance scrutiny by foreign regulators and the over-compliance syndrome among foreign counterparties and banks.

To supply goods from "unfriendly" states, companies engage intermediaries, such as trading houses from neutral jurisdictions. There is a growing use of alternative currencies, primarily the yuan. It is increasingly necessary to use the services of payment agents. However, such solutions involve significant costs: currency conversion losses and agent commissions may reach 15-20 percent of the transaction amount.

Due to limited access to traditional payment solutions, we are seeing a growing interest in alternative payment methods. However, contrary to the expectations of cryptocurrency adherents, crypto payments have not yet become widespread in international trade. Such mechanisms remain niche due to the inconvenience of use and lack of clear legal regulation. For the first time in a long time, we are seeing a revival of barter transactions, which demonstrates the flexibility and adaptability of businesses in difficult conditions, but this method of mutual settlement is currently the exception rather than the rule.

The use of the services of payment agents has made the issue of including agency fees in the customs value of goods more acute. The Federal Customs Service believes that the agency fee should be included in the customs value if the agent acts in the seller's interests. The Ministry of Finance, on the other hand, indicates that such expenses should be included if goods cannot be purchased without such payment agent. These disagreements create legal uncertainty, as there is an objective interest in making payments on both sides, and a different interpretation of the terms of a contract may result in opposite conclusions. So far judicial practice on this issue is only beginning to emerge.

[3] Cases of RHI VOSTOK SERVIS (A62-4221/2024) and Beiersdorf (A08 9560/2021).

[4] Rulings of the Supreme Court's Judicial Chamber on Economic Disputes: No. 305-ЭС22-11464 dd 1 November 2022 in respect of case No. A40-20125/2021, Chanel LLC; No. 310-ЭС22-8937 dd 2 December 2022 in respect of case No. A09-1129/2021, Pull & Bear CIS LLC; and No. 310-ЭС22-9639 dd 2 December 2022 in respect of case No. A09-1751/2021, Bershka CIS LLC.

NAVIGATION SEALS

In 2023, the Eurasian Economic Commission (EEC) completed the creation of the regulatory framework necessary for the implementation of the Agreement on using navigation seals for monitoring transport operations in the EAEU, which entered into force on 3 April 2023. However, not all EAEU Member States have yet confirmed their readiness to start this work.

As expected, the phased deployment of navigation seals will cover nearly all freight transport by road and rail for import, export and transit, as well as within the mutual trade. According to the private sector, this approach involves excessive control measures, additional administrative and financial burden, leading to significantly higher costs of transport services and, consequently, an increase in the price of transported goods.

Another point of concern are the plans to extend the use of navigation seals on a wider range of commodities for export and mutual trade discussed within EEC and impose navigation seals in a mandatory manner for the transportation of all types of goods within the Union State of Belarus and Russia, well ahead of the practical implementation of the Agreement.

We believe that navigation seals should perform only a supporting function to control the movement of certain categories of "high-risk" goods or sanctioned commodity groups. The level of data exchange achieved in the EAEU, forms and methods of control, international instruments provided by the UN conventions and agreements on trade and transport facilitation allow for effective monitoring of the movement of goods and vehicles, including those in transit.

PROPOSED ACTIONS:

- to include in the list of exceptions, i.e. goods and cases when tracking with the use of navigation seals is not applied, goods transported under TIR, *on a permanent basis*;
- not to take decisions on identifying new objects of tracking before the implementation of the Agreement is started and the assessment of its effects is made;
- to limit the set of data in a navigation seal to the minimum required by the Agreement and ensure that data is transmitted into a navigation seal directly from the customs' information systems.

KEY ISSUES

CHANGES IN PARALLEL IMPORTS IN 2024

Partial legalization of parallel imports has been in effect in Russia for two years already. In the past year, the Russian authorities repeatedly stated that they intended to reduce the list of relevant items "by expanding the presence of domestic products on the market"[1]. The list was indeed adjusted several times; the Order of the Ministry of Industry and Trade No. 2701 was amended on 16 January, 5 July and 10 October (the latter will come into force in May 2025). However, the list of trademarks has been decreasing in some categories and increasing in others.

The AEB's position on the risks associated with parallel imports remains unchanged and supported by evidence. It should be noted that unfortunately neither the statements about the reduction of the list of products nor the reductions themselves have led to greater clarity in the situation, which creates additional risks to both businesses and consumers.

In the last issue we described the growth in the numbers of counterfeit goods caused by the authorization of parallel imports, as well as the significant increase in the volumes of

[1] The list of goods for parallel imports has been adjusted once again. Parlamentskaya Gazeta, November 13, 2024

such goods on the market. This situation is largely determined by the novelty of the temporary mechanism, circumvention of existing rules by importers, and enforcement problems. Unfortunately, the trend did not change in 2024. According to research data, the illegal turnover of counterfeit and smuggled goods in Russia has grown more than one and a half times in four years, which is five times more than the global average[2], exceeding 10% of the total retail turnover. At the same time, for certain categories of goods, it is clear that from 2019 to 2022 the volume of counterfeits decreased (for example, perfumes), while in 2023 and 2024 there was a serious increase[3]. For some types of goods, the growth over the past two years has multiplied, and in 2024 the increase in numbers of counterfeit goods continued[4].

Legal regulation has also not contributed to the improvement in this area. Although Federal Law No. 79-FZ of 06.04.2024 raised the threshold of criminal liability for illegal use of trademarks from 250,000 to 400,000 roubles, Federal Law No. 192-FZ of 22.07.2024 transferred the management of administrative cases from the police to Rospotrebnadzor, which lacks a number of important powers to effectively combat the spread of counterfeits. According to the statement of Russia's Federation Council, "fragmented control and lack of authority of supervisory bodies to arrest and seize counterfeit and falsified products"[5] stimulate illegal activities.

Notably, options for the protection of IP rights through civil court proceedings are also getting slimmer. As is known, the Constitutional Court of the Russian Federation in its Resolution No. 8-P of 13.02.2018 established that it would be wrong to demand from importers the same compensations that apply to the manufacture and sale of counterfeit products, and limited the possibilities to destroy illegally imported products. However, Federal Law No. 259-FZ of 8 August 2024 introduced significant amendments to the legislation on taxes and fees, in particular raising state fees for applying to court.

The members of the Association also identified other difficulties. For example, Resolution of the Council of Ministers of the Republic of Belarus (RB) No. 209 of 06.04.2022 defines the list of foreign states committing hostile actions against Belarusian legal entities and/or individuals. In particular, all member states of the European Union (EU) are named among such states. The State Customs Committee of the Republic of Belarus understands this document as banning the registration of IP of companies from the EU and other "unfriendly" states in the customs IP register, despite the absence of such a provision in the Resolution of the Council of Ministers. At the same time, refusals to include trademarks in the register are indiscriminate and do not take into account the presence of the company-owner in the market of the Republic of Belarus, Russia or the EAEU, the enforcement of its rights, the presence of cases involving the distribution of counterfeit goods, and other circumstances.

As a result of lack of customs control, holders of exclusive rights have noticed a significant increase in the number of goods of unknown origin bearing the trademarks of right holders imported into the EAEU through the Republic of Belarus, as well as the sale of such goods through online marketplaces either in Russia or even directly from the Republic of Belarus. This approach does not comply with the EAEU rules and violates the principles of regulation at the level of the Union.

This issue requires cooperation at the EAEU level, as there is usually no customs control of goods imported from Belarus, and Russian state authorities cannot take any decisions aimed at changing the law enforcement practices of another state. AEB has sent a request to the Eurasian Economic Commission on this issue and will continue to work in this direction.

At the same time, the national regulation of marketplaces where the majority of illegally imported goods are sold could be an effective mechanism besides interstate cooperation. Regulatory issues are being raised at various levels, including at the legislative level, and AEB actively participates in discussions on this issue. At the same time over the last year there have been attempts at self-regulation to reduce the volume of counterfeit goods, but they did not include initiatives to combat illegal imports, which makes such efforts not very effective already at the design stage.

Meanwhile, it is impossible to limit oneself to regulating the activities of online marketplaces, as this resembles treating a symptom rather than a disease. Factors causing serious concern include (i) the refusal of some right holders to take measures to protect intellectual property in Russia, (ii) difficulties in bringing wrongdoers to justice, (iii) the transfer of the functions of drawing up protocols on administrative offences from the police to supervisory bodies in the field of consumer protection, and (iv) the refusal of the Republic of Belarus to control the import of goods under the trademarks of companies from certain countries, as they not only create risks for market participants from Europe continuing to operate on the Russian market, but they obviously also create risk for Russian consumers, reduce tax revenues for budgets, and increase threats to the economy as a whole and the opacity of cash flows.

Although AEB considers parallel imports inevitable in the short term and predicts that they will be in force in the near future in respect of certain commodity items, it nonetheless believes that it is critically important to transition to law enforcement that excludes the import of products that violate the exclusive rights of right holders in circumvention of the established mechanisms and entail risks for the market, for consumers, for budgets of various levels, and for the economy as a whole. Otherwise, the negative trends in this area will increase.

[2] RBC experts evaluated the share of illegal turnover in Russia at 10% of all retail. RBC, June 5, 2024

[3] Modern Russian market of counterfeit products: leading factors and trends. Electronic scientific journal "Century of Quality", 2024, No. 3

[4] Prices and counterfeit increase. There is a deficit of original spare parts in Russia. Avtonews, October 31, 2024

[5] Poison in the fields — the price of uncontrolled circulation. The Federation Council website, October 31, 2024

KEY ISSUES

TOPICAL ISSUES IN THE FIELD OF MIGRATION

HQS

The migration concept, which is currently being developed, practically, does not foresee the current advantages and benefits of highly qualified foreign workers (HQS), therefore, equalizing HQS with other categories of foreign citizens. To date, the draft law has not been submitted to the State Duma; at the same time, a number of provisions from the draft law have already been approved by several legal acts.

PROPOSAL:

The Committee has submitted a number of proposals to the draft law in order to maintain the current preferences for HQS.

ATTRACTION OF QUALIFIED FOREIGN WORKERS

The main obstacle to the rapid employing in Russia of foreign nationals from visa countries that do not meet the HQS criteria is the quota procedure, which cannot be used in a quick manner.

PROPOSALS:

To introduce a hybrid option for attracting foreign workers, including elements of the patent system, regular work permits and HQS work permits, the main condition of which could be a monthly payment equivalent to a tax on a fixed salary of, for example, 60,000 roubles per month. To abolish the quota requirement and a permit to hire and use foreign workers for foreign workers employed under the hybrid option.

QUOTAS

One of the issues is the timeline of the standard procedure for attracting foreign labor connected with obtaining quotas, as many federal and regional authorities are involved in the quota approving process. It should be noted that a similar procedure is applied when the allocated quotas for the current year require adjustment.

PROPOSALS:

To revise the current quota mechanism, which was developed under different economic, geopolitical and demographic conditions, in order to simplify or abolish the quota mechanism. In the current situation, Russia is interested in a more flexible, faster and more efficient attraction of foreign labor. Proposals to simplify the quota mechanism are set out below:

- reducing the timing of the process of quota adjustment for the current year to one month;
- establishing the quota adjustment mechanism on a monthly basis;
- establishing deadlines for issuing relevant orders on quota redistribution for the current year, for example, not later than the 5th day of each month;
- supplementing the list of professions, specializations and qualifications of foreign citizens not subject to quotas with the professions, specializations and qualifications most demandable according to economic and (or) social criteria, taking into account the regional peculiarities of the labor market;
- conclusion of bilateral agreements with "friendly" countries in order to simplify the rules for temporary employment of citizens of one state in the territory of another state.

NEW LIST OF NON-QUOTA OCCUPATIONS

On 15 December 2023, the Order of the Russian Ministry of Labor No. 459n of 15.05.2023 came into force, which approved a new list of non-quota positions.

In this Order, the positions previously designated as "Director (General Director, Manager) of an enterprise" are now specified as "General Director of an enterprise (except for small enterprise)" and "Director of an enterprise (except for small enterprise)".

Due to these changes the companies just starting business in Russia, or those with low turnover and a small number of employees, now cannot apply for work permits for the position of 'general director' or 'company director' without going through a lengthy process of quota obtaining for this position. As a result, small and micro-enterprises currently face related bureaucratic difficulties, and they need to develop options for work permits application for other positions for former and future CEOs.

PROPOSAL:

To delete the phrase "except for small businesses" from the following non-quota positions: "General Director of the enterprise", "Director of the enterprise".

PROOF OF RUSSIAN LANGUAGE KNOWLEDGE BY FOREIGN CITIZENS

In practice, foreign citizens, with the exception of HQS, who are hired to work in Russia for a short period do not have a command of the Russian language, knowledge of Russian history and the basics of Russian legislation and, as a result, cannot obtain a work permit.

PROPOSALS:

- To consider the possibility of exempting certain categories of foreign citizens, whose labor duties do not require such knowledge, from the requirement to provide proof of knowledge of the Russian language, Russian history and the basics of Russian legislation. The list of occupations, specialties and qualifications of such foreign citizens may be established by an appropriate authority (by the of the Governmental Decree, the Ministry of Labor Order).
- To consider the change of the requirements for the knowledge level of the Russian language for foreign citizens hired for a deliberately short work period, namely: to establish an elementary level (A1) of Russian language skills for each sphere of employment of foreign workers.
- As regards the other categories of foreign workers who are required to have the necessary level Russian language skills, knowledge of Russian history and the basics of legislation, to allow the submission of the supporting document within a certain period upon a work permit receipt (e.g., within 2-3 months after obtaining a work permit), with the condition that the work permit may be annulled if the supporting document is not provided within the specified period.
- To create conditions for testing foreign citizens with regards to Russian language skills, knowledge of Russian history and the basics of Russian legislation outside Russia (e.g., on the basis of Rossotrudnichestvo).

INVESTORS

Currently, the main obstacle to increase in number of applications for residence permits for foreign investors is the long period between the fact of investment made, and the possibility to submit documents. This is the required 2-year period of economic activity of a legal entity and necessary tax payments for new legal entities, and for existing legal entities the period may be 2-3 years.

As a result, a foreign investor has to solve the issue of entry and stay in the Russian Federation for himself and his family members during several years. In practice, such a problem is solved by establishing a Russian legal entity by a foreign citizen, appointing a Russian citizen as the general director, and only after that, the legal entity may invite the founder to work in Russia with subsequent work permit and visa applications in accordance with the HQS procedure. And later it becomes possible to apply for the HQS residence permit with the subsequent replacement by a permanent residence permit.

PROPOSALS:

- To open an entry visa program that precedes the investor's residence permit with the issuance of an entrepreneur visa. This visa can be valid for 3-4 months for the entrepreneur and his/her family members. During the validity of the visa, the entrepreneur must register the business, invest funds and start business activities.
- In order to prevent overuse of this program, it is possible to limit the frequency of applications for this type of visa, to introduce criteria to confirm the intentions and competences of a foreign citizen.

Currently, the main obstacle to increase in number of applications for residence permits for foreign investors is the long period between the fact of investment made, and the possibility to submit documents. This is the required 2-year period of economic activity of a legal entity and necessary tax payments for new legal entities.

- To foresee the possibility to extend the entrepreneur visa (for investor and his family members) on the basis of realization of the purpose of entry, i.e. confirmation of the legal entity establishment, contribution to the charter capital, economic activity fulfillment.
- To establish the possibility of applying for an investor's residence permit after one year of business activity based on an entrepreneur's visa, provided that during this period the established legal entity has paid the taxes and contributions established by law and has met the criteria approved by the Government of the Russian Federation.
- To consider reduction of the required investment level not only for socially significant projects, but also for other industries requiring urgent development, such as IT, project development and engineering, etc.

BUSINESS TRIPS OF FOREIGN CITIZENS WORKING IN THE RUSSIAN FEDERATION ON THE BASIS OF A PATENT

Currently, foreign citizens working in the Russian Federation based on a patent are not allowed to make business trips or, in the case of itinerant work, to perform labor activities outside the region of the Russian Federation in which the patent was issued. According to the Order of the Ministry of Health and Social Development of the Russian Federation No. 564n of 28.07.2010, exceptions are established only for work permits and temporary residence permits holders.

For example, long-distance lorry drivers from the Central Asian Republics should be able to travel throughout the country to solve the issue of current shortage of drivers.

The same applies to service technicians who need to travel to different regions to visit equipment customers for service and repair work.

PROPOSAL:

A foreign worker who has been granted a patent in one of the constituent entities of the Russian Federation and has concluded an employment contract that foresees itinerant work or business trips to other regions should be allowed to perform such a work for a period not exceeding 30 consecutive calendar days or another period.

KEY ISSUES

PRICE REGULATION IN TRADE

The issue of excessive state regulation in general remains one of the main concerns of Russian trade. In this context, regularly emerging political and legislative initiatives to expand government intervention in pricing freedom continue to be the focus of attention of the trade industry. As a rule, these are proposals through "voluntary self-restriction" of participants or through amendments to the Federal Law "On the Basic Principles of State Regulation of Trade Activities in the Russian Federation" (No. 381-FZ of 28.12.2009) to set price limits, more often for socially important categories of goods, or to introduce restrictions on trade mark-ups.

The regular appearance of such draft laws is certainly worrying against the backdrop of modern inflationary processes, although, as a rule, such initiatives are either rejected or remain pending for a long time, and state intervention in pricing has so far been generally limited in Russia. Obviously, this cautious approach is related to the understanding at the level of Russia's top leadership of the need to remain committed to the fundamental principles of a market economy — especially when, in the crisis conditions of the last five years, this is what has helped the country to successfully overcome extreme economic challenges.

AEB member companies share the government's concern about inflationary processes and certainly support its desire to ensure the affordability of essential goods for consumers. At the same time, the experience of regulation in 2020-2021 has shown that administrative intervention in pricing in the commodity supply chain can only have a short-term effect,

and in the long term is fraught with undesirable consequences and inevitably ends with a "rebound" of prices to higher levels.

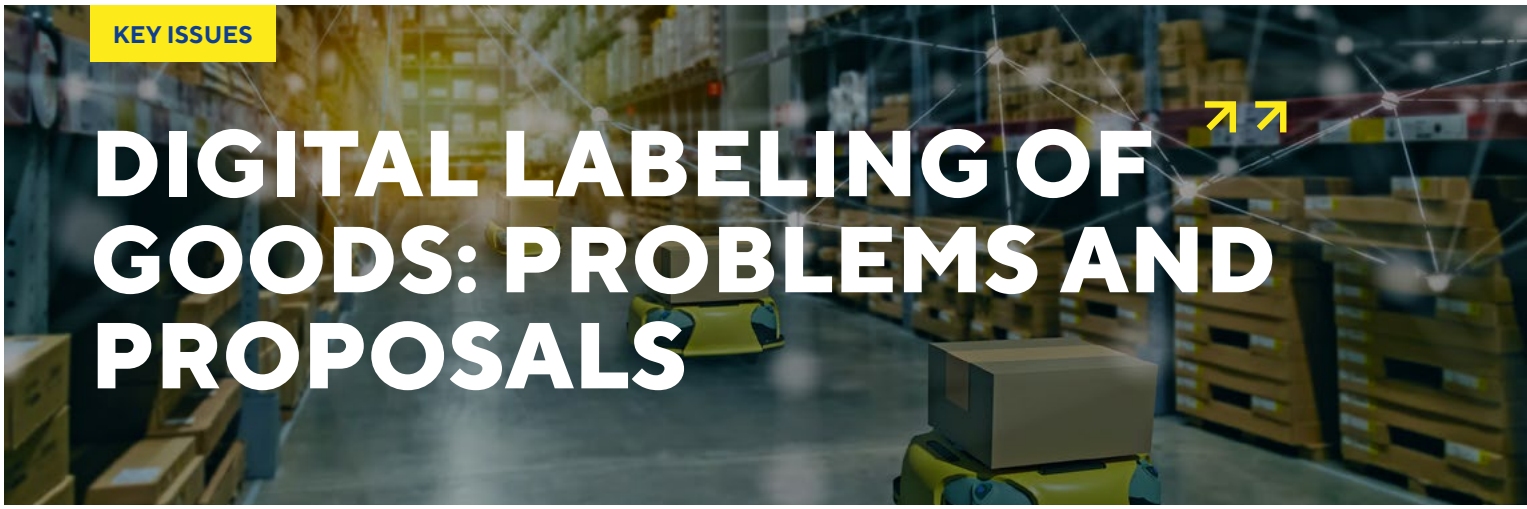
The key problem here is that regulatory intervention discourages market participants from doing business — especially if regulated pricing does not allow them not only to earn a reasonable income, but even to cover the cost of trading services for regulated goods. Small and medium-sized businesses are most exposed to such threats. Accordingly, regulation generates the risk of a reduction in the number of businesses selling regulated goods and, as a consequence, a shortage of the goods themselves.

Moreover, the introduction of price restrictions *only in retail trade*, i.e. in the last link of the commodity distribution chain, can provoke conflicts and failures in the interaction of its participants, especially in conditions of volatile supply and demand caused by multidirectional fluctuations in the production of goods, in their cost, and in consumer demand, as well as increasing difficulties in international payments for goods and international restrictions on imports of many goods into Russia.

It should also be taken into account that the imbalance in commodity markets as a result of administrative interference in pricing significantly distorts *price signals* in the market. This only increases inflationary pressure and expectations of price growth among the population.

It seems much more effective for maintaining price balance in the consumer market to apply measures of targeted budgetary assistance aimed at simultaneous solution of two tasks: strengthening consumer demand — through social payments, tax benefits and other measures — and complex support of producers of socially important goods to stabilize their selling prices.

Overall, the Association is convinced that in the long term stabilization of the consumer market can be achieved only with the help of *market economy tools*. This stipulates the necessity for the state to take a different approach aimed at active promotion of fair competition — both between producers of food products and between food trade enterprises. This always benefits consumers, helps to reduce prices and improve the quality of goods and services offered on the market.



KEY ISSUES

DIGITAL LABELING OF GOODS: PROBLEMS AND PROPOSALS

By the end of 2024 on the territory of the Russian Federation digital labeling of goods by means of identification with marking codes applied to them in the form of Data Matrix presentation has already been introduced in 24 commodity groups, and 16 experiments are being conducted.

Digital labeling is actively developing in the EAEU countries: the Republic of Armenia (21 commodity groups), the Republic of Belarus (9 commodity groups), the Republic of Kazakhstan (10 commodity groups), the Republic of Kyrgyzstan (7 commodity groups).

On September 9, 2024 an Agreement was signed between the Government of the Russian Federation and the Government of the Republic of Uzbekistan on information interaction in order to transmit information about the labeling codes of medicines for medical use.

A mandatory labeling authorization regime at cash registers is being introduced everywhere to check whether it is possible to sell a particular labeled product.

However, despite the active development of the project and the constant improvement of the regulatory framework by the regulator and the operator of the information system together with the business community, many market participants continue to face a number of unresolved problems and tasks, including:

- determination of goods that should be included in a particular commodity group for digital labeling at the 10-character level of the EAEU HS code and determination of exceptions to digital labeling in a particular commodity group;
- determination of methods for applying identification means on goods;
- determination of possible places for applying identification means on goods;
- solving individual product turnover problems for each commodity group;
- turnover of goods in the EAEU zone and mutual recognition of marking codes on goods;
- the role of labeling in the protection of intellectual property rights and the expansion of the volume of information received by a participant in the turnover of goods from the Government Information System for Monitoring the Turnover of Goods (GIS MT).

Considering the complex logistics processes related to imported goods, changes in regulatory requirements, expansion of product range, and duplication of product traceability systems that often collect the same information using different rules, we have to state that it is necessary to improve approaches to labeling and tracking of goods comprehensively.

RECOMMENDATIONS

Within the framework of the described problems, AEB member companies have developed a number of recommendations and proposals that will allow market participants to implement digital labeling of goods less painfully and achieve the project goals stated by the regulator.

1. When deciding on the introduction of labeling in new product groups:
   a. Improve the quality of defining commodity positions included in the list subject to mandatory digital labeling. Consider the specifics of the industry and the unique characteristics of certain commodity positions, their production, import, classification during customs clearance procedures, as well as their circulation and usage. For instance, it is essential to recognize that goods may be used both as standalone products and as components of other goods, whether subject to labeling or not. Additionally, it is necessary to acknowledge that goods circulated in wholesale and retail as a single product may be subject to customs clearance procedures as individual components, accessories, and/or spare parts.
   b. Consider that the obligation imposition to label new product positions affects the determination of the geographical location for applying an identification tool, which may significantly alter interactions with foreign manufacturers (potentially leading to the refusal of supply and further cooperation), changes in delivery logistics, and disruptions in the timelines for delivering goods to the end consumer, for example, regarding warranty obligations for the supply of spare automotive parts.
   c. Take into account the results of experiments from both a technological perspective (the feasibility or infeasibility of applying identification means to commodity positions) and from the standpoint of the potential and costs associated with implementing new business processes, including the introduction of item-level tracking of goods.
   d. Harmonize the approach of all EAEU member countries regarding the introduction of mandatory labeling for new commodity groups, in order to facilitate a seamless implementation of labeling requirements across all five countries for the new product category.
   e. Develop new technological methods for applying identification means to goods, taking into consideration industry-specific characteristics, the feasibility of application, and the properties of the goods and/or consumer packaging to minimize negative factors that contribute to the detachment, unreadability of identification means, and damage or complication of packaging.
2. To improve the functioning of the goods monitoring system in sectors where labeling has already been implemented:
   a. With the active development of a digital ecosystem of state information systems aimed at various types of control based on data provided by participants in the circulation to different supervisory and regulatory authorities, implement a unified software interface for submitting information based on the "Single Window" principle. This will allow participants to submit data in a single instance and according to uniform rules. Such a single window will enable supervisory and regulatory authorities to obtain the entire dataset they require (such as from EGAIS, the "Mercury" system, GIS MT, the National Goods Traceability System of the Federal Tax Service, submissions within the framework of Tax and Customs Monitoring, the Rosaccreditation Information System, etc.).
   b. To balance the requirements of various control and supervisory authorities regarding the array of information submitted in order to eliminate the problem of multiple preparations of submitted information depending on one authority or another.
   c. To increase the level of protection against counterfeit and falsified products in circulation, particularly in the online trading channel. Implement mechanisms to verify the authenticity of goods placed on online platforms.
   d. To implement brand protection mechanisms within the information system for monitoring and traceability of goods as one of the three most important tasks of the digital labeling system. Ensure the protection of intellectual property rights in the circulation of labeled goods in accordance with the Protocol on the Protection and Enforcement of Intellectual Property Rights (Appendix No. 26 to the Treaty on the Eurasian Economic Union).

e. To ensure the ability to apply marking codes on the territory of the Russian Federation at importers' warehouses (after importers have completed customs declaration and customs authorities have released goods for domestic consumption) to reduce significant economic costs for importers and shorten delivery times for consumers.
f. To harmonize the operation of national digital labeling systems for goods and mutual recognition of codes within the territory of the Eurasian Economic Union (EAEU), and eliminate the need to work with multiple traceability systems for a single product group.
g. To implement necessary scenarios for working with goods both as standalone items and as components of larger temporary aggregates, both in the territory of the Russian Federation and throughout the entire EAEU territory, following unified rules (working with temporary and permanent sets of goods in various product groups).
h. To expand the range of information received by participants in circulation from the State Information System for Monitoring and Traceability of Goods (GIS MT) for more optimal construction of production, import, and circulation processes according to their assortment matrix.
i. To mitigate potential degradation of previously functioning services and processes in the GIS MT, for example, the automatic introduction of imported goods into circulation upon the completion of customs procedures and receipt of a positive decision from customs authorities on the import of goods.

KEY ISSUES

PHARMACEUTICAL INDUSTRY: IN SEARCH OF SOLUTIONS TO URGENT PROBLEMS

PHARMA-2030 STRATEGY

The Strategy for the development of the pharmaceutical industry until 2030 was approved by Government Decree No. 1495-r dated 06.07.2023 (hereinafter referred to as Pharma-2030, Strategy). To implement the Strategy, the action plan (roadmap) was approved by Government Decree No. 753-r dated 30.03.2024.

The roadmap includes a number of areas, the implementation of which will have a significant impact on the development of the pharmaceutical industry until 2030. Among them, for example, the introduction of the "second is out" mechanism and the substance traceability system, the development of criteria for the formation of a strategically important drugs' list (SID), etc. On the one hand, these mechanisms are aimed at strengthening drug safety and meeting the needs of the healthcare system. On the other hand, for the development of the pharmaceutical market and maintaining drug supply stability, it is important to balance interests, prevent monopolization of the market (one of the potential risks with the introduction of the "second is out" mechanism), transparency in the formation of criteria and a list of SID in compliance with patent rights.

Regarding the protection of intellectual property, the roadmap to Pharma-2030 involves improving the patent protection mechanism, including through the optimization of judicial practice. And here, the dialogue between the Ministry of Industry and Trade, the Ministry of Health, Rospatent, and the Federal Antimonopoly Service (FAS) with the Supreme Court regarding the application of interim measures is important. Moreover, a positive trend is the recent practice of FAS, which recognized violations of the actions of market participants to bring generic drugs into civil circulation before the expiration of the patent. The state's vector of

maintaining and developing mechanisms for the protection of intellectual rights in pharmaceuticals will contribute to the arrival of innovative solutions for the benefit of Russian patients.

Pharma-2030 also includes the improvement of drug pricing. Current mechanisms, in particular, the mechanism of Government Decrees No. 865 and No. 1771 (shortage/risk of shortage in connection with pricing) contain tools for re-registration of the maximum selling price for essential drugs' list (EDL). However, these mechanisms are not applicable in all cases, for example, the actual inflation rate may significantly exceed the projected one (when indexing the drug from EDL, the projected inflation rate is now used). Therefore, in this case, it would be advisable to consider new price regulation mechanisms adapted to the current situation. It would also be advisable to calculate indexation without reference to changes in the exchange rate of the national currency, which could contribute to increasing the stability of the pharmaceutical market.

In addition, the Strategy pays much attention to the development of new state support measures. One of such measures could be the extension of the reduced income tax rate for industrial complexes. In this regard, the proposal is to consider the possibility of extending the validity of paragraph 5 of Part 1 of Article 284 of the Tax Code until January 1, 2026 (now the deadline is until 01.01.25), either for a longer period, or make it indefinite. The funds received as a result of maintaining this tax benefit will allow industrial enterprises to upgrade fixed assets, modernize production, and also contribute to the preservation of jobs and the development of strategic projects.

Finally, within the framework of Pharma-2030, another important direction is the development of drugs' export. An integrated approach has been developed to stimulate entry into the markets of other countries of drugs made in Russia. Among the possible ways of export optimization is further digitalization of obtaining the CT-1 certificate (confirmation of the "made in Russia" status) by the Chamber of Commerce and Industry (conversion to electronic form by analogy with public services), shortening the time for reviewing documents for obtaining a CT-1 certificate, etc. We believe that these support measures would contribute to the further development of drugs' export.

THE ART OF PRICING IN DETAIL

In the current economic realities, it is essential to ensure physical availability of medicines for the population. One of the ways to support it is introduction of new pricing mechanisms and improvement of current approaches.

Based on the results of discussions in 2024, the Association has introduced amendments to the main regulatory acts governing the pricing of Essential Drug List (EDL). The key document — Government Decree No. 865 of 29.10.2010 — is expected to be updated soon.

At the same time, there are several questions and proposals that were not included in the draft amendments, but which are being actively discussed by the industry and the government:

1. ANNUAL PRICE RE-REGISTRATION FOR FOREIGN MEDICINES

Despite the permanent negative trend of the rouble exchange rate, the existing rule to count the exchange rate on a specific date in the procedure of annual indexation is often a barrier for manufacturers to increase prices even by a level of inflation. To eliminate this barrier, it is proposed switching to the average exchange rate, which will smooth out exchange rate fluctuations.

At the same time, the issue of using only the forecasted inflation rate is still open, as the actual inflation rate may significantly exceed the forecasted one. Simultaneously, the actual inflation in foreign countries where the medicines are produced is not included in the calculations at all.

Thus, current law enforcement and existing barriers do not allow foreign manufacturers to use the procedure systematically and cover their increasing costs. It leads to the risk of shortage, especially for low-price drug groups. To mitigate the negative effect, it is proposed to include the annual inflation rate of the previous year in addition to the forecasted inflation rate for the indexation of foreign drugs up to 100 roubles.

Additionally, the possibility of price re-registration at the level of exchange rate growth will help to avoid the risk of shortage.

2. EXTENSION FROM 1 TO 2 YEARS OF THE EFFECTIVE PERIOD OF THE PRICE INCREASE ORDER UNDER GOVERNMENT RESOLUTION NO. 1771

In cases of temporary or permanent termination of medicines production and supplies, the 1-year period provided by the current rule sometimes does not allow manufacturers to have enough time to purchase the API and necessary materials, renew the production and make changes to the registration documents. It is also worth considering the frequency of the production cycle, which for some medicines are carried out only once or twice a year. Inability to re-register the price in such cases may lead to the assortment availability. There is a proposal to increase the effective period of Price Increase Order from 1 to 2 years and to consider this period for shortage risk assessment.

INTELLECTUAL PROPERTY RIGHTS PROTECTION ISSUES IN PHARMACEUTICALS

From the perspective of intellectual property rights regulation in pharma industry in Russia, the year 2024 was dedicated to addressing a number of strategic issues of legislative regulation and enforcement: a new national pharma strategy with a significant block on IP topics, further development of compulsory licensing, numerous court cases.

Currently, unfavorable conditions have developed in the pharmaceutical market due to the lack of opportunities for manufacturers of original drugs under patent protection to prevent infringement of their rights by unscrupulous market players who introduce analogues into civil circulation without the consent of the right holder.

The lack of effective mechanisms to prevent infringement of intellectual property rights is particularly acute in the registration of drugs and prices for them, as well as in the placement of state orders. The existing problems in the regulation reduce the level of availability of original drugs to patients.

Negative trends are shaping in the market:

- the growing number of cases when analogues being introduced into civil circulation without the consent of the right holder;
- an increase in the number of court disputes, which, coupled with mass refusals by courts of preliminary interim measures, entails significant losses for patent holders;
- a growing number of cases when state purchases of drugs included in the List of VEDs are recognized as invalid due to the negative impact of the registered maximum selling prices of analogues not introduced into civil circulation on the results of tenders.

Early illegal introduction of analogues into circulation leads to losses for the healthcare system since a significant part of income of original drug manufacturers is invested to the development of new innovative molecules.

In addition, despite significant progress in systematizing the use of granting the right to use a patent without the consent of the right holder (order of the Government or a court decision (Articles 1360, 1362 of the Civil Code)), the lack of a transparent system of criteria for determining the presence or absence of the need to apply these mechanisms is also of concern.

We believe that the following proposals could have positive impacts on the ability of Russian and foreign companies to use and protect their intellectual property:

- to improve court practice in the field of interim measures, provide that the court shall issue a ruling on interim measures, in particular, when the plaintiff can confirm the possibility of ensuring the patients' need for medicines for the period of the trial and information confirming the existence of reasons for the plaintiff to believe that there is an infringement of its patent rights;
- to develop measures to prevent the introduction of an analogue into civil circulation before the expiration of patent protection;
- to develop clear and transparent criteria for the Government to make a decision to issue a compulsory license for the right to use an invention related to a medicinal product without the consent of the right holder (Article 1360 of the Civil Code);
- to improve judicial practice in connection with the consideration of disputes on the issuance of a compulsory license on the grounds of insufficient use of a patent within 4 years (Part 1 of Article 1362 of the Civil Code);
- to improve state supervision over state procurement of medicines;
- to improve the procedure of registration of medicinal products and their maximum selling prices.

FEDERAL PROGRAMS TO COMBAT CARDIOVASCULAR AND ONCOLOGICAL DISEASES AS AN INTEGRAL PART OF THE NATIONAL PROJECT "LONG AND ACTIVE LIFE"

In 2025, Russia will launch an updated package of national projects targeted to reach the new and ambitious national development goals of the Russian Federation for 2030 and up to 2036. Preservation of population health and improvement of human well-being is one of the key goals, that is planned to be achieved by increasing life expectancy to 78

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years by 2030 and to 81 years by 2036, with focus on the increase in years of healthy and active life. Primarily, these targets may be achieved by reducing the burden of the most common causes of death both in Russia and globally — cardiovascular and oncological diseases. The corresponding federal projects have been extended until 2030 as part of the new national project "Long and active life".

FEDERAL PROJECT "FIGHT AGAINST CARDIOVASCULAR DISEASES"

The activities of the Federal Cardio project, launched in 2019, made it possible to reduce cardiovascular mortality rate by 4%, including those from myocardial infarction by 22%, and from stroke — by 14%. Implementation of a preferential drug provision program for patients after suffering acute cardiovascular disasters made a significant contribution to this result. Since 2024, the project has been moving towards reducing the risks of acute cardio events in patients with chronic cardiovascular diseases (CVD). The goal is set to increase the number of people with CVD who lived the previous year without acute vascular events to 10% by 2030.

The AEB Health and Pharmaceuticals Committee maintains close dialogue with healthcare authorities to improve solutions to combat diseases of the circulatory system. Modern capabilities of the pharmaceutical industry make it possible to significantly reduce the risks of adverse outcomes associated with cardiovascular disasters. In this regard, further expansion of the Program's reimbursement to patients with chronic CVD, covering socially significant diseases characterized by high blood pressure is the reserve for achieving the national goal of increasing the overall healthy life expectancy.

FEDERAL PROJECT "FIGHT AGAINST ONCOLOGICAL DISEASES"

Since the launch of the relevant federal project in 2019, new medical technologies and modern drugs have been registered in Russia, contributing to both reducing one-year mortality and increasing the 5-year survival rate of patients with cancer. Due to this, the clinical recommendations have significantly expanded. Personalized treatment approaches are being implemented: advances in genomics and biotechnology, targeted and immunotherapy are changing treatment paradigms, significantly minimizing side-effects compared to traditional chemotherapy.

Transferring oncological diseases to a chronic managed status is an important pillar to achieve the new national development goals. To do so, the increase in the detection at earlier stages by implementing screening programs for the most common types of cancer and the use of artificial intelligence technologies should become a priority of the healthcare system in this area by 2030.

In the context of accelerated innovation, the AEB Health and Pharmaceuticals Committee highlights the need to intensify the dialogue with state authorities to develop approaches simplifying regulation in the field of bringing innovative and high-tech treatment methods such as CAR-T therapy to the market.

However, the introduction of innovations to medical care that significantly reduces the burden of malignant neoplasms is possible only if the healthcare system is ready to implement those approaches. This dictates the need to adapt budget planning for the implementation of the federal project "Fight against cancer" by increasing state funding in accordance with the current economic situation and the level of inflation.

An indirect confirmation of the need to expand state funding in this area is the results of the MoH Commissions on the drug lists formation, held in August 2024. A significant amount of innovative drugs was not recommended to for inclusion into EDL or high-cost nosology lists, despite their obvious clinical and financial advantages, which was explained by the increased costs, that those drugs may allegedly bring of the healthcare system. To improve the listing process, the Committee draws attention to the need of elaborating and fixing transparent conditions for the listing procedures. Only in that case pharmaceutical manufacturers will retain the opportunity to form proposals that are in demand by the healthcare system, thus, implementing the principles of social responsibility in terms of ensuring maximum access of patients to treatment.

CONCLUSION

The success in the new national development goals in terms of increasing healthy life expectancy and improving people's well-being directly depends on the ability of the healthcare system to implement innovations, while simultaneously solving emerging issues in open dialogue with the industry. Only by establishing strategic partnerships, investing in digital healthcare solutions, prioritizing sustainability, adopting flexible regulatory strategies, and focusing on equity in patient access to therapy will make it possible to achieve ambitious goals within the framework of the national project "Long and active life".

In 2025, AEB member companies, together with regulatory authorities, public organizations, and the professional community, will have to work out in detail and find solutions to expand the availability of medical innovations that reduce the burden of cardiovascular and oncological diseases.

Recognizing the importance and significance of the implemented healthcare policy, in 2025 we will continue to search for a balance between the capabilities of the state, the track of innovation, and industry proposals in order to increase the availability of modern therapy for Russian patients.

KEY ISSUES

NEW RULES FOR THE MEDICAL DEVICES MARKET

NATIONAL REGIME IN THE PROCUREMENT OF GOODS, WORKS AND SERVICES TO MEET STATE AND MUNICIPAL NEEDS

From 01.01.2025 certain amendments to the Federal Law dated 05.04.2013 No. 44-FZ "On Contract System in the Sphere of Procurement of Goods, Works, Services for State and Municipal Needs" (hereinafter — Law No. 44-FZ) introduced by the Federal Law dated 08.08.2024 No. 318-FZ entered into force.

To implement the adopted amendments to the Law, a Government Resolution has been developed "On measures to provide national treatment in the procurement of goods, works, services to ensure state and municipal needs, purchases of goods, works, services by certain types of legal entities" (hereinafter — Resolution No. 1875), combining the norms of various regulatory legal acts of the Government of the Russian Federation establishing prohibitions, restrictions on purchases of goods for state needs originating from foreign countries (including works/services performed/provided by foreign persons) and providing advantages to goods of Russian origin, works, services performed/rendered by Russian persons.

It is proposed to use a register entry from the Register of Russian Industrial Products and/or the Eurasian Register of Industrial Goods of States as confirmation of the origin of goods of Russian origin or origin from an EEU member country.

The current Russian Federation Government Resolution No. 145 dated 08.02.2017 "On Approval of the Rules for Formation and Maintenance of the Catalogue of Goods, Works, Services for State and Municipal Needs and the Rules for Use of the Catalogue of Goods, Works, Services for State and Municipal Needs" (hereinafter — Resolution No. 145) establishes a ban on the indication of additional characteristics that are not provided for by the CTRA.

Based on the Law and Resolution No. 1875, as well as on Resolution No. 145, we can assume the following risks for the domestic healthcare system, including medical device manufacturers, and ultimately for Russian patients:

- When describing the object of purchase, even if the goods of Russian origin are available, the customer risks receiving products that do not meet its needs. This will lead to misuse of budget funds.

> The Government Resolution combines the norms of various regulatory legal acts establishing prohibitions, restrictions on purchases of goods for state needs originating from foreign countries and providing advantages to goods of Russian origin, works, services performed/rendered by Russian persons.

- Due to the inability of the customer to publish additional characteristics that reflect the functionality required by a particular medical institution when making a purchase, the customer may not receive medical devices that do not meet its needs, and patients may not receive full medical care.
- Registers of industrial products do not contain the characteristics of goods, but only the name of the medical device and the manufacturer. It is not clear what characteristics of goods of Russian origin, in case of application of the established prohibitions or restrictions, must or may be specified by the customer in the course of procurement. The question remains open as to whether it is possible to use the items of the BTC and the quantitative and qualitative, basic and optional characteristics specified therein to describe the subject matter of the procurement.

Since the description of the procurement object will be based only on the characteristics of the medical device included in the Russian or Eurasian registers of industrial products, for foreign companies this may call into question the commercial feasibility of registering medical devices with a similar name of medical devices already registered in Russia/EAEU, as well as making changes to the registration dossier of the updated functionality.

In order to develop a transparent and understandable mechanism of public procurement, taking into account the current prohibitions, restrictions and preferences, as well as the regulatory legal acts being developed, AEB has prepared and sent a request to the Ministry of Finance of Russia to clarify all the above-mentioned issues and minimize risks for the Russian healthcare system.

NATIONAL PROJECTS 2025-2030 FOR THE MEDICAL DEVICES MARKET

In June 2024, the Government of Russia announced the development of several National Projects aimed at the realization of one of the primary national development goals of the country — to save the citizens, improve their health and well-being. These National Projects have come into effect from the beginning of 2025. One of the main National Projects covering the healthcare system of Russia is the project "Long and active life". The Project includes 11 federal projects, including such socially important projects as "Fighting cancer", which now also includes the development of nuclear medicine, "Fight against cardiovascular diseases", "Modernization of primary healthcare", "Development of federal medical centers" and some other projects.

The Federal Project "Fight against oncological diseases" in 2019-2024 has improved the indicators of oncological care for the population and contributed to the increase in life expectancy. The passport of the Federal Project launched in 2019 contained the main parameters and performance criteria, including requirements for refitting and re-equipping with medical equipment of various types[1]. In the course of the Project, hundreds of units of high-tech medical equipment were put into operation, including radiation therapy systems.

The National Project "Long and active life" announced by the President in his Address to the Federal Assembly also provides for the extension of the Federal Project "Fight against oncological diseases"[2].

Based on published media coverage, the Project's targets for the period up to 2030 for federal and regional oncology services include, inter alia, the following:

- increase in five-year survival rate of cancer patients up to 67%;
- reduction of one-year mortality rate to 16%.

Among the main objectives of the Project are stated:

- equipping or re-equipping the medical institutions providing medical care using radiological methods;
- ensuring territorial accessibility of medical care for patients in each region[3].

According to the information on the official website of FGBU 'NMRC of Radiology of the Ministry of Health of Russia': "Radiation therapy (radiotherapy) is one of the most effective and popular treatment methods in oncology. It is used in at least 50% of cancer patients and often plays a key role."[4]

Preparation for Federal Projects involves careful planning on the part of both healthcare organizations and responsible ministries and agencies, as well as manufacturers and suppliers. In particular, it is necessary to plan production capacity, service personnel, as well as maintaining the status of current and registration of promising medical devices. Given the continued increase in the incidence and prevalence of malignant neoplasms, increased life expectancy, and increased emphasis on non-invasive therapies, it can be anticipated that there will be an additional need for hundreds of new radiation diagnostic and therapy systems over the coming five years of the Project, as well as the need to replace a large number of obsolete units each year.

Taking into account the significant fleet of medical equipment in the Russian Federation, the above tasks require great attention and efforts. As the Project passport or a similar document is currently unavailable, it is difficult to formulate appropriate plans and prepare resources. We propose to consider the possibility of publishing the parameters of the Project in the public domain, specifying in it the quantitative requirements for the supply of high-tech equipment, including radiation diagnostic and therapy systems, in particular, linear accelerators.

1 Passport of the Federal Project "Fighting against oncological diseases" (National Oncology Program — 2030)

2 Presidential Address to the Federal Assembly

3 Fight against oncological diseases: what is the bottom line?

4 https://new-nmicr-ru.turbopages.org/turbo/new.nmicr.ru/s/pacientam/rekomendacii/luchevaja-terapija/

KEY ISSUES

INSURANCE MARKET: CHALLENGES AND SOLUTIONS

NEW REQUIREMENTS FOR INTERNAL CONTROL AND RISK MANAGEMENT IN INSURANCE SECTOR

The State Duma is currently considering a new draft law[1] to amend Article 28.1 of the Law "On the Organization of Insurance Operations in the Russian Federation" No. 4015-1 dated 27.11.1992 (hereinafter — the Insurance Law). The bill seeks to introduce requirements with respect to the formation of insurers' risk and capital management systems. The proposed amendments include:

- providing a definition of "Risk and Capital Management System";
- requiring either the appointment of an officer or the formation of a structural unit responsible for risk and capital management;
- stipulating that any officer responsible for risk and capital management may only be appointed by, and shall report exclusively to, the sole executive body (General Director);
- permitting the combination of internal control and risk management functions whilst forbidding their combination with the internal audit function;
- requiring the approval of the risk management policy by the supervisory board; and
- allowing the possibility of outsourcing certain risk management functions.

The current version of the Insurance Law establishes requirements for the internal control framework (Article 28.1) and internal audit (Article 28.2) in insurance companies but does not contain any detailed provisions regarding risk management.

Internationally recognized practices, including the Three Lines of Defence Model, describe how risk management and control functions should be allocated and coordinated within an organization. These principles apply to any organization, regardless of its size or structure, as only the coherent and transparent interaction of structural units will enable the effective operation of the internal control system, thus helping the organization to reduce risks and achieve business objectives.

The first line of defence (business units) owns the risks and controls and manages them on a daily basis. The second line of defence typically includes risk management and compliance functions, as well as security service, quality control service, financial control service and other units whose task is to ensure that proper risk and control mechanisms are being developed and implemented by the first line of defence. Internal audit as the third line of defence provides the supervisory board and management with objective assessments of the effectiveness of the internal control, risk management and corporate governance systems.

The key approaches to the formation of a risk management system as set out in the draft law reflect best international practice. As such, approval of the bill should contribute to improving the culture of risk management within the Russian insurance market, systematizing and more clearly integrating risk management processes into insurers' decision-making. It should be noted that besides establishing general requirements for insurers' risk management systems the bill also assumes the preparation of detailed regulatory documents by the Bank of Russia. Although it is not possible to predict the trajectory of the bill, prudent insurers would be well advised to now review and assess the efficacy of their existing risk management systems in readiness for likely legislative changes.

[1] Draft Federal Law No. 405773-8 "On Amendments to the Law of the Russian Federation "On the organization of insurance operations in the Russian Federation" and certain legislative acts of the Russian Federation" (regarding the formation by Russian insurers of an effective and rational corporate governance system consistent with international regulations)

RUSSIAN INSURANCE MARKET UNDER SANCTIONS

The consequence of foreign economic sanctions, which represents the greatest challenge for the Russian insurance market, is a significant *reduction in the available international reinsurance capacity.* Until 2022, more than 70% of all reinsurance protection was placed in the international market. In conditions of its inaccessibility due to the imposed anti-Russian sanctions and counter-restrictive measures, the emerging risk of further expansion of sanctions restrictions on Russian insurers and insureds, Russian insurance companies are at risk of being unable to reinsure their assumed risks in full.

The *reduction in reinsurance capacity has most severely affected* legal entities' insurance contracts with high limits and potential large losses, as well as contracts with an international element: insurance of cargo (international transportation), aircraft and marine vessels and other property of legal entities, construction and installation risks, civil liability and directors' and officers' risks.

In 2023, the Russian National Reinsurance Company (the RNRC) faced an unprecedented increase in the number of large losses (over RUB 5 billion per insured event) under corporate insurance programs, which led to a significant change in the *conditions for accepting standard risks in reinsurance and the cost of reinsurance in 2024*.

In the current situation, the RNRC has become the only available large reinsurance capacity in the Russian market.

RISK MANAGEMENT AND UNDERWRITING

In the absence of alternative capacities to the RNRC, the tariffs, risk appetites and insurance terms of insurers, which *are forced to symmetrically change their approaches*, as otherwise they will not be able to reinsure the accepted risks, entail a "mirror" tightening of underwriting approaches, an increase in tariffs on direct insurance contracts, and a reduction in the availability of insurance.

The market is gradually adapting to the changes. The monopoly established by the RNRC in respect of large risks, in circumstances limiting the ability to place risks in traditional foreign markets, requires adaptation of interaction taking into account the requirements of antimonopoly legislation. A balance of interests is being sought. The work is still in progress and it will take several years to restore clarity and coherence of processes and reach agreements that take into account the interests of all parties.

LIFE INSURANCE

In 2025, a new type of insurance will appear on the insurance market — shared life insurance (SLI). The product will be similar to the existing endowment life insurance products on the market. The contract will include an insurance part in case of events related to the life and health of the Client, in which part the contract will have all the same advantages as other insurance contracts. The second part is an investment part, which will be fully aimed at purchasing units in mutual funds. In this case, the owner of the units will be the Policyholder, the funds invested in the mutual fund will be managed either by the management company-partner of the Insurer or the insurer itself, which will receive the license of the management company.

The amendments adopted in the Law on the Organization of Insurance Business in terms of equity life insurance, as well as Instruction No. 6818-U published by the Bank of Russia, are quite general. During the development of SLI products, a number of open questions have already accumulated regarding insurance conditions, sales mechanics and the operational part of managing such products. At present, it is difficult to estimate how much this product will be both maximally client-oriented and economically profitable for insurers, but it seems that this type will be an additional way to diversify the investment portfolio, so as not to "keep all your eggs in one basket".

Undoubtedly, shared life insurance will also be an additional source of medium-term and long-term investments in the Russian economy, which is also important.

> The reduction in reinsurance capacity has most severely affected legal entities' insurance contracts with high limits and potential large losses, as well as contracts with an international element: insurance of cargo, aircraft and marine vessels and other property of legal entities.

For insurers themselves, shared life insurance is, to a certain extent, an interesting challenge that will force the market to fight for a competitive product, in which it will be necessary to preserve the maximum balance between the interests of the insurer and the requirements of the law, while maintaining customer value.

AI AND INSURANCE: MANAGING RISKS

Starting January 2025, amendments to the Federal Law on Experimental Legal Regimes (ELRs) in the Sphere of Digital Innovation in Russia will take effect.

These amendments address the growing need to clarify accountability for harm caused by solutions developed by artificial intelligence (AI) technologies and to establish a standardized framework for liability insurance in such cases.

The updated legislation expands the definition of parties potentially responsible for harm, encompassing not only the subject but also the participant of an ELR. A participant refers to both the ELR subject itself and any party engaging in legal relations with that subject.

The Law stipulates that ELR programs will now be required to include:

- provisions for civil liability insurance for ELR participants who are legal entities or individual entrepreneurs, covering harm to the life, health, or property of other persons during the implementation of the experimental legal regime. This specifically includes damages resulting from the use of AI-based solutions;
- requirements for the terms of such insurance, including the minimum insured amount, the list of insured risks, and applicable insurance cases (where relevant).

Furthermore, ELR subjects will face new obligations. In addition to maintaining a registry of individuals and organizations involved in legal relationships with them, they must also record details of insurance contracts, including the insured sums and the names of insurers.

The investigation of incidents and circumstances of harm caused by AI technologies will be handled by a dedicated commission established for this purpose. The Ministry of Economic Development of the Russian Federation will approve the procedure for forming and operating this commission. Other interested parties, including insurers, will be able to join the commission.

KEY ISSUES

INNOVATIONS IN THE HOME APPLIANCES MANUFACTURING

ELECTRONIC INSTRUCTIONS

Electronic documents and digitalization of services, including government services, owe their success to the high level of mobile and wired Internet coverage in the Russian Federation, they contribute to the confident development of the economy and support the environmental agenda by reducing the cost of producing paper media and CO2 emissions from transport.

Since 2011, technical regulations for household appliances and electronics (TR CU 004/2011, TR CU 020/2011) allow the use of electronic instructions instead of paper media in the production of B2B products. This practice can and, in our opinion, should be extended to B2C products.

AEB has held a number of meetings with regulators and sees a principled similarity of opinion that electronic instructions can be used already now for B2C products equipped with a

display, for which the function of displaying information is the main one by downloading the instructions to the device.

For other product groups, not only household products, it is necessary to work out the principles of replacing paper instructions with QR codes, which requires special attention to the risks of the absence of the Internet in remote areas and to consider the interests of the elderly and people with disabilities.

The potential benefits of the initiative for both the environment and the economy are undeniable, and the initiative deserves to be implemented as soon as possible.

PRODUCTS CONTAINING OZONE-DEPLETING SUBSTANCES (LIST F)

In 2024, the risks of importing products (refrigerators and air conditioners) containing ozone-depleting substances from the List F of Decision of the EEC Collegium No. 30 of 16.03.2021 have significantly increased.

Despite the fact that the position of the Russian Federation was formed on the need to cancel licensing for such products, in 2024 several initiatives were approved at the national level, tightening the licensing rules for the import of products containing ozone-depleting substances into the Russian Federation.

On October 3, 2024, the Decision of the EEC Collegium No. 113 amended the Decision No. 30 in terms of supplementing the list D of Section 1.1 with separately imported external units of air conditioners according to the customs commodity code 8415 90 000 9, which expanded the nomenclature of finished products subject to licensing and complicated their import.

On October 8, 2024, the Russian Ministry of Natural Resources and Environment posted on its official website information on the need to receive a license for the import of products containing substances from List F in relation to products (equipment) included in List D of Section 1.1 of the Unified List of Goods, regardless of whether these products contain mono-substances of List F or their mixtures. Earlier in 2022 on the website of the Ministry of Natural Resources of the Russian Federation different information was published, namely that the regulation does not apply to the mixtures of gases. Thus, an even greater range of products, primarily industrial air conditioning equipment and refrigeration units with freon R-410a has qualified for a license, and it's importation is more complicated now, products in transit have been blocked at customs warehouses.

The Association expresses its concern over the introduction of regulation without reasonable transition periods, and the constant complication of licensing procedures that are contrary to the international obligations of the Russian Federation (the Russian Federation has no international obligations to restrict the movement of finished products containing substances from List F, nevertheless the procedure was introduced as additional restrictive measures), and considers it advisable to revise the existing procedures and restrictions for finished products in order to simplify and further on to abolish them.

RADIOELECTRONIC PRODUCTS LABELING

In November 2024, the first stage of the experiment on labeling by means of identification of certain types of radioelectronic products (REP), enforced in accordance with the Decree of the Government of the Russian Federation No. 1993 of 25.11.2023 "On conducting on the territory of the Russian Federation the experiment on labeling by means of identification of certain types of radio electronic products" ended. From March 2025, it is scheduled to introduce mandatory digital labeling, the regulatory act is at the final stage of approval.

In general, AEB supports the idea of introducing means of identification for certain types of REPs, which it is advisable to trace in circulation to reduce the risks of consumers acquiring low-quality, non-original and counterfeit goods, when they are finished products intended for use by consumers.

At the same time, AEB sees significant risks if digital labeling is extended to spare parts, component parts and components.

The same REP, for example a LED, can have three statuses: a finished good; a spare part for service repair; a component for production.

At the same time, depending on the status of the REP, the costs of digital labeling differ significantly, as well as the risks associated with the purchase of low-quality, non-original and counterfeit REP. While finished goods can be industrially labeled at relatively reasonable costs, the same cannot be done for spare parts, for components the labeling process is too costly, as there may be up to several hundred components in one product, and the labeling of each component adds to the cost of the final product assembled.

Spare parts are delivered in limited quantities, piece by piece, in consolidated cargoes, in non-standard packaging and can be labeled at import only at the customs warehouse. Costs per unit of labeling in this case are significant and will average 60 roubles per unit. Besides this, they are supplied under production contracts, undergo internal quality checks to ensure their originality, and are unambiguously identified as components during customs clearance.

Components are supplied only to factories that manufacture finished goods. Labeling costs per unit will be significant in this case as well, as a significant number of different components are used to produce the final item. At the same time, they are supplied under production contracts, undergo internal quality control, which ensures their originality, and they are identified as components during customs clearance.

The Association takes the position that REP labeling should be obligatory only for finished products and should not affect spare parts and components.

KEY ISSUES

CHANGES IN CONFORMITY ASSESSMENT OF PRODUCTS

MANUFACTURER'S AUTHORIZED ENTITY

Manufacturer's Authorized Entities (abbreviated — MAEs) are organizations authorized to represent manufacturers of products in the territory of the Eurasian Economic Union for the purposes of conformity assessment of serial products and to bear responsibility for the violation of mandatory requirements of technical regulations. MAEs have traditionally performed representative functions for foreign manufacturers. On May 25, 2023 Paragraph 10 of the Protocol was approved and signed as part of the decisions of the Eurasian Economic Commission, Annex No. 9 to the Treaty on the Eurasian Economic Union was amended regarding the key conditions for acquiring the status of the entity authorized by the manufacturer. Now, to perform the functions of a manufacturer's authorized entity, it is mandatory to carry out not only conformity assessment, but also to bring products into circulation, which in the case of a foreign manufacturer production means the obligation to import it into the territory of a member state of the Eurasian Economic Union. The concentration of the functions of conformity assessment of products and import in one legal entity hasn't always been provided at the business models of some market players, suggesting the possibility of separation of these roles. The new rule requires the organization to be empowered by the manufacturer to perform both certification of series products as well as their import.

At the same time, the completeness of the range of products imported by MAE in relation to the product scope whose conformity assessment shall be carried out by MAE, as well as the regularity of import, are not defined by a new norm. At the same time, the legislation of the Eurasian Economic Union, in particular, subparagraph b) of paragraph 10 of the Decision of the Council of the Eurasian Economic Commission of 12.11.2021 No. 130 of the Union "On the Procedure for the importation into the customs territory of the Eurasian Economic Union of products subject to mandatory conformity assessment in the customs territory of the Eurasian Economic Union", implies the right to delegate a foreign manufacturer's products import to other legal bodies by allowing the use of documents confirming compliance with technical regulatory measures.

> Now, to perform the functions of a manufacturer's authorized entity, it is mandatory to carry out not only conformity assessment, but also to place products on the market, which in the case of a foreign manufacturer production means the obligation to import it into the territory of a member state of the Eurasian Economic Union.

To create effective mechanisms aiming to form quality and safe products market, the Committee considers it necessary to recommend that regulators, when introducing criteria for MAE, establish adequate and proportionate requirements that shall be directly related to compliance with the requirements of technical regulations and liability for their violation.

The formation of approaches to setting up the Register of MAEs has also raised a particular concern. Preliminary discussions with representatives of the Eurasian Economic Commission held on the AEB platform in 2022 on the subject of the procedure for maintaining the Register of MAEs demonstrated that the regulator did not intend to introduce a scrupulous check of the applicants' credentials, which opens up opportunities to carry out conformity assessment of serially produced products for unfair players who are not related to the manufacturer and do not have reliable information about the production processes. Thus, already now in the Russian national register of certificates and declarations of conformity there is a significant number of documents on conformity for serially produced products, the applicants for issuance of which were companies unknown to the foreign manufacturers themselves. The practice of parallel imports contributes to the emergence of an increasing number of such applicants, which by their nature cannot perform the functions of entities authorized by the manufacturer under the Treaty on the Eurasian Economic Union.

A significant risk for bona fide market players and consumers is the possible introduction of restrictions on the number of registered MAEs for certain products within each of the Eurasian Economic Union member states. The occupation of the role of MAEs by nimble organizations that do not burden themselves with collecting the necessary set of documents confirming their rights will become a significant barrier for bona fide companies that, unlike such "squatters", are authorized by foreign manufacturers. It should be noted that this risk is somewhat hypothetical, as the EEC representatives did not mention any plans to introduce such restrictions on the number of MAEs.

At the same time, it should be considered that the presence of several MAEs for one and the same product, if they are not controlled by the manufacturer, may lead to dilution of responsibility when detecting cases of violation of the requirements of technical regulations.

EVOLUTION OF TECHNICAL REGULATIONS TR CU 004/2011 AND TR CU 020/2011

Technical Regulations of the Customs Union "On the Safety of Low Voltage Equipment" (TR CU 004/2011) and "Electromagnetic Compatibility of Technical Means" (TR CU 020/2011) are basic for the electrical industry and came into force on February 15, 2013 among the first. From the very beginning, certification testing for conformity assessment of products had to be provided exclusively in accredited laboratories of the member states of the Eurasian Economic Union.

Many international companies implementing product conformity assessment within the framework of the global international CB IECEE scheme were deprived of the opportunity to use the results of tests conducted in laboratories participating in the scheme of mutual recognition of test results within CB Scheme for product conformity assessment procedure in the Eurasian Economic Union.

Standard conformity assessment schemes approved by Decision of the Customs Union Commission No. 621 of April 7, 2011, and Decision of the Council of the Eurasian Economic Commission No. 44 of April 18, 2018, also do not allow to recognize for certification purposes the results of product tests conducted outside the Eurasian Economic Union.

For this reason, many market participants have positively received draft amendments to Technical Regulations TR CU 004/2011 and TR CU 020/2011, which provide for the possibility to apply tests and measurement protocols and certificates issued under the International Electrotechnical Commission (IEC) mutual recognition of test results for certification. At the meetings between the industry experts and representatives of regulators it was decided to establish the possibility of applying tests and measurement protocols issued under the IECCE system, namely under scheme 9c — by all certification bodies of the Eurasian Economic Union member states, under schemes 1c, 3c and 4c — only by certification bodies of member states that are IECCE members (national certification bodies).

Participants in the electrical industry support the recognition of international product testing results and will closely monitor the development of the situation and prospects for improving the regulatory mechanisms of the Eurasian Economic Union in order to reduce costs of both manufacturers and consumers of products while ensuring the necessary level of safety of products brought into circulation on the market.

In the Russian national register of certificates and declarations of conformity there is a significant number of documents on conformity for serially produced products, the applicants for issuance of which were companies unknown to the foreign manufacturers themselves.

KEY ISSUES

EPR: EXPERIMENT AND USING SECONDARY RESOURCES IN PRODUCTION

CHANGES IN LEGISLATION ON EXTENDED PRODUCER RESPONSIBILITY (EPR)

In 2023, Federal Law No. 451-FZ dated 04.08.2023 'On Amendments to the Federal Law "On Production and Consumption Waste" and Certain Legislative Acts of the Russian Federation' was adopted. The Law provides for stricter requirements to the subjects of regulation, especially to importers not from the EAEU countries and to recyclers. In 2024, to develop this Law, regulations establishing detailed rules and procedures were approved, a register of recyclers was created, basic rates of ecological fee, coefficients considering the complexity of waste recovery and recycling, recycling standards and other regulations were approved.

A significant problem in the current economic situation is the growth of the ecological fee. Despite a rather moderate increase in the base rates and disposal norms, the introduction of increasing coefficients that take into account the complexity of waste recovery and recycling will eventually lead to a 2-3-fold increase in the ecological fee in 2025.

One of the additional negative factors from the new regulation is the fulfilment in 2024 of recycling volumes for two periods at once (for 2023 and 2024) due to the change of reporting periods. This has caused the market to look for double the amount of waste to be recycled in 2024 or will result in the payment of double the ecological fee in 2025.

Industry participants also note that the filling of the recyclers' register is very slow and during 2024 no more than 25% of the recycling companies that could have been included in the register were included, the shortage is particularly acute in terms of paper packaging recycling. Accordingly, problems with recycling occurred in 2024 and there are still significant risks that in 2025 companies will also not be able to fulfil the EPR independently due to the lack of sufficient number of recyclers included in the register on the market.

Industry participants also note that it was practically impossible to conclude a guarantee agreement with a recycler in 2024, as a third party represented by Federal Service for Supervision of Natural Resource Usage (Rosprirodnadzor) refused to sign it and imposed requirements to the execution of the agreement that do not comply with the current legislation.

Separate risks are associated with the current experiment on fulfilment of obligations under extended producer responsibility until the day of release of goods by the customs authority for domestic consumption.

EXPERIMENT ON PAYMENT OF ECOLOGICAL FEE

In accordance with the Decree of the Government of the Russian Federation No. 750 of 01.06.2024 'On conducting an experiment in respect of certain groups of goods, including packaged goods' (hereinafter — Decree No. 750), an experiment is being conducted between September 2024 and September 2025 for importers of goods, packaging and packaged goods not from the EAEU countries to fulfil their obligations under extended producer responsibility before the day of release of the goods by the customs authority for domestic consumption by paying an ecological fee or by providing information on the composition and weight of the packaging used by the importer.

AEB notes that payment of the ecological fee before the goods are released by the customs authority for internal consumption is extremely difficult for importers, as the importer cannot provide accurate information on the composition and weight of the packaging by type of packaging used (paper, plastic, wood, etc.) when the goods are imported.

AEB believes that spare parts, components, samples for certification and marketing samples should be excluded from the EPR regulation based on the results of the ongoing experiment. This is due to the following:

- when supplying spare parts, the importer forms assembled consignments of different spare parts, which are packed in group packaging that is selected based on the size of the spare parts and has an individual composition each time, both in terms of the type of packaging and its weight;
- when supplying components for production, the problem is similar to that of spare parts. The process of reserving/planning the supply of components for production is structured in such a way that the same raw material or component comes from several manufacturers, and the individual packaging of the raw material or component will also differ from one supplier to another;
- when samples for certification and marketing samples are supplied, products may contain additional packaging elements or be imported in a pre-production version of packaging that differs in weight from the final version;
- spare parts, components, certification samples and marketing samples become, at the end of their life cycle, industrial or municipal waste that is disposed of in accordance with the existing legal procedures established for this type of waste and does not harm the environment, with the appropriate fees paid for the management of such types of waste and the disposal operations carried out by specialized organizations;
- the inclusion of the above-mentioned wastes in the EPR means that there is effectively double payment for the recycling of these wastes, which imposes an unfair and excessive burden on importers.

AEB considers that it is not possible to fulfil the current procedure in compliance with all legal requirements until the day the goods are released by the customs authority for domestic consumption and it is necessary to postpone the moment of responsibility for payment of the ecological fee and/or reporting until after the release of the goods. This is due to the following:

- The importer in some cases lacks information on the final exact weight of the goods and the composition of their packaging. Suppliers are not interested in supplying information about the goods and their packaging, especially in the case of delivery of small batches of goods, which will lead to the inability to import goods by small and medium-sized businesses.
- Dozens of reports and payments of the ecological fee for each shipment must be made on a daily basis, which creates a significant administrative burden. Hundreds of containers arrive per month, and as a rule they are registered as separate cargoes, accordingly, the ecological fee is paid separately and a report on the quantity of imported goods and packaging is prepared. Thus, according to the estimates of AEB member companies, it takes about 16 man-hours to process and pay the ecological fee for one shipment in accordance with Decree No. 750, which, given the hundreds of containers per month, leads to economically unjustified costs for companies.
- Cases of non-rhythmic delivery of cargoes. Some cargoes arrive ahead of the delivery date, and it is technically impossible to make the necessary reporting on the weight of goods and packaging in advance.
- Cases of returning goods to the sender. Goods declared for customs clearance for various reasons (for example, failure to pass phytosanitary control or absence of a compulsory licence) are prohibited for import and returned to the supplier. At the same time, the ecological fee for such goods and/or the packaging of such goods must already be paid. There is no procedure for refunding or offsetting such payment, which will lead to unjustified expenses of companies.

It seems reasonable to consider the possibility of amending Clause 18 of Article 24.2-1 of Federal Law No. 89-FZ and related regulations to allow reporting and payment of the ecological fee on a monthly or quarterly basis, using actual data on the importation of goods and/or packaging of goods in respect of which the ecological fee is to be paid or a notification of self-disposal is provided. At the same time, the instruments already available in Federal Law No. 89-FZ (bank guarantee, guarantee agreement from the disposer) remain to guarantee the importer's fulfilment of its responsibility. For the largest importers it is possible to introduce reliability criteria that are already applied in other areas of payment collection (for example, they have the status of the largest payer of customs payments, authorized economic operator, etc.), for such companies a regime of exemption from providing a bank guarantee or guarantee agreement can be introduced. Such a system has been successfully used to ensure payment of excise duty on imports of excisable goods such as tobacco and nicotine-containing products.

AEB considers that it is not possible to fulfil the current procedure in compliance with all legal requirements until the day the goods are released by the customs authority for domestic consumption and it is necessary to postpone the moment of responsibility for payment of the ecological fee and/or reporting until after the release of the goods.

KEY ISSUES

SEEDS AND PESTICIDES: ADVOCATING A BALANCED APPROACH TO IMPORTS

INTRODUCTION OF QUOTAS FOR IMPORTS OF AGRICULTURAL SEEDS TO RUSSIA

Strengthening the trend of import substitution in agriculture, aimed at ensuring food security of Russia, is justified and understandable in the current situation. At the same time, quotas on imports of agricultural seeds into the Russian Federation as one of the main mechanisms of its implementation carry significant risks for ensuring food security of the country.

LEGAL AND REGULATORY FRAMEWORK

At the beginning of 2024 regulatory legal acts were adopted, establishing quotas for import of seeds until 31.12.2024:

- Decree of the Government of the Russian Federation from 27.01.2024 No. 72 "On introduction of temporary quantitative restrictions on import of certain types of seeds of agricultural plants";
- Order of the Ministry of Agriculture of Russia from 14.02.2024 No. 73 "On distribution among participants of foreign trade activities of quantitative restrictions in relation to imported into the territory of the Russian Federation certain types of seeds of agricultural plants specified in paragraph 1 of the Decree of the Government of the Russian Federation from 27.01.2024 No. 72 'On the introduction of temporary quantitative restrictions on the import of certain types of seeds of agricultural plants'".

Let us note the following points:

- According to the legal acts, quotas could only be obtained by companies that provided the Ministry of Agriculture with a letter of guarantee on localization of seed production.
- In the Order of the Ministry of Agriculture No. 73 among the companies that received quotas, a number of organizations that were not previously known as seed importers were listed.
- Seeds of parental lines could not be imported in 2024. The import tax codes of parental line seeds and commercial seeds coincide. The absence of quotas for commercial seeds meant that it was impossible to import seeds of parental lines.

ORGANIZATION OF IMPORT OF AGRICULTURAL SEEDS TO RUSSIA

In the countries that are the main suppliers of seeds to Russia, seed production is a high-tech and, therefore, very expensive process. The formation of seed production volumes, including exports to other countries, is carried out in accordance with carefully prepared and approved production plans with a breakdown by importing countries. As a rule, the creation of seed stocks not subject to planned sales is not practiced. The only exception is commercially justified adjustments due to changes in the area planted to certain crops in the importing country. Under current conditions, the logistics of importing imported seeds has become much more complicated procedurally and time-consuming.

CURRENT SITUATION

From November 1, 2024 the quota for sugar beet seeds was increased by 900 tons by the Decree of the Government of the Russian Federation from 01.11.2024 No. 1470 "On Amendments to the Decree of the Government of the Russian Federation from 27.01.2024 No. 72 'On the introduction of temporary quantitative restrictions on the import of certain types of seeds of agricultural plants'".

In 2025, the volumes of seed imports from "unfriendly" countries are regulated by the Decree of the Government of the Russian Federation dated 30.12.2024 No. 1983 'On the introduction of temporary quantitative restrictions on the import of certain types of agricultural plant seeds' and distributed among importing companies according to the Order of the Ministry of Agriculture of Russia dated 23 January 2025 No. 38. The total volume of quotas was reduced from 34 thousand tons in 2024 to 18.3 thousand tons in 2025. For maize and sunflower seeds, the quotas were reset to zero, taking into account the availability of seeds of

these crops in Russia. Quotas remained the same or almost the same as in 2024 for sugar beet seeds (taking into account the increase by 900 tons from 01.11.2024), rapeseed, malting barley, waxy maize and high oleic sunflower. For seed potatoes quotas were reduced by 2 thousand tons.

Decree of the Government of the Russian Federation of 30.12.2024 No. 1983 does not contain a requirement to submit to the Ministry of Agriculture a letter of guarantee on localization of seed production in order to receive quotas.

AEB POSITION

Taking the current restrictions on competition and rising prices into account, AEB, as well as leading industry unions, proposes to thoroughly analyze the results of the introduction of quotas on seed imports. It is also necessary to consider the opinion of agricultural producers, primarily agricultural holdings, on how effective the seeds of domestic breeding turned out to be in the current year. This will help to form a balanced approach to the development of effective measures for the development of seed breeding and seed production and strengthening of the agrarian sector of Russia.

PLANNED INTRODUCTION OF QUOTAS FOR PESTICIDE IMPORTS TO RUSSIA

Authorized government bodies continue to discuss and agree on a non-tariff measure to regulate pesticide turnover — introduction of quotas for pesticide imports. In October of 2024 the Ministry of Economic Development as an authorized government body of the Russian Federation for interaction with the Eurasian Economic Commission (EEC) addressed the EEC with a proposal to introduce quotas on the territory of the Eurasian Economic Union (EAEU). In November, the Russian Federation's proposal was sent to the EAEU member countries for consideration.

RUSSIAN CPP/PESTICIDE MARKET

The Russian CPP/pesticide market is a dynamically developing and highly competitive one.

In 2023, consumption of CPP remained almost at the level of 2022 — 226 thousand tons. At the same time, the share of pesticides produced in Russia increased to 160 thousand tons and accounted for slightly more than 70% of the consumption volume. The share of imports decreased to less than 30% of the consumption volume — 66 thousand tons. Of these, the share of pesticides from China amounted to more than half, while the share of pesticides from the European Union countries, Great Britain, Serbia and Switzerland amounted to just over 1/3.

Currently, more than 85% of raw materials, including almost all active ingredients required for CPP production, are not produced in Russia and are imported mainly from China and other countries.

PROJECTED RISKS AND CONSEQUENCES OF INTRODUCING PESTICIDE IMPORT QUOTAS IN RUSSIA

AEB member companies currently produce in Russia at least 60% of pesticides from the total volume of products sold in the country and are steadily increasing local production. However, it is practically impossible to quickly restructure plans and increase production in Russia. This is due to both the reorientation of logistics chains and the requirements of state registration of pesticides in Russia. Transfer of production to a Russian plant requires additional toxicological and hygienic studies to develop hygienic standards for the content of residues of active substances of pesticides in the air of the working zone and in the air of populated areas near the production site and to obtain an official opinion of Rospotrebnadzor, which is issued only if the hygienic standards are approved (the last time they were approved in January 2021). After that, it is necessary to make changes to the container label and obtain its new number, which takes at least one year.

It should be separately noted that the introduction of quotas will reduce in the short and medium term the supply of new — more effective and safer CPP, the production of which is not always expedient to be carried out at several plants at once due to their specificity and volume. Due to market uncertainty, which will inevitably be present in the conditions of quota restrictions, it will be difficult for exporting companies to make decisions on introducing new CPP to the EAEU markets, which requires significant investments and time for registration trials. The availability of new, effective pesticides for agrarians in the EAEU member countries, especially those in demand in the context of climate change, increasing resistance of pests and diseases to pesticides and the introduction of stricter environmental regulations, will be reduced.

AEB member companies currently produce in Russia at least 60% of pesticides from the total volume of products sold in the country and are steadily increasing local production. However, it is practically impossible to quickly restructure plans and increase production due to both the reorientation of logistics chains and the requirements of state registration of pesticides.

Thus, the introduction of pesticide import quotas poses significant risks for EAEU agriculture. Leading industry unions express serious concern about the planned measure, the introduction of which will lead to a decrease in the availability of pesticides for agricultural producers. The reduction in imports of pesticides and the lack of their replacement in terms of quality will lead to reduced competition in the EAEU markets and an increase in counterfeit products. As a result of quota introduction, the cost of production of all crops is expected to increase, since the share of CPP in the cost structure averages 10–15%.

AEB ACTIONS

International AEB member companies continue to operate in Russia and fulfill their obligations to Russian farmers by providing them with innovative crop protection products. The introduction of quotas for imports of crop protection products requires a balanced approach, taking into account all possible consequences and risks for agriculture. In discussions with representatives of the Russian Ministry of Industry and Trade and in official AEB communications, the following consolidated position of the Crop Protection Committee was presented:

- Withdraw from quotas the pesticides which active substances and combinations of active substances are under patent protection.
- Quantitative restrictions should not be applied to pesticides registered from January 1, 2024 for a period of at least 5 years.
- When developing the calculation methodology, it is necessary to take into account the distribution of volumes by categories/types of pesticides rather than by specific products.

KEY ISSUES

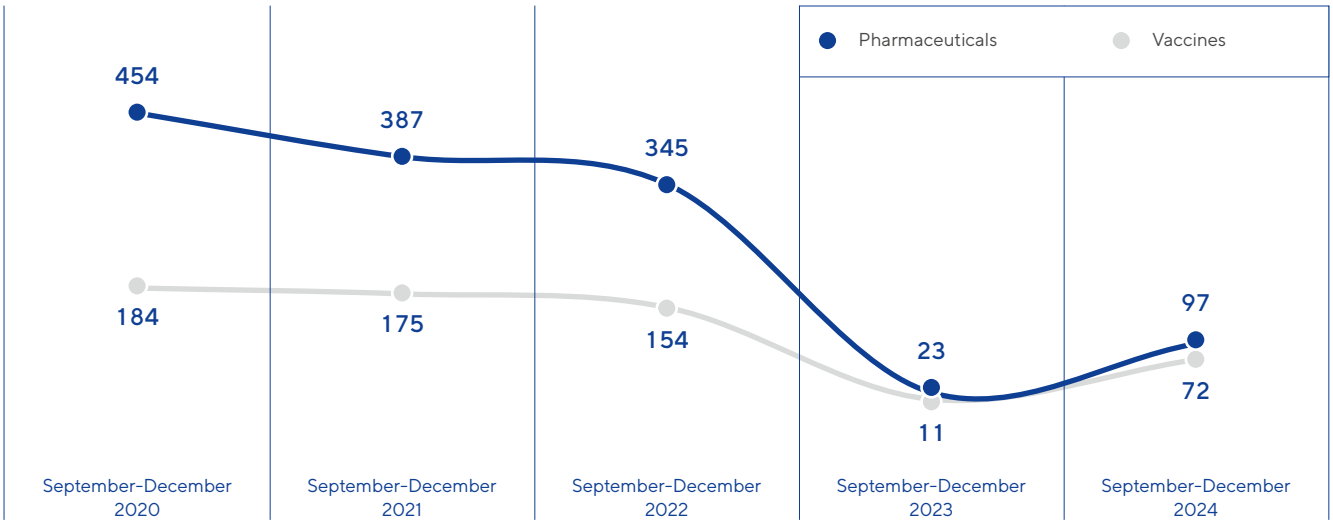
REGULATION OF THE VETERINARY MEDICINAL PRODUCTS: OLD CHALLENGES ON A EURASIAN SCALE

NOVEL REGULATIONS ARE ACKNOWLEDGED TO HAVE SHAPED BOTH THE MARKET OF VETERINARY MEDICINAL PRODUCTS AVAILABLE TO CONSUMERS AND EUROPEAN COMPANIES WORKING IN RUSSIA. THE YEAR 2025 WILL BE CHARACTERIZED BY DEEPER EURASIAN INTEGRATION AND APPLICATION OF RUSSIA'S NATIONAL REGULATIONS TO THE SUPRANATIONAL LEVEL, A STRONG CHALLENGE TO THE VETERINARY MARKET.

In 2024, the impact of Russia's market release procedure still reverberated across European animal health companies and most foreign suppliers of veterinary medicinal products. As seen from Graph 1, the period after September 2023, when the measure was introduced, saw a sharp decline and prolonged recovery of imports of vaccines and pharmaceuticals, which was stifled by a lack of valid Eurasian Economic Union (EAEU) GMP certificates issued by Russian authorities. As of the end of the period, the number of veterinary medicines available to local consumers constituted just 40%

of that in the pre-regulation period. Another bottleneck was of logistical and regulatory nature, as it had become quite difficult to ship, primarily from the European Union, reagents and other materials necessary for quality control operations under the new procedure.

Graph 1. Veterinary medicines imported from September to December, 2020-2024



Source: Analysis of Association of Veterinary Pharmaceutical Manufacturers (AVPHARM)

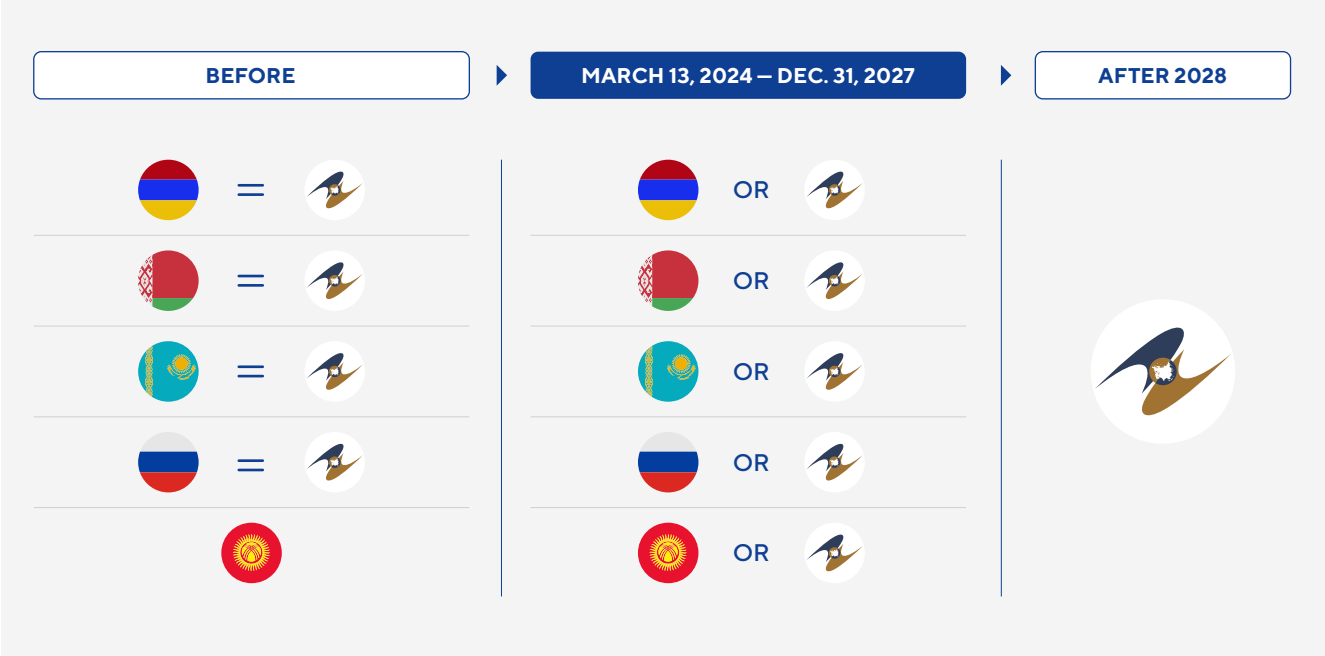
Here is the list of the key developments in the veterinary market in 2024 and 2025:

- March 13, 2024: the entry into force of the Rules for regulating the circulation of veterinary medicinal substances in the EAEU customs territory (EAEU Rules), approved by EEC Council Decision No. 1 of January 21, 2022.
- October 1, 2024: the introduction of compulsory track-and-trace labelling of imported veterinary medicines, stipulated by the Russian Government's Order No. 675 of May 27, 2024.
- March 1, 2025: the introduction of regulatory measures governing veterinary medicine prescriptions, laid down by the Order of the Russian Ministry of Agriculture No. 776 of November 2, 2022.

One important long-term goal of the EAEU Rules is to create a common regulatory space within which veterinary medicines will circulate freely, with the deadline for the transition being set for 2033. Graph 2 shows that starting from March 13, 2024, new veterinary medicines intended for circulation within the Union's customs territory must be authorized under the uniform Eurasian standards established by the EAEU Rules. As for veterinary medicines already authorized under the legislation of EAEU member states, they must be harmonized with the effective document. However, the regulatory framework has so far produced the opposite of what was initially intended. The reality is that none of the international manufacturers will be able to authorize new veterinary medicines or harmonize those already granted marketing authorizations with the Rules until the relevant legislation has been adopted by every member state. To make matters worse, market participants believe that the Rules approved by EEC Council Decision No. 1 of January 21, 2022 run the risk of being interpreted differently by the parties, which may unfairly result in a reduced circulation area for a number of authorized medicines when confirming and updating their marketing authorizations.

One important long-term goal of the EAEU Rules is to create a common regulatory space within which veterinary medicines will circulate freely, with the deadline for the transition being set for 2033.

Graph 2. Valid marketing authorizations on a country basis under the transitional period (excluding national requirements)



Source: EEC Council Decision No. 1 of January 21, 2022 (as amended by EEC Council Decision No. 36 of April 22, 2024)

The main issues requiring national-level regulation include:

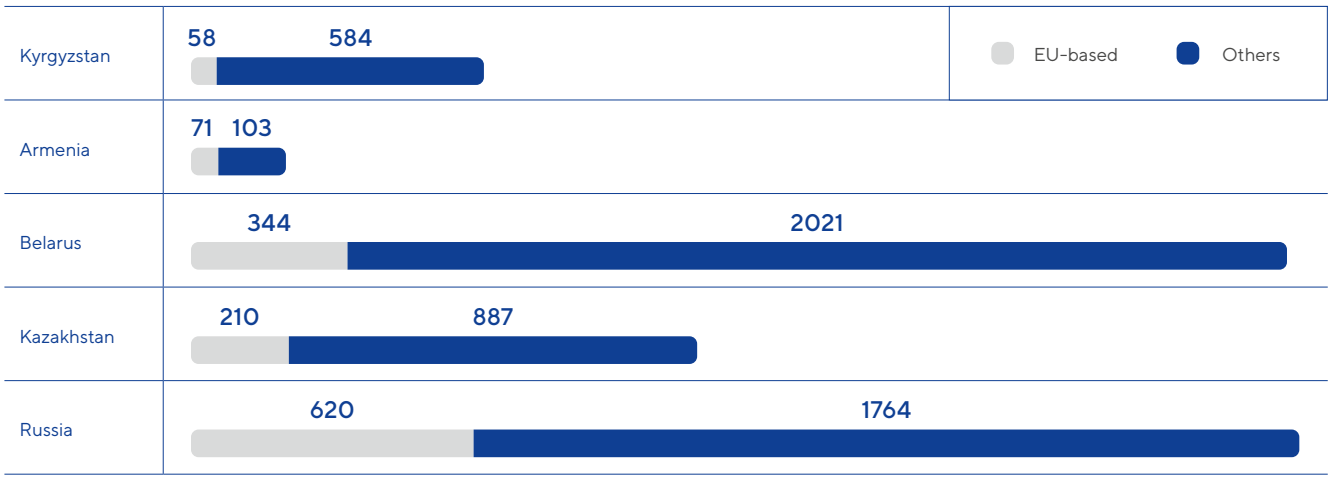
- joint pharmaceutical inspections;
- the cost and payment schedule of any activities related to marketing authorization;
- expert examination procedures;
- pharmacovigilance;
- the functioning of national registers and databases (prior to the introduction of the common EAEU registers and databases).

With each EAEU nation developing respective legal requirements at its own pace, there seems to be no end in sight to the process. For example, not all countries have been staffed with the functional inspectors ready to audit manufacturers from third countries. At the same time, the EAEU Rules allow such producers to obtain new and harmonized marketing authorizations provided that they have GMP certificates as a result of joint inspections. Since the introduction of market release in September 2023, the lack of sufficient "GMP coverage" on part of Russia's regulatory bodies has presented a serious challenge for global animal health companies. Following the first and second inspections, most of them were recognized as non-compliant with the principles of GMP embraced by Russia.

As is clear from the name, joint inspections regulated by the EAEU Rules must include pharmaceutical inspectors of all member states where the circulation of veterinary medicines is planned. To date, there has been no uniform procedure for organizing joint inspections of facilities manufacturing animal medicines, let alone the experience of doing so, with veterinary pharmaceutical inspectorates operating in only three countries, namely Armenia, Belarus and Russia. It is worth mentioning that Armenia's inspectorate is only tasked with assessing the GMP compliance of veterinary pharmaceuticals. The veterinary industry holds that in 2025 an introduction of relevant legal requirements and hands-on experience gained through joint inspections will pave the way for implementing the EAEU Rules by early 2026.

Delayed joint inspections remain a major obstacle to the large-scale and demanding project of harmonizing valid marketing authorizations with the EAEU Rules. Issuing EAEU GMP certificates takes an average of 200 working days from the application date, excluding the potential queue time and failure to be GMP-certified. Meanwhile, the AVPHARM's estimate suggests that it is necessary to harmonize more than 1,500 marketing authorizations of veterinary medicines of Eurasian and foreign origin with the new regulations prior to the end of the first transitional period in December, 2027.

Graph 3. Marketing authorizations granted to local and foreign manufacturers in EAEU



Source: AVPHARM's analysis of the Union's official registers (as of November 18, 2024)

Another veterinary development in 2024 was the introduction of mandatory track-and-trace labelling which, as envisaged by the Russian Ministry of Industry and Trade, may be extended to the entire EAEU territory. The system is likely to become applicable at least to holders of those new EAEU marketing authorizations that are intended for subsequent recognition within Russia's borders. The issue is currently on the Union's agenda. Moreover, every member state is expected to enjoy latitude in setting out the time and procedure for introducing the compulsory track-and-trace labelling system in its respective territory.

Finally, one more regulatory document, which comes into force on March 1, 2025, obliges manufacturers to update their package leaflets and designs of prescription medicines. This national requirement will also apply to the subnational level, that is, to all new marketing authorizations of veterinary medicinal products planned for circulation in Russia.

RECOMMENDATIONS

With high demand for their products in mind, European manufacturers of veterinary medicines recognize their key role in making sure that consumers have access to good-quality food and veterinary medicine. Guided by humanist values, such companies commit to maintaining the availability of veterinary medicines under Russia's legislation.

Amid the shifting dynamics of the regulatory environment, it is European companies that remain the main source of innovative veterinary solutions. In this light, the importance of AEB cannot be overestimated, as it provides the key platform for discussing emerging challenges and ways of overcoming them.

The brief offers the following recommendations for 2025:

- Global animal health companies that operate within the EAEU's borders should join their efforts to monitor risks and exchange experience and best practices.
- Associations of European Businesses that operate in the EAEU nations should create a platform for exchanging views on the regulatory agenda in the veterinary realm.
- The veterinary industry should maintain contact with the Eurasian Economic Commission and the competent authorities of the EAEU nations to make mutually beneficial decisions about the implementation of the EAEU Rules and other Eurasian rules.

With high demand for their products in mind, European manufacturers of veterinary medicines recognize their key role in making sure that consumers have access to good-quality food and veterinary medicine.

KEY REGULATORY DEVELOPMENTS

ARTIFICIAL INTELLIGENCE: REGULATORY PERSPECTIVES

EU ARTIFICIAL INTELLIGENCE ACT: REGULATORY FEATURES AND MARKET IMPLICATIONS

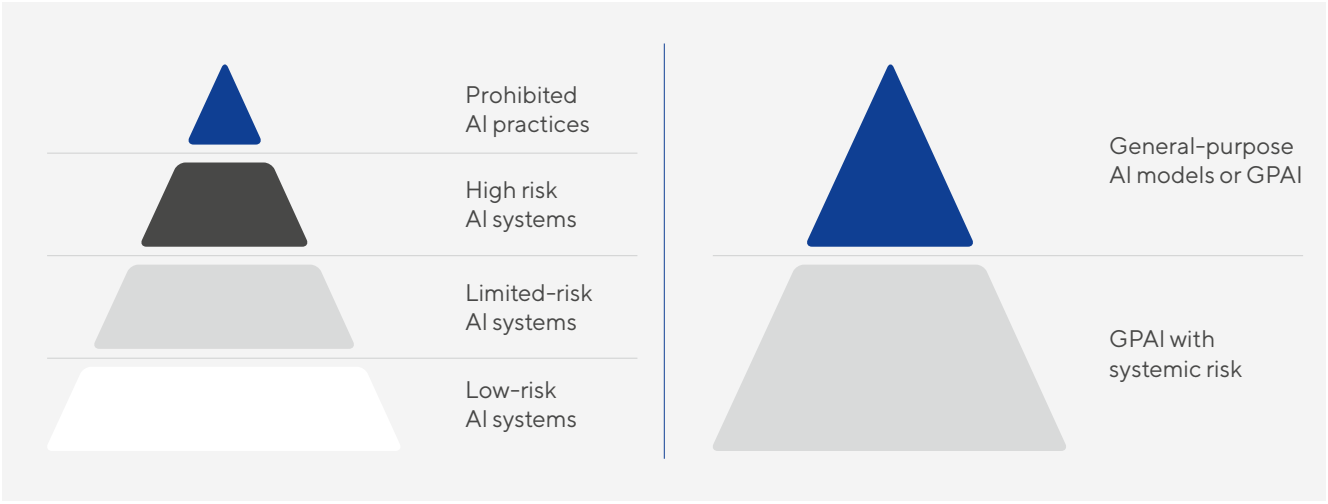
On 1 August 2024, the European Union's AI Act[1] (the 'Act') came into force. It is the most comprehensive and inclusive regulation of artificial intelligence in the world to date.

The Act sets out rules for placing on the market, putting into service and the use of AI in the European Union. It also contains extraterritorial provisions and applies to companies that use AI (AI outputs and derivative products) within the EU, regardless of their location.

The Act covers the activities of providers, importers, distributors and deployers of AI that utilize it for their own benefit.

The requirements for compliance with the Act are substantial and are largely determined by the level of risk posed by the use of AI. The Act identifies the following categories of AI (Graph 1).

Graph 1. AI categories identified by the EU AI Act



[1] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonized rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance)

For each category of AI model or system (except for low-risk AI), the Act establishes specific requirements, and a number of obligations related to the use of AI are imposed on regulated subjects (primarily providers and deployers).

At the level of the law, these requirements and obligations are formulated rather abstractly. Standards, codes of practice, codes of conduct, and guidelines will be developed shortly to help regulated subjects determine their compliance with the Act.

Thus, to date, the Act is at the forefront of AI regulation.

However, despite its groundbreaking nature, the Act has been largely criticized. Tech companies note that the regulation restricts the use of technology. Significant costs related to compliance could become prohibitive for businesses, threatening an outflow of companies and a decline in the EU's competitiveness.

Experts in Russia have come to similar conclusions. For example, participants in the 2024 BRICS Digital Forum concluded that there is no urgent need to create a comprehensive law to regulate AI, and at this stage it is sufficient to refine the code of ethics in the field of AI.

It is still not entirely clear what position the Russian authorities will take in this regard. Given the opinion of the expert community, which is closely cooperating with the government on this issue, it is not worth expecting the adoption of a comprehensive AI law in Russia soon.

Nevertheless, the experts confirm the need for targeted regulation, and in this part, the EU AI Act is very likely to serve as an example and a starting point for the development of norms addressing specific issues of AI use.

AI IN THE CONTEXT OF RUSSIAN LEGISLATION

Russia does not have an analogue of the EU AI Act, which would systematically regulate the permitted and prohibited use of AI technologies, the issues of risk mitigation and the allocation of liability. Nevertheless, the existing general legal regulation and certain industry requirements already establish the framework and vectors of permissible use of AI technologies.

SPECIFIC REGULATION OF AI

Specialized legislative acts and industry standards have been adopted in recent years, which lay the basic principles of AI regulation and fragmentarily cover certain issues of neural networks use in certain areas.

The main goals and objectives of AI development in Russia, as well as measures aimed at introducing and regulating AI technologies were laid down in the *National Strategy for the Development of Artificial Intelligence until 2030* (approved on October 10, 2019 by Presidential Decree No. 490) and the *Concept for the Development of Regulation of Relationships in the Sphere of Artificial Intelligence and Robotics Technologies until 2024* (approved on August 19, 2020 by Government Order No. 2129-r).

In 2020, a number of federal laws establishing experimental legal regimes in the field of digital innovation, including AI, were adopted:

- *Federal Law No. 123-FZ dated April 24, 2020* governs an experiment to establish special regulation in order to create the necessary conditions for the development and implementation of AI technologies in Moscow, as well as the subsequent possible use of the results of AI application.
- *Federal Law No. 258-FZ dated July 31, 2020* establishes general principles and rules for the application of special regulation for the development, testing and implementation of digital innovations to the participants of the experimental legal regime for a certain period of time. To date, within the framework of the above law, Russia has more than 15 experimental legal regimes providing for the application of AI technologies in various industries, including autonomous vehicles, healthcare, etc.

Ethical aspects of the creation and implementation of AI technologies are reflected in the *Code of Ethics in the field of artificial intelligence*, which was developed and adopted in 2021 by the AI Alliance, which unites leading Russian technology companies. The Code is not a legally binding document, but represents the consolidated position of the largest players in the Russian market, aimed at creating an environment of trusted development of AI technologies in Russia. Participants in the Code include not only Russian companies, but also government authorities and foreign entities.

In addition, there are more than 60 standards in the field of AI that regulate certain issues of neural networks use in various industries.

In certain sectors — for example, in healthcare — the problem of implementing AI solutions has been developed quite deeply. An example of such sectoral approach is the regulation of medical devices that are AI-enabled software. Such products are classified as the third, highest risk class, they can only be used by a medical professional who has undergone the necessary training, and the manufacturer of such a medical device must conduct post-registration safety monitoring of the medical device for three years.

GENERAL REGULATION APPLICABLE TO AI

So far (with rare exceptions — for example, in terms of the use of recommendation technologies), AI regulation concerns narrow sectoral issues.

But there is also general legal regulation that should be considered when using and implementing AI in particular: intellectual property; personal data.

In 2024, a law was passed to improve the mechanism for processing personal data obtained through anonymization. The initiative is aimed at the development of technologies, including AI systems.

The document envisages ensuring that developers of AI systems have access to the data of Russians when implementing various projects — but it only concerns datasets containing and processed in the state information system, which will be created specifically for this purpose, and does not cover anonymization of data for AI training outside this system.

This means that any processing of personal data outside the state information system is subject to the general rules for the processing of personal data, therefore, in order to train generative models or use recommendation technologies, it is necessary to take into account the requirements on cross-border transfer of personal data, the principles of personal data processing, the conditions for decision-making based on automated processing of personal data, as well as to have a legal basis for processing personal data.

REGULATORY REQUIREMENTS

When training AI models and using the AI generation results, it is necessary to take into account the applicable restrictions of the Russian legislation on content distribution, including the requirements of the legislation on advertising, etc.

In addition, when processing information using AI systems, it is necessary to take into account the procedure for handling restricted information — state secrets, information for "internal" use, other confidential information.

RESPECTING IP RIGHTS IN THE AI TRAINING PROCESS

Training AI models requires large data sets, often including intellectual property items (such as literary works, images, databases, etc.).

The key issue for businesses is whether it is permissible to use protected content for the purposes of AI training without the right holders' consent. As provided in Article 1274 of the Civil Code of the Russian Federation, the use of works without the right holder's consent is only possible in exceptional cases, for example, for personal use. However, the use of data in the AI training process does not fall within the scope of personal use and could be viewed as an unauthorized reproduction of the work and subsequent unauthorized storage. Such use of data requires the right holder's consent until further exceptions are legislated relating to the development of AI technologies. At present, the Federation Council is discussing the need to protect authors' rights when training AI using their works[2], provided that the interests of businesses and authors are balanced.

However, technically, sometimes AI training only involves using metadata (which is not protected by law) to analyze statistical patterns, rather than the works themselves. The legal framework for using such data has not yet been defined.

For the purposes of respecting IP rights in the AI training process, some companies have resorted to producing synthetic data, which helps them level off the risks of infringement, as such data is specifically created for AI training purposes.

Some legal systems require *specifying the data used in AI training,* but in Russia there is no such requirement at the moment, which makes it easier to bring new AI-based technologies to the market.

DATASETS AS DATABASES FOR AI TRAINING

Datasets used for AI training do not always meet the criteria of databases established by Articles 1260 and 1334 of the Russian Civil Code. Databases as copyright protected items imply the existence of a systematically arranged set of materials that can be searched and processed using a computer. However, in the AI context, datasets are often raw data intended for model training rather than for traditional searches and processing, which makes it difficult to determine their legal status. For AI developers, such uncertainty may be beneficial as it reduces barriers to accessing data. Creators of unique datasets, on the contrary, are interested in strict legal protection to *safeguard* their investments.

RESPECTING IP RIGHTS WHEN GENERATING CONTENT AND USING GENERATED CONTENT

Generative AI, at the request of users, can create texts, images and other works which may bear a resemblance to IP protected items owned by third parties. This raises the issue of reworking a work or creating an independent work (parallel creation) if no specific work has been used as AI training content. If such generated objects are recognized to be "reworkings" for the purposes of Article 1270 of the Civil Code of the Russian Federation, then based on the position of the Supreme Court of the Russian Federation, the mere fact of reworking does not constitute an infringement of exclusive rights. Only the subsequent use of the reworked work may be deemed to be a potential infringement.

In practice, companies mitigate liability risks for generated content by including restrictions in their user agreements, such as provisions prohibiting the commercial use of generated content or making the user responsible for generating prohibited content.

OWNERSHIP OF GENERATED CONTENT

The issue of the ownership of AI-generated content is not covered by the Russian Civil Code. For example, the Shedevrum and Kandinsky AI networks deal with this issue in different ways: the former vests the rights in the company, while the latter vests them in the user. In 2024, in a number of disputes courts

[2] https://www.pnp.ru/politics/matvienko-predlozhila-zashhitit-avtorskie-prava-pri-ispolzovaniya-ii.html

recognized AI-generated content to be protectable. At this stage, it is advisable that the allocation of rights is left to companies who will include the relevant provisions in their user agreements, depending on their business model.

PRACTICAL ISSUES OF APPLYING AI IN CONSUMER BEHAVIOUR ANALYSES

An AI analysis of consumer behaviour is applied to user behaviour on websites, in mobile applications and to the *user's offline behaviour* (e.g., analyses of retail data on the goods purchased over a certain period of time).

The most common examples of AI use include segmenting consumers, optimizing pricing and creating recommendation engines which help increase sales.

The key practical issue is compliance with the data processing laws. Generative networks are often a black box and the developers themselves are not fully aware of the processes and actions that occur in relation to consumers' personal data. First, this makes it difficult to provide data subjects with information on the actions performed on their data and their proper description in the data processing consent form. Second, if such data subject requests its data be deleted and no longer processed using AI, it will be necessary to ensure that their data is indeed deleted, which could be problematic if a neural network has already been trained using such data, or if it is not entirely clear how such data was used by the generative network.

Since 2023, Russia has had regulations in place on the use of recommender algorithms, which impose a requirement to inform users of the use of such technologies, and not to permit the use of algorithms which violate the rights of citizens and entities or provide information in violation of the law.

DEEPFAKE REGULATION APPROACHES: LEGISLATIVE INITIATIVES

The absence of comprehensive legal regulation for deepfakes has recently emerged as a significant public concern. Today, almost anyone, even without specialized skills, can create a deepfake using readily available digital tools.

An analysis of legislative initiatives and law enforcement practices reveals several approaches to addressing this issue.

APPROACH 1: TREATING DEEPFAKES AS A METHOD OF COMMITTING EXISTING OFFENCES WITHOUT AMENDING LEGISLATION

Under this approach, deepfakes are regarded as one of many tools used to commit offences, making specific legislative amendments unnecessary.

For example, according to Paragraph 20 of the Plenum Resolution of the Supreme Court of the Russian Federation No. 17, dated 25 June 2024, the use of deepfakes for campaigning purposes falls under Part 1 of Article 5.12 of the Code of Administrative Offences of the Russian Federation. This Article governs the production, distribution, or placement of campaign materials in violation of electoral and referendum laws.

While this resolution does not explicitly use the term "deepfake", it effectively defines the concept: false images, audio, and audiovisual information including created using computer technologies, presented misleadingly as accurate.

APPROACH 2: RECOGNIZING THE USE OF DEEPFAKES AS A QUALIFYING FACTOR IN EXISTING CRIMINAL OFFENCES

This approach involves amending existing criminal legislation to explicitly include deepfakes as a qualifying feature in certain crimes.

For instance, Bill No. 718538-8, titled "On Amending the Criminal Code of the Russian Federation" proposes incorporating identity substitution technologies (including deepfakes) as a qualifying feature in crimes such as "Slander", "Fraud", "Theft", "Extortion", "Computer Fraud", and "Causing Property Damage by False Pretences or Breach of Trust".

The Supreme Court of the Russian Federation, however, has expressed reservations about this proposal. Its response to Bill No. 718538-8 points out that more serious crimes, such as public calls for terrorist acts or knowingly false reports of terrorism, can also involve identity substitution technologies. This raises questions about the appropriateness of introducing this qualifying feature only for the aforementioned offences.

In 2024, in a number of disputes courts recognized AI-generated content to be protectable. At this stage, it is advisable that the allocation of rights is left to companies who will include the relevant provisions in their user agreements, depending on their business model.

APPROACH 3: ESTABLISHING SPECIFIC LEGAL PROVISIONS FOR DEEPFAKE-RELATED OFFENCES

This approach suggests creating distinct legal norms addressing offences committed using deepfakes, artificial intelligence, or technologies related to computer information. However, there have been no attempts to implement this approach in Russia to date.

OTHER PROVISIONS OF LAWS AND LEGISLATIVE INITIATIVES THAT MAY BE APPLIED IN THE FIGHT AGAINST DEEPFAKES

Most recently, the Federal Law No. 421-FZ of November 30, 2024 "On Amending the Criminal Code of the Russian Federation" was adopted.

This Federal Law introduced Article 272.1, which criminalizes the use, transmission, collection, or storage of personal data obtained unlawfully through computer systems. It also addresses the creation or maintenance of resources for storing or disseminating such data.

Article 272.1 of the Criminal Code of the Russian Federation distinguishes this new offence from existing ones, such as those outlined in Article 13.11 of the Code of Administrative Offences ("Violation of Russian Personal Data Laws"), as well as from other types of crimes.

However, the defining characteristic of deepfakes is not the unlawful acquisition of data but the manipulation of appearance or voice to create misleading images, audio, or audiovisual content.

The proliferation of deepfakes has also inspired legislative efforts to protect personal rights more comprehensively. For example, Bill No. 718834-8 proposes adding Article 152.3 to the Civil Code of the Russian Federation. This Article would grant the voice the same protection as an individual's image, recognizing it as a personal non-property right. It would cover cases of voice imitation or real-time speech synthesis.

This initiative is particularly significant in combating deepfakes, as it provides a means to hold offenders civilly liable in situations where their actions do not meet the threshold for criminal or administrative offences.

KEY REGULATORY DEVELOPMENTS

CORPORATE AND FINANCIAL TRANSACTIONS: KEY CHANGES AND TRENDS

The special economic measures introduced in 2022 against "unfriendly" actions of foreign states towards Russian persons continue in 2024. During this time, currency control procedures, as well as rules for transactions and financial operations with counterparties from "unfriendly" countries and persons controlled by them, have been changed towards greater restrictions.

TERMS AND CONDITIONS OF CORPORATE TRANSACTIONS

The transactions aimed at disposal of shares/participatory interests in Russian legal entities, entered with persons of "unfriendly" foreign states are subject to approval in accordance with Presidential Decrees (Nos. 81, 138, 520, 618 and 737). Payments of more than RUB 10 million to shareholders from such countries to their foreign accounts in case

of reduction of the authorized capital or liquidation of the company are also restricted.

The approval procedure includes submission of the application to the "industry-specific" federal body, consideration of the application by the body, including meetings/requests, consideration by the Ministry of Finance, and issuance of a decision by the Sub-Commission.

The process has become longer and takes approximately 3-12 months. In addition, the authorized bodies have become stricter in reviewing of evaluation reports, conducting retrospective analysis of previous transactions (operations) of the parties and transaction targets, requesting detailed business plans and inspecting the presence of intra-group debts, which in practice are often required to be forgiven.

The approval requires several conditions, such as providing an independent evaluation report, an expert opinion on the report, applying a discount of at least 60% of the market value of assets to the purchase price, setting installment payments to foreign accounts, and an obligation to achieve key performance indicators of the acquired company.

Another condition for approval is the voluntary transfer of funds to the federal budget in the amount of at least 35% of the market value of the assets concerned. Herewith, 25% is paid within the first month from the date of implementation (execution) of the transaction (operation), 5% — within one year, 5% — within two years.

Control over compliance with the terms of approval of transactions has also increased. Thus, starting from summer 2024, the number of inspections by the Russian Accounts Chamber of the achievement of key performance indicators by the companies, the sale of shares (participatory interests) in which the Sub-Commission approved in 2022 and 2023, has raised.

LIABILITY FOR NON-COMPLIANCE WITH THE COUNTER-SANCTIONS PROCEDURES

The current legislation contains no special provisions establishing liability for non-compliance with the procedure stipulated by the counter-sanctions decrees. The Ministry of Finance and the Ministry of Justice are currently considering draft laws aimed at amending the Russian Code of Administrative Offences to establish such liability.

According to the civil law general provisions, transactions with shares/participatory interests implemented without the Sub-Commission approval may be declared invalid (Articles 10, 168, 169 of the Russian Civil Code). In October 2022, the Prosecutor's Office was authorized to challenge such transactions on the above grounds. Court practice has already begun to form, in some cases all executed under invalid transactions were turned to the state income.

In addition, the regulation on holding top management liable for losses to the company resulting from unlawful behavior of controlling persons (Article 53.1 of the Russian Civil Code, Article 61.11 of the Bankruptcy Law) may be applied. However, these measures are relevant only in the context of corporate conflicts, since public authorities are not authorized to file lawsuits on these grounds.

Also, deprivation of voting rights of foreign shareholders in Russian companies for closing a corporate transaction without the required approval is provided by Presidential Decree No. 520. It should be taken into account that in practice it is hindered to make payments through Russian banks and register the transfer of rights to shares/participatory interests without the Sub-Commission's approval, as the approvals must be submitted to banks and notaries.

NEW REQUIREMENTS FOR APPROVAL OF PAYMENT OF DIVIDENDS TO "UNFRIENDLY" NON-RESIDENTS

From 2023, the conditions for obtaining approval for dividend payments to foreign creditors over RUB 10 million per calendar month to foreign accounts remain unchanged (e.g., dividend amount, retrospective analysis of payments). Payments may be approved without compliance with the conditions if the amount of dividends does not exceed the amount of foreign investment in Russia and is accompanied by the development of production and technology.

In addition, the authority to approve dividend payments above the limit was transferred from the Ministry of Finance to the Sub-Commission by Presidential Decree No. 767, which increased the timeframe for consideration. At the same time, the practice of approving dividend payments to foreign shareholders from "unfriendly" countries is exceptional.

INTERIM ADMINISTRATION

The possibility of interim administration of Russian assets of foreign "unfriendly" companies is established by Presidential Decree No. 302. This measure is taken in response to cases of deprivation of Russian persons of the right of ownership of property in "unfriendly" states, or in case of a threat to Russia's national security. Rosimushchestvo has been appointed as interim administrator, which receives the ownership rights (except for the right of disposal) and appoints a new executive body and members of the Board of Directors. The interim administrator is introduced for an indefinite period of time and may be terminated only by a new Presidential Decree.

In 2024, interim administration was imposed on Russian subsidiaries of such large foreign companies as Bosch, Amedia Eastern Europe, Universal Company and others. In the cases of Danone Russia JSC and Baltika Breweries LLC, interim administration was lifted due to subsequent transactions for the purchase and sale of the companies.

Introduction of the interim administration mechanism and the possibility of it being applied to all foreign assets of "unfriendly" non-residents without any particular criteria creates significant additional risks affecting the activity of foreign companies in Russia.

FINANCIAL TRANSACTIONS CONTINUED EXISTENCE AND ELABORATION OF RESTRICTIONS

Restrictions on granting and repaying loans to foreign creditors remain in effect. In particular, it is generally prohibited to perform the following operations without a special approval:

- Foreign currency operations related to providing loans in foreign currency to both "unfriendly" and "friendly" non-residents. Up to the end of September 2022, the general permission for providing foreign currency loans to "friendly" non-residents was in place, but despite its multiple extensions in the past, it was not extended. On May 23, 2022, the Ministry of Finance permitted the issue of loans in foreign currency by residents-individuals to non-residents who are under the control of residents-individuals and whose control is disclosed to the Russian tax authorities, for the purposes of maintaining property located in foreign countries and owned by non-resident borrowers. The amount of the loan must not exceed the amount of financing for the purposes specified in the approval for the previous calendar year.
- Transactions related to granting loans in RUB to "unfriendly" non-residents.
- Performance of obligations under loans in favor of "unfriendly" non-residents, if their amount exceeds RUB 10 million per calendar month, to a foreign account (rather than to a special type "C" account).

The regime of these accounts significantly limits the available operations with funds. The allowed operations include transferring funds to other type "C" accounts with specific purposes, payment of the debtor's own taxes and duties in Russia and several more specific operations. Currently it is not allowed to transfer money from a type "C" account to ordinary accounts, including with an approval of any kind.

The type "C" account regime has been amended. In particular, refundable amounts of taxes, duties, levies and other compulsory payments payable in accordance with the Russian budget legislation may now be credited to a type "C" account opened to a resident.

In November 2023 Presidential Decree No. 844 was issued, which allowed exchanging funds held in the type "C" accounts for blocked foreign securities held by Russian residents, but the total amount of such exchange is limited to RUB 100 thousand. Conditions of trading and implementation of transactions (operations) with foreign securities, as well as the list of foreign securities, in respect of which deeds may be committed, are established by the Sub-Commission Decision No. 225/2 dated February 2, 2024. The second stage of the exchange of blocked assets was held until October 12, 2024. Based on its results, foreign securities were sold for RUB 2.54 billion.

Moreover, in accordance with the Bank of Russia's Clarification No. 1-OR dated March 22, 2024, any actions (transactions) taken by a resident, aimed to terminate an obligation to an "unfriendly" entity without crediting funds to the type "C" account, are allowed only subject to approval.

In addition, from April 1, 2024, Russian residents do not need to obtain an approval for payment of shares, deposits and units in the property of non-residents, if the amount of such transactions in favor of one legal entity does not exceed RUB 15 million. Similar requirements apply to contributions to non-residents under simple partnership agreements (Decision of the Bank of Russia dated March 6, 2024).

From April 1, 2024, Russian residents do not need to obtain an approval for payment of shares, deposits and units in the property of non-residents, if the amount of such transactions in favor of one legal entity does not exceed RUB 15 million. Similar requirements apply to contributions to non-residents under simple partnership agreements.

KEY REGULATORY DEVELOPMENTS

PERSONAL DATA: WHAT TO EXPECT FROM REGULATORY CHANGES

LIABILITY FOR PERSONAL DATA LEAKS

On 30 November 2024, the law on increasing administrative liability for personal data leaks (No. 420-FZ) (hereinafter referred to as the "Law") was signed. The Law comes into force on 30 May 2025.

According to the Law, liability is differentiated depending on the category of illegally transferred personal data and the existence of previously imposed fines.

For actions (omissions) of a company that resulted in the illegal transfer of "ordinary" personal data (data of 1,000 or more subjects and/or 10,000 or more identifiers (unique designations of information on a person in an information system)) the following shall be imposed: 1) a fixed fine on the company in case of an initial incident (from RUB 3 million — and the fine amount increases depending on the increase in the threshold of the volume of data) and 2) a turnover fine (from 1 to 3% of the company's annual revenue, but not less than RUB 20 million and no more than RUB 500 million) in case of a repeated incident (i.e. when the company is considered to be brought to administrative liability). In the event of unlawful transfer of special or biometric categories of data, liability may arise even if only one personal data subject is affected, and the fixed fines for the initial incident increase (to a minimum of RUB 10 and RUB 15 million, respectively), while the turnover fines for repeated incidents are the same as above (except for the lower minimum of RUB 25 million).

At the same time, conditions are established under which the turnover fine is reduced to 0.1% (but not less than RUB 15 million and no more than RUB 50 million), namely the following three at the same time: 1) expenses on information security measures carried out by licensed companies within 3 calendar years prior to the violation being detected amounted to at least 0.1% of the data controller's annual revenue; 2) there is current documented compliance of the company with requirements for protection of personal data when processing them in information systems; 3) there are no aggravating circumstances such as fines imposed on the company during the year prior to the violation for violations of personal data legislation, etc.

When imposing turnover fines, an aggravating circumstance will include, among other things, an administrative offense in the form of failure to notify Roskomnadzor on a leak (the initial notification must be sent electronically within 24 hours from the moment the incident is detected). Also, failure to notify on a leak is in itself a separate administrative offense — the fine for this is set at no less than RUB 1 million for the company.

ROSKOMNADZOR INSPECTIONS

The moratorium on unscheduled inspections, previously extended until 31 December 2024 by Resolution No. 2516 of the Russian Government dated 29 December 2022, is coming to an end. Already from the beginning of 2025 one can expect Roskomnadzor to resume unscheduled inspections of businesses.

In this regard, we recommend that businesses bring their data processing arrangements in line with current legal requirements and be prepared for the start of inspections.

When preparing for an inspection, one should use Roskomnadzor's "checklist" as a reference. Such checklist was approved by Roskomnadzor Order No. 253 dated 24 December 2021 (amended on 10 January 2023). In total, there are more than 60 questions on the list so far.

CROSS-BORDER DATA TRANSFER

As of 1 March 2023, data may only be transmitted across borders after submitting a special notification to Roskomnadzor. This notification must be preceded by an assessment of the recipient of the personal data abroad in terms of its compliance with confidentiality and personal data protection measures.

In practice, notifications about the cross-border transfer of personal data raise many questions.

Another aspect of cross-border transfers that requires the attention of operators is the use of foreign services to collect data from websites and applications. According to Roskomnadzor, the use of such services indicates cross-border transfer and entails the need to comply with the relevant requirements for notifying the regulator and assessing the recipient of data abroad.

The trend of increasing the regulator's control over cross-border transfer by operators will grow.

INVESTIGATION OF INCIDENTS IN CASE OF PERSONAL DATA LEAKAGE

Operators are obliged to notify Roskomnadzor about the leak within 24 hours and again within 72 hours about the measures taken to remedy the incident. The preparation of both notifications involves an internal investigation of the incident.

Prompt investigation of the incident requires proactive incident management processes, including implementation of mechanisms to identify the source of the event, adoption of documented policies and instructions for responding to IS incidents, and regular training for employees.

ANONYMIZATION OF PERSONAL DATA AND CREATION OF A STATE SYSTEM OF ANONYMIZED DATA

On September 1, 2025, amendments to the Federal Law "On Personal Data" will come into force. They provide for the creation of a state information system (the "SIS") in which anonymized personal data will be collected and processed for the formation and use of datasets. A separate legal regime has been established for Moscow. The free circulation of depersonalized/anonymized data will continue to be impossible.

At the request of the Ministry of Digital Development, Communications and Mass Media of the Russian Federation (the "Mindigital"), any PD operators will be required to provide anonymized PD to the SIS. The list of data, as well as the time frame for their provision, will be indicated in the relevant request.

After receiving the request of the Mindigital, the operator will have to anonymize the requested PD and send the anonymized data to the SIS. The requirements for anonymization of PD, methods and procedure for anonymization will be established by the Government in coordination with the Federal Security Service (the "FSS"). The data obtained as a result of PD anonymization shall not include information, access to which is restricted by federal laws (such as state secret, banking secret, insurance secret).

The processing of datasets can only be carried out in the SIS; recording, extracting or transferring datasets from the SIS is not allowed.

Access to the SIS for processing datasets can be obtained by Russian persons. Foreign persons are prohibited from directly accessing the SIS and from obtaining the results of processing datasets.

We recommend monitoring the adoption of regulations exploring the new provisions on PD anonymization in order that company's processes, systems and technical solutions be timely adapted to new requirements.

AUTHORIZATION OF USERS TO ACCESS THE WEBSITE

Starting January 1, 2025, Russian owners of digital resources operating on the Internet in Russia must authorize users only by the ways provided in Part 10 of Article 8 of Federal Law No. 149-FZ of July 27, 2006 "On Information, Information Technologies and Information Security". These are mobile phone number, the Unified Identification and Authentication System, the Unified Biometric System or another information system. The latter must belong to a Russian citizen or an organization controlled by a Russian public law entity or a Russian citizen.

SEPARATE FORM OF DATA PROCESSING CONSENT

On 29 October 2024, draft Law No. 679980-8 was adopted in its first reading on the separate form of consent to personal data processing. With effect from 1 March 2025, consent to personal data processing will need to be drawn up separately from any other information or documents signed or accepted by the data subject.

The rule contained in the draft Law is complementary to a certain degree, as according to the provisions of the current version of the Federal Law "On Personal Data", data processing consent already should be "specific, substantive, informed, conscious and unambiguous", and the practice of including "hidden" data processing consent in documents is contrary to the abovementioned principles.

The adoption of the draft Law may require businesses to analyze current practices of obtaining users' data processing consent and, likely, make certain changes to the procedure for entering into user agreements (for example, when entering into user agreements on online platforms, a separate/additional step will be required to obtain the users' consent).

KEY REGULATORY DEVELOPMENTS

LABELING OF INTERNET ADVERTISING: REGULATION AND PRACTICE

GENERAL OVERVIEW OF REGULATION

On September 1, 2022, amendments to Federal Law No. 38-FZ "On Advertising" dated March 13, 2006, came into force, introducing requirements for the labeling of "internet advertising." Over the subsequent two years, these requirements were refined and clarified by the regulator, including specific provisions on the placement of labels and the establishment of administrative liability.

In summary, the labeling requirements are based on three key obligations:

- Submitting information about the advertisement, the chain of parties involved in its dissemination, and their contractual relationships to the Unified Register of Internet Advertising (ERIR) through designated Advertising Data Operators (ADOs). Certain information, such as ad view data, must also be provided after the advertisement is published.
- Including a unique identifier (a "token") in the advertisement, issued by the ADO for the advertising material.
- Displaying the label "advertising" and providing details about the advertiser.

A key feature of these regulations is that the obligation to submit data to the ERIR and to include the token in the advertisement applies to all parties in the advertising dissemination chain — advertisers, distributors, and advertising system operators. However, the obligation to display the "advertising" label and advertiser details rests solely with the distributor.

Consequently, each participant in the chain bears responsibility for fulfilling these obligations. On September 1, 2023, amendments to the Code of Administrative Offenses of the Russian Federation (CAO RF) came into effect, introducing new fines for non-compliance with marking requirements.

For example, failure to submit information to the ERIR can result in fines ranging from 200,000 to 500,000 roubles for legal entities (Part 15 of Article 14.3 of CAO RF); incorrect or missing token placement carries similar fines, from 200,000 to 500,000 roubles for legal entities (Part 16 of Article 14.3 of CAO RF).

In practice, these tasks are often centralized, with a single party in the chain handling data submission to the ERIR and token obtainment and placement. In this context, it becomes critically important to select reliable partners who adequately fulfill their labeling obligations.

Additionally, the regulations allow certain advertisers to delegate the "public" obligation (and corresponding liability) of submitting data to the ERIR to another party in the chain. This option is available to advertisers who either (a) have exclusive rights to the advertised object or (b) are manufacturers of the advertised products (per Russian Government Decree No. 948 dated May 25, 2022).

Another important aspect is the scope of these requirements. The law stipulates that labeling requirements apply to advertisements disseminated online. Advertising is broadly defined as any information addressed to an indefinite audience and aimed at attracting attention to an object, fostering interest in it, or promoting it in the market.

This definition makes advertising an evaluative category, and the final determination of what qualifies as advertising often depends on the Federal Antimonopoly Service (FAS) in individual cases.

However, FAS has clarified through its practice and official guidance that the following is not considered advertising:

- reference and analytical materials, including market overviews and scientific research and test results;
- information about products or services posted on the manufacturer's or seller's website, pages, or social media;
- reviews of multiple products from different manufacturers in videos or posts by bloggers, provided the primary goal is not product promotion;
- organic integration, such as mentions of a product, its identity features, its manufacturer or seller in scientific, literary, or artistic works, provided such mentions are organically integrated and not inherently promotional;
- listings by individuals or organizations unrelated to business activities (e.g., private sales on classifieds platforms);
- hyperlinks provided by search engines that are not specifically aimed at drawing attention to a particular object.

DEVELOPMENT OF ENFORCEMENT PRACTICES

In 2024, penalties for non-compliance with labeling requirements were increasingly enforced. According to Roskomnadzor, total fines for violations in 2024 exceeded 21 million roubles.

It is important to note that typical violations identified by FAS or Roskomnadzor (RKN) include not only the absence of required labels, but also the failure to submit or delays in submitting ad impression data after publication.

Moreover, RKN holds not only market participants accountable, but also ADOs themselves. For instance, ADO-A was recently fined for delays in submitting data received from market participants to the ERIR (Decision of the Moscow Arbitration Court dated October 18, 2024, in case No. A40-184733/2024).

At the same time, courts and administrative bodies (FAS and RKN) frequently reduce fines or replace them with warnings, particularly for first-time offenses or promptly corrected violations (e.g., Decision of the Irkutsk FAS Office dated October 15, 2024, in case No. 038/04/14.3-2088/2024; Decision of the Arbitration Court of the Penza Region dated November 12, 2024, in case No. A49-9248/2024; Ruling of the Ninth Arbitration Appellate Court dated October 7, 2024, in case No. A40-83951/2024).

An interesting development is the growing recognition that labeling requirements apply to advertisements posted on so-called "banned social networks" (Decision of the Amur FAS Office dated September 3, 2024, in case No. 028/05/18.1-430/2024). Previously, FAS and RKN lacked a unified stance on this issue.

Additionally, recent practice highlights a general trend for improved coordination between FAS and RKN in addressing violations of labeling requirements (e.g., Decision of the Komi FAS Office dated October 2, 2024, in case No. 011/04/14.3-856/2024; Decision of the Sverdlovsk Arbitration Court dated June 24, 2024, in case No. A60-14604/2024; Decision of the Chelyabinsk Arbitration Court dated August 9, 2024, in case No. A76-18744/2024). For market participants, this indicates more effective oversight, by FAS and RKN, and faster identification and resolution of violations.

Recent practice highlights a general trend for improved coordination between the Federal Antimonopoly Service and Roskomnadzor in addressing violations of labeling requirements. For market participants, this indicates more effective oversight, by FAS and RKN, and faster identification and resolution of violations.

KEY REGULATORY DEVELOPMENTS

COUNTERACTING THE SPREAD OF COUNTERFEIT PRODUCTS IN RUSSIA

The administrative liability established by Article 14.10 of the Code of Administrative Offenses of the Russian Federation for the illegal use of someone else's trademark, service mark, name of place of origin of goods or similar designations for similar goods may be applied and it is applied in practice not only to manufacturers of the counterfeit products, and not only to the person(s) that illegally import counterfeit goods into Russia, but also to any seller of counterfeit products. In this case, the liability of the offender occurs, including in the event that the person knew or should have known that he was using someone else's trademark, but did not check whether he was using it on legal grounds. That is, the offense can be committed not only intentionally, but also through negligence.

In this regard, Article 14.10 of the Code of Administrative Offenses has long been an efficient or at least practically working instrument of legal combat against counterfeiting both at the borders of Russia and in its domestic market.

If the infringement is committed repeatedly or causes major damage, i.e. more than 400,000 Russian roubles, criminal liability may occur under Article 180 of the Criminal Code of the Russian Federation.

Until October 2024, in accordance with Article 28.3 of the Code of Administrative Offenses of the Russian Federation, officials of the internal affairs bodies, along with officials of the customs authorities and bodies exercising functions of control and supervision in the area of consumer protection and the consumer market, were authorized to draw up protocols on administrative offenses provided for in Article 14.10 of the Code.

Federal Law No. 192-FZ of 22 July 2024 "On Amendments to the Code of the Russian Federation on Administrative Offenses" introduced amendments to Paragraph 1 of Part 2 of Article 28.3 of the Code of the Russian Federation on Administrative Offenses that exclude the authority of officials of the internal affairs bodies (police) to draw up protocols on administrative offenses provided for in Article 14.10 of the Code of Administrative Offenses.

The purpose of the Law was to eliminate duplication of powers of state bodies in the exercise of their functions. Article 14.10 of the Code of Administrative Offenses is only one of many articles of Russian codes and other laws affected by these amendments. Employees of the Ministry of Internal Affairs will also no longer be able to draw up protocols on administrative offenses in environmental protection, nature management, and treatment of animals, communications and information, etc. The same applies to Article 7.12 of the Code of Administrative Offenses, which provides for liability for infringement of copyright or neighboring rights.

The new version of Paragraph 1 of Part 2 of Article 28.3 of the Code of Administrative Offenses came into effect on 21 October 2024.

Consequently, from this date, the following persons have the right to draw up protocols on administrative offenses provided for in Article 14.10 of the Code of Administrative Offenses:

- officials of customs authorities (Paragraph 12 of Part 2 of Article 28.3 of the Code of Administrative Offenses);
- officials of bodies implementing federal state supervision in the area of consumer rights protection (Paragraph 63 of Part 2 of Article 28.3 of the Code of Administrative Offenses) (Rospotrebnadzor).

In turn, as explained by the Plenum of the Supreme Arbitration Court of the Russian Federation in the Resolution of 17 February 2011 No. 11 "On Certain Issues of Application of the Special Part of the Code of the Russian Federation on Administrative Offenses", customs authorities have such powers only with respect to goods imported into the Russian Federation and exported from it, since in both cases the turnover of goods is carried out across the customs border. The powers of customs authorities to protect intellectual rights with respect to goods in circulation within the territory of the Russian Federation, and with respect to which there is no information that they were previously imported into the country from abroad, are not provided.

Consequently, when goods with signs of counterfeiting are detected on the territory of Russia, the only officials authorized to draw up protocols on administrative offenses provided for in Article 14.10 of the Code of Administrative Offenses, since 21 October 2024, are officials of Rospotrebnadzor.

Considering the specifics of the offenses related, among other things, to the sale of counterfeit products, drawing up a protocol on administrative offenses often requires prompt control and investigative measures, test purchases on the spot, etc.

In addition, in order to quickly and efficiently respond to the actions of unscrupulous players in the market who deliberately sell counterfeit products and other products that infringe intellectual property rights, as a rule, additional specific powers of law enforcement agencies are required, as well as accumulated experience in this area.

Officials of the internal affairs bodies (police) have long been the main link in the state system ensuring that persons selling counterfeit products on the domestic market of Russia are held liable, including conducting operational activities, drawing up protocols and initiating cases on administrative offenses, etc. At the same time, representatives of Rospotrebnadzor have previously spoken out about the impossibility of carrying out the above-mentioned activities and drawing up protocols on administrative offenses in the case of trademark infringements in response to inquiries from trademark owners. At the same time, cases of bringing infringers to administrative liability under Art. 14.10 on protocols drawn up by officials of the bodies exercising functions on control and supervision in the sphere of consumer rights protection and the consumer market have also occurred.

We hope that Rospotrebnadzor officials in the current situation and in their new role will efficiently counteract the spread of counterfeit products on the domestic market of the Russian Federation, and they will be able to organize not only a fairly complex set of measures to bring infringers to administrative liability in different regions of Russia, but also to establish centralization and processing of information on offenses, and establish contacts with the trademark owners.

We believe that the trademark owners are ready to support this work of Rospotrebnadzor officials in terms of information and organization within the law and within their capabilities.

Nevertheless, it is obvious that at the initial stage of this work, some temporary decrease in the efficiency of the fight against counterfeiting in Russia is still inevitable.

KEY REGULATORY DEVELOPMENTS

CONSUMER PROTECTION: WHAT BUSINESSES FACE IN RUSSIA

Consumer protection remains relevant and is being discussed at the state level and in business. The attention that government agencies and public organizations pay to consumer protection and the observance of consumer rights has increased, especially with the development of electronic marketplaces, the entry of new Russian producers of goods into the market, and with the resolution of the parallel imports issue.

One of the latest legislative initiatives in terms of changes to the Consumer Rights Protection Law concerns unfair pre-contractual practices involving the imposition of goods and services. The document proposes the establishment of a direct prohibition on imposing additional goods or services on a consumer prior to the conclusion of a contract, as well as automatically assuming the consumer's consent to the purchase of additional goods or services.

The topic of business integrity is regularly reflected in reviews of court practice and the media. Less attention is paid to the integrity of consumer behavior. At the same time, at the moment business is observing a surge in behavior by consumers and public associations, where the goal is not to protect their rights and interests, but to obtain certain benefits and income. In this case, legal mechanisms laid down in the law are used, such as, for example, a penalty of 1% of the cost of goods per day. This phenomenon has been called "consumer extremism". Despite the fact that this phenomenon is the exception rather than the rule, even a small percentage of consumers who abuse their rights cause significant losses to businesses, especially in those areas where the cost of goods is high.

In addition, the mechanism of filing class actions against companies is gaining momentum. At the moment, more stable practice is emerging in the acceptance and processing of class actions. The law has tangible gaps on a number of issues in such proceedings, but these gaps are gradually being filled in based on the consideration of specific cases. Public organizations have also become more active in filing lawsuits in defense of an indefinite circle of persons.

We can single out the following main "pain points" in the interaction of business with consumers and the law enforcement system.

FAILURE TO TRANSFER GOODS FOR QUALITY CHECK AT THE PRE-TRIAL STAGE, FAILURE TO RETURN GOODS AFTER FILING A CLAIM AND EVEN AFTER A COURT DECISION

The Law on the Protection of Consumer Rights does not provide for a pre-trial dispute resolution procedure, but does establish a company's right to conduct a quality check, sometimes referred to as an expert review. As part of such a check, the validity of the buyer's claims regarding the quality of the goods is established, the nature of the claimed defect is studied, etc. This measure was introduced to ensure that as many consumer claims as possible are resolved by companies out of court, thereby reducing the burden on the judiciary. However, the absence of the obligation to present the goods for a quality check leads to disputes being immediately referred to the court. At the same time, during the trial, the consumer can use the "low-quality" goods, unless appropriate interim measures are imposed. Such measures are rarely imposed by the courts, which can lead to the loss of goods and the subsequent resumption of litigation.

SIGNIFICANT AMOUNTS OF PENALTIES LEVIED AND FORFEIT FOR THE FUTURE

It is the significant amounts of penalties levied, which include a penalty and a fine, that are attractive to consumers. According to the Law on the Protection of Consumer Rights, a consumer is awarded a penalty of 1% of the price of the goods per day for the entire period of delay in satisfying the consumer's claims and a fine of 50% of the amount awarded in favor of the consumer. If a public organization is involved in the defense of the consumer, it receives 25% of the fine imposed in favor of the consumer.

At the request of a company, the court may reduce the amount of the penalty and the fine if it recognizes such a request as justified, but only in exceptional cases. In practice, the amounts of the penalty and the fine awarded in favor of consumers in relation to low-quality goods, even after their reduction by the court, can be 300-400% of the original price of the goods. The court may award a penalty in the amount of 1% of the price of the goods per day from the date the decision comes into force until the date the decision is enforced — the so-called "forfeit for the future". In this case, the amount to be paid increases significantly. After all, neither the bailiff nor the bank has the right to reduce the amount of the penalty, as the court can do, but calculates it at the rate provided for by the law. As a result, unscrupulous consumers deliberately delay the provision of their bank details for as long as possible since they are entitled to obtain a writ of execution within 3 years from the date the decision comes into force and, as a result, receive a much larger amount than the amount awarded by the court. At the same time, it is important to note that the penalty imposed is based on the price of the goods; not the price the consumer paid for the goods, but taking into account the difference in price between the goods purchased by them and the price of new goods. This issue will be discussed below.

PRICE DIFFERENCE

In the current version, Paragraph 4 of Article 24 of the Law on Protection of Consumer Rights provides that when returning goods of improper quality, the consumer has the right to demand compensation for the difference between the contractual price of the goods and the price of the relevant goods at the time of voluntary satisfaction of such a claim or at the time of the court decision. In other words, if the consumer bought the goods for 1 million roubles, and by the time the decision was made in their favor, the cost of the goods had increased to 1.5 million roubles, then the compensation awarded in favor of the consumer is 1 million roubles + 0.5 million roubles = 1.5 million roubles.

> At the moment, business is observing a surge in behavior by consumers and public associations, where the goal is not to protect their rights and interests, but to obtain certain benefits and income.

However, the law does not clarify what exactly a "relevant product" is and how its price is determined. In particular, there are no clear criteria for determining what kind of product is considered to be relevant for the product purchased by a consumer that was originally in use. In practice, this issue is resolved by arranging a forensic examination, but this does not lead to a more precise application of the provision. Rather, on the contrary, in a situation of limited product choice and increasing prices for all goods, the experts, at their own discretion, choose a "relevant" product, which may have improved characteristics, a different configuration, be of a different model range, etc., and accordingly, cost much more. As a result, huge amounts of difference in price are collected from businesses.

INTEREST ON LOANS

According to Paragraph 6 of Article 24 of the Law on Protection of Consumer Rights, in the event of return of goods of improper quality purchased by the consumer using consumer credit (a loan), the seller is obliged to return to the consumer the amount of money paid for the goods, as well as to reimburse the interest paid by the consumer and other payments under the consumer credit (loan) agreement. This rule has been applied quite consistently to find the seller liable. At the same time, according to the position of the Supreme Court of the Russian Federation, set out in the Review of Judicial Practice in Consumer Protection Cases (approved by the Presidium of the Supreme Court of the Russian Federation on October 19, 2022), this rule may also be applicable to the manufacturer. Businesses should take this provision into account when assessing potential losses.

We believe that the existing law needs qualitative study, first of all, to exclude the attractiveness to consumers of using the law for personal enrichment. Russian companies suffer multimillion dollar losses from "consumer extremism". At the same time, the law should promote greater consumer protection and access to protection of their rights.

KEY REGULATORY DEVELOPMENTS

SUSTAINABILITY IN RUSSIA: MOVING FORWARD

RUSSIA'S SUSTAINABILITY LEGAL FRAMEWORK

The legal foundations for sustainable development in Russia include:

1. **binding obligations —** such as for regulated entities in all Russian regions to report on their greenhouse gas (*GHG*) emissions[1] and for regional regulated entities in Sakhalin Oblast to comply with GHG emission caps[2];

2. **regulatory incentives —** such as for construction of renewable power plants in the wholesale power and capacity market[3], as well as for retail power markets[4];

[1] Federal Law of July 2, 2021 No. 296-FZ "On Limitation of Greenhouse Gas Emissions".

[2] Federal Law No. 34-FZ dated March 6, 2022 "On Conducting an Experiment to Limit Greenhouse Gas Emissions in Certain Constituent Entities of the Russian Federation".

[3] Resolution of the Government of the Russian Federation dated May 28, 2013, No. 449 "On the Mechanism for Promoting the Use of Renewable Energy Sources in the Wholesale Power and Capacity Market".

[4] Resolution of the Government of the Russian Federation No. 47 of January 23, 2015 "On Amendments to Certain Acts of the Government of the Russian Federation Concerning Promotion of the Use of Renewable Power Sources in Retail Power Markets".

3. **legal "infrastructure" —** such as for climate projects and carbon markets[5], raising green, adaptation and social finance (*Sustainability Taxonomy*)[6], energy service agreements[7];

4. **recommendations —** such as from the Ministry of Economic Development of the Russian Federation on sustainability reporting[8] and from the Bank of Russia to public companies, financial organizations and institutional investors to invest responsibly, develop sustainability and climate transition strategies, consider ESG-factors in corporate governance and disclose non-financial information[9];

5. **national development strategies and other governmental initiatives —** such as the Low Carbon Development Strategy up to 2050[10], concepts for EV[11] and hydrogen development[12], socio-economic development initiatives up to 2030, including Clean Power (Hydrogen and Renewables), Electric and Hydrogen Vehicles, Major Clean Up, Circular Economy, Geology: Revival of a Legend and other initiatives[13];

6. **voluntary corporate programs —** such as purchasing renewable power and/or guarantees of power origin, improving technologies and operations to reduce carbon footprint and negative environmental impact, running numerous social programs and integrating sustainability into corporate governance.

In the course of 2024:

1. The President issued a decree on national development goals up to 2030 and with an outlook up to 2036[14]. The decree defines the fundamental policy goals of improving living standards, life expectancy and quality, boosting infrastructural and technological development, environmental protection and achieving multiple other goals that *de facto* overlap with the UN Sustainable Development Goals.

2. The Government expanded the list (taxonomy) of projects of technological sovereignty and technological adaptation of the economy (*TS and SAE*)[15]. The expanded taxonomy includes, for example, renewable power construction projects, production of equipment for hydrogen and treatment of non-hazardous waste for final disposal.

3. The Government enabled owners of carbon credits registered in the Russian carbon registry to redeem their credits to offset carbon footprint for the benefit of third parties not having an account in the registry. The aims are to simplify access to the Russian carbon market and in this way attract more buyers of the credits[16].

4. The Bank of Russia extended incentives for banks to finance TS and SAE projects[17], and announced the intention to extend such incentives to projects that fit the Sustainability Taxonomy.

5. The Ministry of Economic Development and Fedresurs enabled companies to publish information on sustainability reporting disclosure on Fedresurs[18]. Earlier, Interfax and ESG Alliance launched a service comparing the ESG-indicators of companies[19].

[5] See footnote 1.

[6] Resolution of the Government of the Russian Federation of September 21, 2021, No. 1587 "On Approval of the Criteria for Sustainable (including green) Development Projects in the Russian Federation and Requirements for the Verification System of Sustainable Development Financing Instruments in the Russian Federation".

[7] Federal Law dated November 23, 2009 No. 261-FZ "On Energy Saving and Increasing Energy Efficiency and on Amendments to Certain Legislative Acts of the Russian Federation".

[8] Order of the Ministry of Economic Development of the Russian Federation dated November 1, 2023 No. 764 "On Approval of Methodological Recommendations for the Preparation of Sustainable Development Reporting".

[9] Bank of Russia - Information Letters and Recommendations on Sustainable Development <https://www.cbr.ru/develop/ur/na/>

[10] Order of the Government of the Russian Federation dated October 29, 2021 No. 3052-p "On Approval of the Strategy for Social and Economic Development of the Russian Federation with Low Greenhouse Gas Emissions up to 2050".

[11] Order of the Government of the Russian Federation dated August 23, 2021 No. 2290-p "On the Concept, Target Indicators and Action Plan ("Road Map") for the Development of Production and Use of Electric Transport in the Russian Federation".

[12] Order of the Government of the Russian Federation dated August 5, 2021 No. 2162-p "On Approval of the Concept Plan for Hydrogen Energy Development in the Russian Federation".

[13] Order of the Government of the Russian Federation of October 6, 2021 No. 2816-p "On Approval of the List of Initiatives of Social and Economic Development of the Russian Federation up to 2030".

[14] Decree of the President of the Russian Federation dated May 7, 2024 No. 309 "On National Development Goals of the Russian Federation for the Period up to 2030 and the Outlook up to 2036".

[15] Resolution of the Government of the Russian Federation of November 6, 2024 No. 1492.

[16] Resolution of the Government of the Russian Federation of August 13, 2024 No. 1076.

[17] Decision of the Board of Directors of the Bank of Russia of October 14, 2024 "On Assessment of the Credit Risk on Credit Claims and Claims for Accrued (Accumulated) Interest in the Framework of Financing Technological Sovereignty Projects and Projects for Structural Adaptation of the Economy of the Russian Federation, Including Those Implemented under Concession Agreements".

[18] Unified Federal Register of Information About Legal Entities <https://fedresurs.ru/>.

[19] Service for Comparing Key Indicators of Non-Financial Reporting of Russian Companies <https://esg-disclosure.ru>.

6. The Federal Antimonopoly Service issued recommendations on preventing untrue or inaccurate green claims (*greenwashing*). Greenwashing may entail administrative liability for unfair competition[20].

7. The Moscow Exchange obliged issuers whose shares are included in the first or second listings to publish non-financial information, starting 2024, in accordance with international and Russian sustainability disclosure standards[21].

8. Businesses continued implementing ESG-initiatives, including use of the tools enabled by said regulatory developments. For example, the number of climate projects registered in the Russian carbon registry amounted to more than 40. Companies continued raising ESG funding, obtaining ESG ratings, disclosing ESG reports, and implementing numerous environmental, social and governance initiatives underpinning such ratings and reports.

RUSSIA ON THE PATH TO ENERGY TRANSITION

The concept of Energy Transition 4.0 has gained significant traction over the past 5-10 years in the global economy, including the oil and gas sector. Western countries along with several others have been at the forefront of promoting a green agenda, which has led to the development of ideas on the early abandonment of fossil fuels in favor of renewable energy sources such as solar, wind, geothermal, tidal and others.

The question of how quickly the global shift towards renewables, electrification, transformation, and other low-carbon solutions should occur is also a key topic of discussion at the Conference of the Parties to the United Nations Framework Convention on Climate Change (COP), which takes place in a different country each year. Despite the adoption at COP28 of the outcome document on 'transitioning away from fossil fuels in energy systems' by 2050, it has become evident that there is a growing divergence of opinion on the necessity for a rapid departure from the previously reliable energy sources that have been the foundation of the three previous transitions, with a corresponding shift towards renewables and sustainable sources of energy, particularly from an energy security standpoint. In addition, an increasing number of countries and companies are recognizing the potential of nuclear power as a means of facilitating the growth of artificial intelligence and the big data economy.

Russia, like other major global producers of coal, oil, and gas, is an active participant in this discussion. Russia is in a unique position to contribute to the global energy transition. Although it is the third largest oil producer, second largest gas producer and sixth largest coal producer, Russia has an enviable low-carbon energy balance. As highlighted by Deputy Prime Minister A. Novak, Russia boasts one of the most diversified energy mixes in the world. Currently, coal accounts for only 12% of the energy balance. When solar, wind, hydro and nuclear generation are included, these sources account for over 40% of the total, with gas representing almost 50%.

Russia is developing renewables, hydrogen power, energy storage, electric mobility and other globally widespread technologies and associated engineering industries. It is also developing lithium deposits and intends to establish itself as a major player in the global market for energy transition metals. Russia's stance on energy transition is founded on the principles of fairness and equity, taking into account the specific national development priorities and the distinctive composition of each country's fuel and energy balance. In line with this stance, particular emphasis is placed on technological neutrality, encompassing the utilisation of a comprehensive range of fuels, energy sources and technological solutions that not only curtail greenhouse gas emissions but also mitigate the potential adverse socio-economic impacts, including imbalances in labour markets and rising electricity prices.

This position was first articulated at the G20 Energy Ministers' Meeting in October 2024 and was subsequently reflected in the adopted consensus ministerial declaration and the Principles for Just and Inclusive Energy Transitions.

Russia has consistently demonstrated its commitment to a constructive approach to just energy transitions that will enable the continued achievement of climate goals without compromising economic and social growth. This vision is also shared by the BRICS+ countries.

In particular, Russia views energy efficiency improvements as the most cost-effective method for decarbonizing the economy, including the fuel and energy sector. Regarding the potential for reducing the carbon footprint of the oil and gas sector, some estimates indicate that up to 40% of decarbonization opportunities reside in energy efficiency solutions, which would be commercially attractive as they do not require significant additional investment and can be implemented at current energy price levels.

Back in 2021, the Government approved the Strategy for Low-GHG Socio-Economic Development of the Russian Federation through 2050. The Strategy's intensive scenario anticipates that Russia will achieve carbon neutrality[22] by 2060 at the latest. To implement the Strategy, a plan of measures will be adopted that will affect all sectors of the Russian economy, including the fuel and energy sector. As of December 2024, the government is currently developing an updated version of the energy strategy for the period up to 2050, which will form the basis for the development of the energy sector for the next 25 years.

The Russian Energy Agency of the Ministry of Energy of Russia forecasts that global gas consumption will grow by 26% by 2022. Therefore, in the most probable scenario, gas will

[20] Information of the Federal Antimonopoly Service dated October 22, 2024 "Recommendations on Avoiding Greenwashing in Marketing Communication".

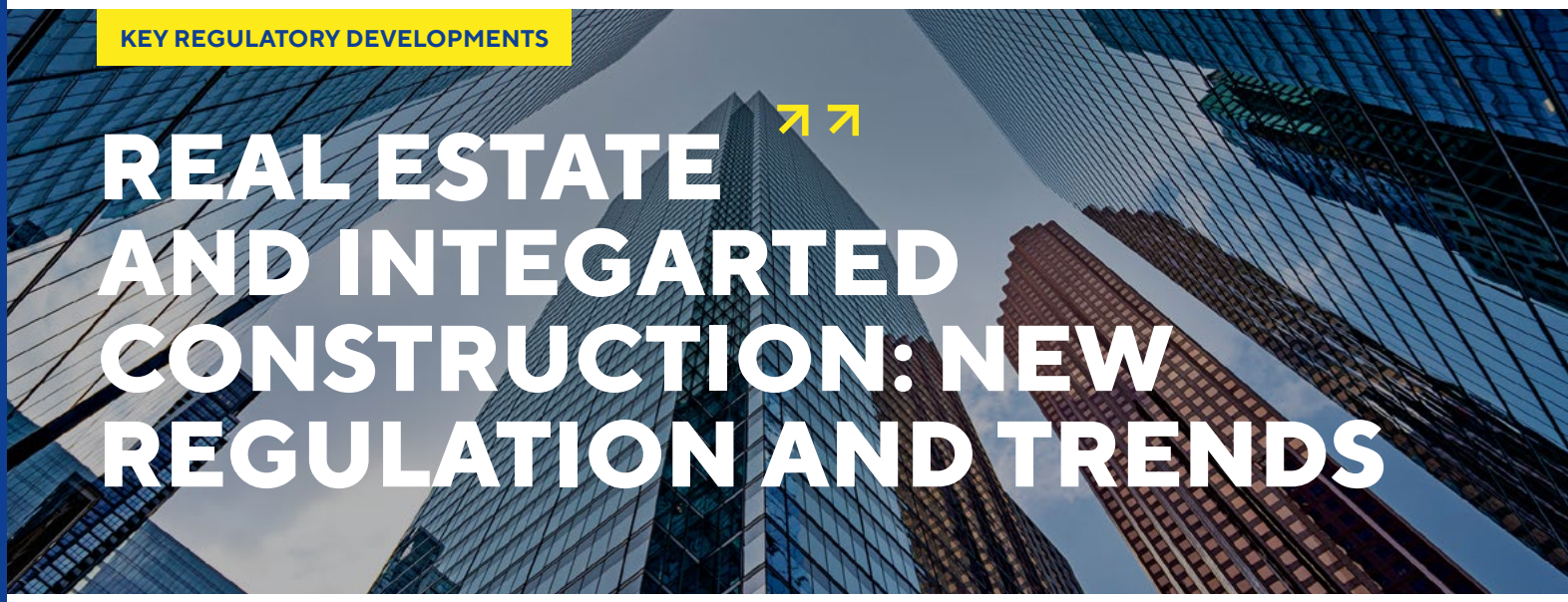
[21] Additional Rules, Requirements and Recommendations on Information Disclosure by Issuers whose Shares are Included in the First or Second Level of September 24, 2024 (approved by Order of PJSC Moscow Exchange No. MB-P-2024-3132 of September 24, 2024).

[22] Balance between anthropogenic greenhouse gas emissions and removals.

become the primary fossil energy source in the global energy balance in terms of consumption by 2050. Meanwhile, electricity generation from renewables and other low-carbon energy sources is expected to grow beyond the 2050 horizon.

In conclusion, energy transition 4.0 is a complex and multifaceted process that requires a balanced approach, taking into account the specific circumstances of each country. Russia, which has significant hydrocarbon reserves and is developing a low-carbon energy mix, is well positioned to contribute constructively to global decarbonization initiatives. Considering the anticipated expansion in gas and renewable energy consumption, it is crucial to maintain the discourse on a balanced and sustainable energy sector future that safeguards both environmental security and economic development. The successful implementation of such strategies can serve as the foundation for a more sustainable and inclusive energy system at the global level.

KEY REGULATORY DEVELOPMENTS



REAL ESTATE AND INTEGARTED CONSTRUCTION: NEW REGULATION AND TRENDS

This section outlines the most significant and substantial trends and changes in real estate and integrated construction – changes that are very important for the business community.

CHANGES IN THE FEDERAL LAW ON PARTICIPATION IN THE SHARED CONSTRUCTION

2024 saw changes in the Federal Law on Participation in the Shared Construction[1] limiting developers' liability toward participants in shared construction. The law now exhaustively lists penalties for developers. After the changes, other penalties not covered by the law will no longer apply.

The Federal Law on Participation in the Shared Construction contains the following penalties for developers:

- The warranty period for participants in shared construction projects is now three years, down from five.
- The developer's penalty for not correcting defects on time, commensurate decrease in price and compensation of costs was set at 1/300 of the Russian Central Bank's refinancing rate in effect at the time the defects were not corrected. The penalty is doubled if the participants in shared construction purchased the housing for personal needs, but it cannot exceed the cost of correcting the defects.
- A person who entered into an agreement for personal needs will be compensated for moral harm caused by the developer violating the person's rights, if the developer was at fault.

[1] Federal Law No. 214-FZ of December 30, 2004, on Co-Investment in the Construction of Apartment Buildings and Other Real Estate and on Amending Certain Legislative Acts of the Russian Federation.

- A developer may be charged a fine of 5 percent of the court-awarded amount for willfully failing to honor the requests of a participant in shared construction who entered into an agreement for personal needs. The Consumer Protection Law previously charged a fine of 50 percent.

These changes may be intended to help developers while many individuals are unable to purchase apartments through mortgage loans.

Notably, the new Federal Law on the Construction of Residential Buildings Under Construction Contracts Using Escrow Agreements will come into effect on March 1, 2025.[2] The new law will apply when legal entities or sole proprietors build homes on land plots owned, leased or used for free by Russian citizens in order for individuals to become the owners of those homes. The law will apply if the parties to the construction contract have agreed to deposit money in an escrow account to pay the contract price. In other words, it will still be possible to build single-family homes without using escrow accounts.

CHANGES IN THE FEDERAL LAW ON REGISTRATION

The Federal Law on Registration[3] is frequently amended. Most changes are local or technical. Here we will focus on what we believe are the most significant changes.

Starting in 2025, the state fee will need to be paid not only for state registration of title, but also for state cadastral registration. Prior to 2025 only state registration of title was subject to the state fee.

In 2026 it will be possible to file administrative appeals of registrars' decisions to suspend the registration process.[4] A central appeal commission as well as regional and interregional appeal commissions will be created to handle this administrative procedure.

The central appeal commission and the regional commissions will be comprised of three Rosreestr representatives and three members of the national cadastral engineers' self-regulating organization. The interregional commission will include one representative each from every registration authority active in the Russian Federation regions where the commission is set up, and an equal number of representatives of the national association. Commission members will rotate once every five years.

To appeal a decision suspending the registration process, a written application will need to be submitted to the commission within 15 business days of the decision. The application can be submitted in person, by mail or online (through the public services portal). The appeal commission will have 15 business days to consider the application.

The appeal commission will consider whether the application has merit, and applicants will be able to attend commission sessions. The appeal commission will announce the operative part of its decision during the session at which it is made. The commission's decision will be sent to the appropriate Rosreestr department and will be the basis to both cancel an unreasonable decision suspending the registration process and for the registrar to review the filed registration documents. If the appeal commission denies the application, the decision can be appealed to a court together with the decision suspending the registration process.

CHANGES TO THE LAND CODE OF THE RUSSIAN FEDERATION

Most of the changes to the Land Code of the Russian Federation[5] in 2024 were technical. However, as of March 1, 2025, one of the major changes obligates the titleholder of a land plot in residential areas to develop and use the land plot.[6]

Developing the land plot involves the titleholder taking one or more actions to make the land plot suitable for use according to its designated purpose and permitted use. The Russian government will generate a list of these actions and criteria for determining that the land is not being used. Land plots in residential areas will need to be developed within three years. The titleholder of a land plot in a residential area will start using the land plot as of the date they acquire title to it, and will develop it within three years if the plot needs to be developed.

Failure to use a land plot will entail administrative liability. The administrative fine on legal entities will be 3 to 5 percent of cadastral value, but at least RUB 400,000. The fine will be RUB 400,000 to RUB 700,000 if no cadastral value has been set.[7]

[2] Federal Law No. 186-FZ of July 22, 2024, on the Construction of Residential Buildings Under Construction Contracts Using Escrow Agreements.

[3] Federal Law No. 218-FZ of July 13, 2015, on the State Registration of Real Estate.

[4] Federal Law No. 207-FZ of July 22, 2024, on Amendments to the Federal Law on the State Registration of Real Estate and Repealing Certain Provisions of Legislative Acts of the Russian Federation.

[5] Russian Federation Land Code, No. 136-FZ of October 25, 2001.

[6] Federal Law No. 307-FZ of August 8, 2024, on Amending the Russian Federation Land Code and Article 23 of the Federal Law on the Conduct of Gardening and Vegetable Gardening by Citizens for Their Own Needs and on Amending Certain Legislative Acts of the Russian Federation.

[7] As per Article 8.8(3) of the Russian Federation Code on Administrative Offenses.

EPC NATIONAL STANDARD: DEVELOPING MAJOR CONSTRUCTION IN RUSSIA

Globally, most major and costly construction projects are done using the Engineering Procurement Construction (EPC) model. It involves a single contractor in completing the entire project.

EPC is also widely used in Russia, where such projects are often referred to as turnkey projects. However, to date there has been no systematic regulation of EPC.

This legislative gap was filled in early 2024 with the entry into effect of the GOST R 71177-2023 National Standard titled Management of Large Construction Projects Using Integrated Contracts[8] (the Standard). This document was developed by the EPC community, which unites professionals and experts with real-world experience of major investment projects.

The Standard is the fundamental information source for doing EPC projects in Russia. It factors in both international experience and the practical specifics of construction in Russia. The Standard describes, among other things:

- common terminology;
- project participants and their roles;
- contract strategies;
- how to choose a contractor for a project;
- key elements of the EPC contract and methods for managing revisions to it;
- pricing methods;
- project life cycle and description of processes within a project;
- standard division of responsibilities between client and contractor.

In this way, the process of completing such investment projects in Russia now has a legal framework that streamlines cooperation between construction market players. It also improves project structuring and ultimately makes more efficient use of resources in these turbulent times for Russia's economy.

The Standard's developers haven't stopped there: they are currently working on guidelines for the Standard.

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EPC is also widely used in Russia, where such projects are often referred to as turnkey projects. However, to date there has been no systematic regulation of EPC.

[8] Approved by Order No. 1683-st of the Federal Agency for Technical Regulation and Metrology of December 27, 2023.

ANNEX 1.

LEGISLATIVE NOVELTIES IN 2024

ORDER OF THE GOVERNMENT OF RUSSIA NO. 99-R OF 20.01.2024

The Government has approved the roadmap of the programme for transformation of the business climate "Tourism". Among other things, the document will simplify the registration of citizens at the place of temporary stay in hotels. Guests will not have to present a Russian paper passport, it will be enough to show its electronic version in the "Gosuslugi" application. It will also be possible to register using a foreign passport regardless of the place of a person's permanent residence.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 72 OF 27.01.2024

The Government has set quotas for the import of seeds from "unfriendly" countries. The list of seeds subject to restrictions includes potato, wheat, rye, barley, corn, soya beans, rapeseed, sunflower and sugar beet seeds. Seeds will be imported within the quotas established by the Government of the Russian Federation. Their distribution among participants of foreign trade activity is entrusted to the Ministry of Agriculture of Russia.

DECREE OF THE PRESIDENT OF RUSSIA NO. 143 OF 26.02.2024

The powers of the Government Commission for the Control of Foreign Investments to consider the expediency of transactions are established. This concerns transactions with securities of Russian legal entities and shares in them owned by foreign persons associated with "unfriendly" countries, the prohibition on the performance of which is established by Presidential Decree No. 520 of 5 August 2022. The Commission prepares a motivated recommendation on the expediency or inexpediency of such transactions.

ORDER OF THE GOVERNMENT OF RUSSIA NO. 491-R OF 01.03.2024

The Russian Government has approved a list of economically significant organizations (ESOs). It includes six holding companies. The Ministry of Economy specified that the list may be expanded.

FEDERAL LAW NO. 45-FZ OF 11.03.2024

Digital financial assets may now be used in international settlements. Under the new rules, digital financial assets and utilitarian digital rights may be used as a counter-provision under foreign trade agreements (contracts) concluded between residents and non-residents providing for the transfer of goods, performance of work, rendering of services, transfer of information and results of intellectual activity, including exclusive rights thereto.

DECREE OF THE PRESIDENT OF RUSSIA NO. 186 OF 13.03.2024

The transfer of Danone's Russian assets to the management of Rosimushchestvo was cancelled. This is the first such decision on the assets of foreign companies in Russia. Under the presidential decree of 16 July 2023, stakes in the Russian subsidiary Danone owned by foreign companies were placed under temporary management by Russia.

FEDERAL LAW NO. 79-FZ OF 06.04.2024

Law increases by 1.5 times the "threshold values" of large and especially large amounts of unpaid customs payments, special, anti-dumping and (or) countervailing duties for the purposes of criminal liability under Article 194 of the Criminal Code of the Russian Federation and is set out in Note 1 to this Article. At the same time, Note 2 to Article 194 of the Criminal Code provides for the authority of the Government to determine the list of certain goods for which liability for evasion of payments will be incurred on the basis of the currently valid values of large and especially large size.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 458 OF 11.04.2024

The requirements for an investor to conclude a SPIC have been amended. Previously, it was prohibited for an investor to be controlled by legal entities established under the laws of foreign states and registered offshore. Now it is required that the share of participation of these legal entities in the investor's authorized (share) capital should not exceed 25% (unless another maximum percentage is stipulated by the provisions of the Russian legislation, on the basis of which the investor or persons attracted by it are entitled to apply incentive measures specified in the SPIC).

ORDER OF THE MINISTRY OF INTERNAL AFFAIRS OF RUSSIA NO. 260 OF 16.05.2024

The Ministry of Internal Affairs has clarified the methods for employers and customers of works (services) to send notifications: on the fulfilment of obligations to pay salaries (remuneration) to foreigners – highly qualified specialists; on the conclusion and termination (cancellation) of an employment or civil law contract with a foreigner.

DECREE OF THE PRESIDENT OF RUSSIA NO. 430 OF 20.05.2024

Decree approving a temporary procedure for transactions involving the acquisition of rights to the results of intellectual activity from residents of "unfriendly" countries. Such transactions will be made on the basis of a permit issued by the Government Commission for Control over Foreign Investments in the Russian Federation.

DECREE OF THE PRESIDENT OF RUSSIA NO. 442 OF 23.05.2024

Russian holder of rights to property represented by the state or the Central Bank, in the event of confiscation of this property in the United States, has the right to apply to the court with a request to establish the fact of "unjustified deprivation of his rights to property" in the United States. If the court agrees with the application, it requests a list of US property in Russia from the government Commission for the Control of Foreign Investments.

ORDER OF THE MINISTRY OF INTERNAL AFFAIRS OF RUSSIA NO. 288 OF 24.05.2024

The Ministry of Internal Affairs has updated the rules for the dactyloscopic registration of foreigners. From 23 June 2024, a new procedure for the fingerprint registration and photographing of migrant workers and foreigners coming to Russia for other purposes for a period of more than 90 days has been in force. Foreigners will be able to undergo it outside Russia if the relevant state is included in the list approved by the Russian Government.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 750 OF 01.06.2024

A pilot EPR mechanism is in place for importers of goods and packaging until 2026. The importer participating in the experiment, until the day of release of goods and packaging by customs to the domestic market, must: pay the ecofee; submit a notification of intention to dispose of waste from the use of goods independently with the attachment of a bank guarantee to EFGIS EOIT; submit a notification of intention to dispose of waste from the use of goods independently with the attachment of a guarantee agreement concluded with a disposer from the register.

DECREE OF THE PRESIDENT OF RUSSIA NO. 500 OF 13.06.2024

State bodies and strategic companies will be prohibited from using cyber security services from "unfriendly" countries. The document prohibited government agencies, state corporations and critical information infrastructure entities from using protection systems from "unfriendly" countries from 1 January 2025. The new Decree extends the ban to cybersecurity services (work or services) provided by companies from such countries.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 896 OF 29.06.2024

Decree on digital passports of industrial products. Digital passports will be formed in the State Information System of Industry and will ensure the improvement of the product cataloguing system. Passport data will be published in the public domain on the Internet.

ORDER OF THE GOVERNMENT OF RUSSIA NO. 1765-R OF 04.07.2024

The Government of the Russian Federation has updated the list of labelled goods. The updated list divides labelled goods into food and non-food products. The list includes products in respect of which mandatory labelling will be introduced from 1 September 2024. It concerns non-alcoholic beer, canned food, edible vegetable oils, certain types of rehabilitation equipment, bicycles, pet food and veterinary medicines.

FEDERAL LAW NO. 174-FZ OF 08.07.2024

From 1 March 2025, OSAGO will be excluded from the list of documents for registering a car. From the beginning of March, the insurance policy (OSAGO) will disappear from the list of documents that the registration authority may request from the car owner in the case of putting the vehicle on state registration or registration actions in the event of a change of ownership.

FEDERAL LAW NO. 176-FZ OF 12.07.2024

The Law provides for five steps in the personal income tax rate scale. The minimum rate is 13% for income up to 2.4 million roubles. Then come the rates of 15% and 18% for income up to RUR 5m and RUR 20m per year respectively. For income up to 50 million roubles a rate of 20% is set. The maximum rate is 22%, which is applied to income over 50 million roubles. In addition, according to the document, the profit tax for companies that apply the general rate will increase by 5% – it will reach 25%.

GOVERNMENT DECREE NO. 1041 OF 01.08.2024

The government approved new ecological levy rates for 2025-2027. The increase in rates will take place in the

following format: in 2025 by 15% in relation to 2024; in 2026 by 8% in relation to 2025; in 2027 by 4% in relation to 2026.

FEDERAL LAW NO. 229-FZ OF 08.08.2024

Russia ratified a protocol on the regulation of electronic commerce in the EAEU. With respect to goods delivered to an individual directly from the seller, customs duties are paid at a single rate determined by the EEC for all EAEU member states, and from bonded warehouse – at the rates established by the EAEU's unified customs tariff.

FEDERAL LAW NO. 260-FZ OF 08.08.2024

A new regime for the expulsion of migrants and the introduction of a register of controlled persons. It is assumed that the register will be set up by the Ministry of Digital Development of Russia and the operator will be the Ministry of Internal Affairs of Russia. The register will include migrants illegally staying (residing) in Russia. They will be subject to the expulsion regime and bans. It is assumed that the expulsion regime will prohibit them to change their place of residence or place of stay in the Russian Federation without the permission of the Ministry of Internal Affairs, to travel outside the region established for their stay, to obtain a driver's licence, to acquire property and transport, to register as an individual entrepreneur, to take a loan, to open bank accounts and transfer money, as well as to marry.

FEDERAL LAW NO. 287-FZ OF 08.08.2024

The amendments determine the mechanism for interaction between a JSC and shareholders who have not exercised their corporate rights for a long period of time and in respect of whom the company does not have up-to-date information. Company has the right to suspend the sending of notices of general meetings and the payment of dividends to such shareholders.

FEDERAL LAW NO. 318-FZ OF 08.08.2024

'Foreign' goods, works, and services shall be provided with equal conditions for participation in procurement with goods, works, and services of Russian origin, except in cases where the Russian Government takes measures establishing: prohibition of procurement of 'foreign' goods, works, services; restriction of purchases of 'foreign' goods, works, and services (the 'second is a crowd' mechanism is applied); advantage in respect of Russian goods, works and services (provided by reducing by 15% the price offer submitted by a 'Russian' participant, including those offering domestic goods for delivery).

ORDER OF THE GOVERNMENT OF RUSSIA NO. 2330-R OF 28.08.2024

A list of types of products, in the production of which it is necessary to use secondary raw materials, was approved. The list includes various types of cement, polyethylene products, rubber crumb coatings, rubber tiles, crates and boxes made of corrugated paper or cardboard, wood fuel briquettes, and chemical ameliorants, among others. For each type of product, the minimum proportion of recyclable materials to be used in production is specified.

GOVERNMENT DECREE NO. 1196 OF 31.08.2024

Until 1 September 2025, the simplified procedure for confirming the conformity of products to the requirements of technical regulations, as well as national and interstate standards when importing them from abroad or putting them into circulation on the territory of the country is extended. Producers and exporters have six months to confirm the conformity of goods with the requirements of the EAEU technical regulations or the requirements of Russian legislation in the area of technical regulation after submitting a declaration under the simplified scheme and putting the products on the market.

GOVERNMENT DECREE NO. 1255 OF 13.09.2024

A long-term indexation scale of the disposal fee until 2030 has been approved for cars, light commercial vehicles, trucks, buses, trailers and semi-trailers, as well as for certain types of road construction equipment. The disposal fee for motor vehicles and trailers will be indexed from 1 October 2024 – at the first stage the rate will increase by 70-85% on average, and thereafter it will be indexed by 10-20% from 1 January of each subsequent year.

ORDER OF THE MINISTRY OF INDUSTRY AND TRADE NO. 4611 OF 08.10.2024

Amendments to the List approved by Order No. 2701 of the Ministry of Industry and Trade of Russia dated 21 July 2023 (the list of goods subject to parallel imports) have been published. In particular, some goods under KIA and Hyundai brands (pipes, tubes, hoses made of plastics, glass mirrors, including rear view mirrors, screws, bolts, nuts made of ferrous metals and a number of other goods) were excluded from the list. The order will come into force on 8 May 2025.

ORDER OF THE GOVERNMENT OF RUSSIA NO. 2839-R OF 14.10.2024

The government has approved the quota for temporary residence of foreigners in the Russian Federation in the amount

of 5.5 thousand permits in 2025. Compared to 2024, when the quota was 10,595, it has been almost halved. Moscow and the Moscow region traditionally receive the largest number of permits – 1,000 and 350 respectively in 2025 (1,500 and 750 in 2024). The quota for St. Petersburg will be reduced from 300 to 200 permits.

FEDERAL LAW NO. 362-FZ OF 29.10.2024

Law providing for changes in the payment of certain taxes, excise duties, state duties and insurance contributions. The document, initiated by the Russian government, amends the Tax Code of the Russian Federation and is part of the 'budget package', which was submitted to the State Duma simultaneously with the draft federal budget for 2025-2027. The document doubles the state duty for state registration of a property lease agreement. At the same time, the Law establishes the fee for state cadastral registration and state registration of rights to an enterprise as a property complex, as well as for state registration of the transfer of rights to it, transactions with restriction of rights and encumbrances.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1471 OF 01.11.2024

The Government has extended until the end of 2027 the experiment for the reimbursement of VAT to foreign nationals when exporting goods purchased in Russia. The Tax Code of the Russian Federation allows foreign citizens to reclaim VAT when exporting goods purchased in Russia outside the EAEU. The tax refund system applies to goods, including appliances, food, clothing, jewelry, books, medicines, purchased within one day for an amount not less than 10,000 roubles.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1510 OF 07.11.2024

An experiment on submitting biometric data by foreigners entering Russia will start on December 1, 2024. At the first stage, foreigners entering through the international airports of Moscow and the Moscow region, as well as through the automobile checkpoint in the Orenburg region (Mastakovo), will submit biometric data (photos and fingerprints) at checkpoints. At the second stage, from June 30, 2025, foreigners entering visa-free through any checkpoint will submit biometric data in advance through the EBS mobile application and submit an application with their data and information about the purpose of the visit through the State Services application.

FEDERAL LAW NO. 377-FZ OF 09.11.2024

A complete ban has been established for intermediaries to take part in organizing and taking exams for migrants.

FEDERAL LAW NO. 383-FZ OF 09.11.2024

According to the initiative, the organization of illegal migration by an organized group or for the purpose of committing grave or especially grave crimes is considered a particularly serious crime. Measures of increased liability have also been established for forging or trafficking in forged documents and for offences related to the fictitious registration and registration of foreign nationals.

FEDERAL LAW NO. 384-FZ OF 09.11.2024

A circumstance aggravating the punishment was recognized as committing a crime by a person illegally staying on the territory of Russia.

DECREE OF THE PRESIDENT OF RUSSIA NO. 978 OF 14.11.2024

The authorities have extended restrictions on contributions by Russian residents to the authorized capital of non-resident companies until 31 December 2025. These acts prohibit two types of transactions without the prior consent of the Central Bank: payment by a resident of a share, contribution, unit in the property (authorized or share capital, share fund of a cooperative) of a non-resident company; contribution by a resident to a non-resident within the framework of a simple partnership agreement with investment in the form of capital investments (joint activity agreement).

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1612 OF 23.11.2024

The Russian government has expanded the list of goods for price stabilization agreements. Regional authorities have been allowed to conclude price stabilization agreements with manufacturers and retail chains for any goods important to Russians. Previously, this was only possible for socially important food products (bread, milk, eggs, meat, oil, sugar, etc.). The agreements under consideration should contain, among other things, ways to stabilize prices for goods on the domestic market. These include their reduction, non-increase and introduction of maximum (marginal) trade mark-ups (surcharges).

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1638 OF 28.11.2024

The federal investment deduction from 1 January 2025 will be available to organizations investing funds received in the development of their production. The amount of the deduction will be 3%. Companies and organizations engaged in the extraction of minerals, as well as companies working in

the field of manufacturing industries will be able to reduce income tax by this amount. The only exception will be producers of food, beverages and tobacco products.

FEDERAL LAWS NOS. 420-FZ AND 421-FZ OF 30.11.2024

The Laws toughen administrative and criminal liability for personal data leakage. The administrative liability for the actions/inaction of an operator resulting in the leakage of personal data will be multiplied. The penalty will directly depend on the volume of leakage: for legal entities it will be from 5 to 15 million roubles. In case of repeated leakage, the company will have to pay a negotiable fine: from 1 to 3% of its last year's turnover. The toughest sanctions are provided for biometric data leaks. In case of repeated violation, the turnover penalty will be up to 25 million to 0.5 billion roubles.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 2240 OF 07.12.2022

The Decree extends until the end of 2025 increased duties on certain goods from "unfriendly" states. This applies, in particular, to perfumes and cosmetics, alcohol and sweets, batteries and building materials, weapons and certain other products. The extension of the measure is due to the continuation of sanctions by "unfriendly" countries against Russia, as well as support for domestic production.

PRESIDENTIAL DECREE NO. 1046 OF 09.12.2024

A temporary procedure that allows some Russian companies to disregard the votes of co-owners from "unfriendly" countries has been extended until the end of 2025. The temporary decision-making procedure applies to companies that simultaneously fulfil the following conditions: operate in the field of energy (including electric power), machine building or trade; foreign sanctions or restrictions have been imposed on the controlling person or beneficial owner; persons from "unfriendly" countries own no more than 50% of the authorized capital of a Russian company; the volume of revenue for the year preceding the year of the decision exceeds 100 billion roubles.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1772 OF 13.12.2024

The Decree adds the powers of a Subcommission of the Government Commission for Control over Investment in the Russian Federation with regard to the issuance of permits for the payment of dividends, as well as loans and credits in favour of persons of "unfriendly" states. The Subcommission's authorization may specify special conditions for the payment of loans or dividends, including deadlines for the fulfilment of such obligations. At the same time, the amendments also formalize some of the requirements for such applications, which were previously regulated by extracts from protocol decisions of the Subcommission.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1901 OF 26.12.2024

From 1 January 2025, companies using recyclable materials for the production of goods or packaging for goods will receive a discount when paying an ecological fee. A special reduction coefficient is introduced for this purpose. Indicators are established for companies to be eligible for compensation when paying the ecological fee.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1989 OF 30.12.2024

The government has increased customs duties on a number of goods imported from "unfriendly" countries. The scope of the already introduced increased duties on perfumes and cosmetics from "unfriendly" countries is expanded. Increased duties are introduced on certain types of meat and fish products, canned finished products of vegetables, fruits and nuts, confectionery and flour products, sauces, soft drinks.

DECREE OF THE GOVERNMENT OF RUSSIA NO. 1990 OF 30.12.2024

The rules for the collection of an ecological fee have been updated. The fee is calculated by producers and importers of goods who do not themselves utilize waste from the use of goods and packaging. A disposer shall be charged a fee if it: has not disposed of waste from the use of goods in the mass of goods specified in contracts with the producer or importer of goods or acts; recycled waste in violation of the Law on Production and Consumption Waste. The rules are valid until 1 January 2031.

ANNEX 2.

AEB COMMITTEES AND WORKING GROUPS

INDUSTRIAL COMMITTEES

AGRIBUSINESS COMMITTEE

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AIRLINES COMMITTEE

COMMITTEE PAGE >>

AUTOMOBILE MANUFACTURERS COMMITTEE

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BANKING COMMITTEE

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CONSTRUCTION EQUIPMENT COMMITTEE

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CONSTRUCTION INDUSTRY & BUILDING MATERIAL SUPPLIERS COMMITTEE

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CROP PROTECTION COMMITTEE

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ENERGY COMMITTEE

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FOOD PROCESSING COMMITTEE

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HEALTH & PHARMACEUTICALS COMMITTEE

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HOME APPLIANCES MANUFACTURERS COMMITTEE

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MACHINE BUILDING & ENGINEERING COMMITTEE

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RETAIL TRADE COMMITTEE

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SEED COMMITTEE

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CROSS-SECTORAL COMMITTEES

COMPLIANCE & ETHICS COMMITTEE

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INTELLECTUAL PROPERTY COMMITTEE

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CUSTOMS & TRANSPORT COMMITTEE

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PRODUCT CONFORMITY ASSESSMENT COMMITTEE

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REAL ESTATE COMMITTEE

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SUSTAINABILITY COMMITTEE

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SAFETY, HEALTH, ENVIRONMENT & SECURITY COMMITTEE

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TAXATION COMMITTEE

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WORKING GROUPS

HEATING SYSTEMS MANUFACTURERS WORKING GROUP

WORKING GROUP PAGE >>

NON-FOOD FMCG WORKING GROUP

WORKING GROUP PAGE >>

TOBACCO PRODUCTS WORKING GROUP

WORKING GROUP PAGE >>

WORKING GROUP ON LABELING AND TRACK & TRACE SYSTEM

WORKING GROUP PAGE >>

WORKING GROUP ON PARALLEL IMPORTS

WORKING GROUP PAGE >>

WORKING GROUP ON THE REGULATION OF CHEMICAL PRODUCTS

WORKING GROUP PAGE >>

WORKING GROUP ON WASTE MANAGEMENT

WORKING GROUP PAGE >>

REGIONAL COMMITTEES

NORTH-WESTERN REGIONAL COMMITTEE

COMMITTEE PAGE

SOUTHERN REGIONAL COMMITTEE

COMMITTEE PAGE