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EUROPEAN BUSINESS IN RUSSIA: POSITION PAPER 2022

KEY ISSUES

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Dear readers,

It is with great pleasure that we are introducing you to the "European Business in Russia: Position Paper 2022 — Key Issues". In this book we have accumulated views of experts from AEB member companies on the most profound issues which the Association efficiently addressed in 2021.

To be more specific, articles submitted for this edition cover a diverse range of topics: AEB activities on the green agenda; Russian legislative initiatives on the extended producer responsibility; measures to revive international business interactions amid the pandemic; changes in migration procedures for highly qualified specialists; issues of production localization in Russia; current aspects of taxation and customs valuation; novelties in digital technologies and personal data; development of the labeling system; study of the antimonopoly regulation cases; consumer protection rights issues; positions with regard to the "two is a crowd" rule; problems of parallel imports legalization and discussion on dual quality; recommendations for product conformity assessment during the pandemic.

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We hope that the publication will be of help to a broad audience: government officials, foreign investors operating in Russia, companies potentially interested in joining the AEB. Enjoy your reading!

Contents

AEB "GREEN INITIATIVE": MAJOR WORKSTREAMS

SUSTAINABLE DEVELOPMENT AND CLIMATE GOALS

Climate change is becoming a determining factor in foreign economic collaboration between countries over the long-term. Today, governments and companies are looking for new approaches to solve, on the one hand, climate issues, and on the other, to preserve their economic competitiveness.

According to the World Bank, more than 64 countries have currently implemented or plan to implement CO_2 reduction initiatives (including ETS or carbon tax) worldwide and their number is growing every day.

On July 14, the EU presented a comprehensive EU Green Deal (formerly "Fit for 55"), which aims to reduce emissions by 55%, to 1990 levels by 2030. The plan will be discussed and probably modified, but it will radically change all areas of the EU economy and influence collaboration with the EU's main commercial partners, including Russia.

2021 marks 5 years since the Paris Agreement came into force. During this time, we saw how the world community, countries, and international companies have rapidly changed their attitude towards the issues of combating climate change and reducing the level of greenhouse gas emissions. The global climate agenda has a great impact on all sectors of the economy.

Limiting global warming to below 1.5–2 degrees Celsius, comparable to pre-industrial levels, became our common responsibility. According to the International Energy Agency (IEA), to reach net zero emissions by 2050, the world needs technologies, 40% of which do not exist now. That is why our states and companies must create special technological alliances.

To share the best European practices in sustainable development and the green economy and to promote strong collaborative relations between European and Russian companies, in 2020, AEB decided to create a Steering Committee on the Green Initiative (SC). We have divided the activity of the SC into three workstreams that allows us to cover the most important issues:

- green finance;
- carbon management;
- future of energy.

Within the activity of all workstreams, we brought together stakeholders in the European and Russian green economy to discuss the most beneficial forms of collaboration. Together, governments, businesses, banks, professional societies and universities should build a strong sustainable economy capable of facing new climate challenges. According to the IEA, to be ready to achieve carbon neutrality by 2050, we should triple annual clean energy investment globally by 2030 to around USD 4 trillion.

We will be developing and using new green financial instruments more frequently. Companies can count on long-term cheap money for transformation and modernization. Growth in energy efficiency will help to increase the competitive advantage of business.

GREEN FINANCE

Successful implementation of ecological projects aiming to significantly reduce GHG emissions depends to a large extent on their financial and commercial feasibility. The state will play an important role through both direct subsidies to innovative projects and advantageous financing provided by national and intergovernmental development banks.

AEB welcomes the fact that the Russian government is offering financial resources for climate protection mitigation, for example, as part of the national project Ecology, worth 4 trillion roubles.

It would be further welcomed to set binding quantitative and qualitative milestones as to when and to what extent the long-term goal of GHG neutrality is to be achieved. Ambitious goals could be implemented by means of a roadmap that includes specific projects such as the development of a hydrogen economy, which have already been announced.

Governmental and semi-governmental support measures to mitigate climate change must always be accompanied by market-driven financing solutions. This requires the development of a strong capital market for "green" bonds, performance-linked loans, impact funds and other financial products that refer to so-called "ESG" standards: environment, social, and governance. In this context, the government's approvement of the 1587 decree ("Taxonomy on Green Finance") on September 22, 2021, is a very important step and highly appreciated by the European business community in Russia.

As the experience from marketplaces outside of Russia shows, a stringent verification of green financial projects is of utmost importance in maintaining trust in the architecture of the financial market and increasing the liquidity for green financial projects. Transparency and stringency should be demanded from the Russian central bank in its efforts to set up an accreditation and verification system. AEB stands ready to provide expertise.

The sustainable bond market is expected to grow by 32% in 2021 as per forecasts from Moody's. The previous year saw a stable issuance value of USD 270 billion. With a 60% average growth since 2015, the green debt capital market hit the landmark of a cumulative 1 trillion dollars issued by December 2020. Given that Russia ranks as the No. 11 largest country per GDP in the world, a Top-30 position as a market for green finance would be desirable. The Moscow Stock exchange is actively promoting the issuance of green bonds. However, liquidity is yet lacking.

Any increase in liquidity for green financing in the Moscow financial center requires trust. AEB is committed to informing international investors about green finance activities in the Moscow financial center. In addition, cooperation with other financial centers is recommended to channel capital from the euro, dollar, and yuan area to Moscow. From a regulatory point of view, it is important here that the standards of the capital market and the underlying taxonomies are harmonized with those of large non-Russian capital markets.

The experience of one of the EU's financial centers, in Luxembourg, which is the leading green finance center, shows that the demand for green financial products exceeds supply, so that issuers sometimes bear lower coupon costs for bonds than in the case of traditional securities. This opens the possibility for Russian companies to place euro-based green bonds cheaply in EU financial centers.

AEB advocates a partnership between Russian and European financial centers so that companies can issue bonds in multiple currencies for the same green project with the same standards. The banks among the AEB members are ready to get involved.

Sanctions imposed by the European Union since 2014 against Russia caused all activities of European development banks, such as the EBRD or the EIB, to cease. Until 2014, these banks had played a positive role for Russia, for example, in financing energy efficiency projects.

In connection with the EU's Green Deal, they should be allowed to continue co-financing climate protection projects, including those in Russia. After all, the Green Deal is not a purely EU project. Rather, through measures such as the planned Carbon Border Adjustment Mechanism (CBAM), to take effect from 2023 at the latest, affects large countries such as Russia that trade with EU states. Thus, the EU's climate protection policy takes on an external economic dimension.

The AEB advocates that the EU, within the framework of a foreign trade policy in connection with the Green Deal, reduces sanctions, at least to the extent that development banks of the EU and its member states can continue to finance green projects in Russia.

CARBON MANAGEMENT

Russia — EU interaction in the frameworks of SDG UN implementation, joint projects as well as experience exchange between European and Russian companies contribute to the formation of an ecologically-sustainable future for our planet and to the process of decarbonization.

Russia ranks 4th in the world in terms of carbon dioxide emissions and, in this regard, the problem of forming a common business approach for a smooth transition to the decarbonization of the economy represents a pressing issue and poses a challenge for the Russian Federation, which requires a significant improvement in its network of power supply infrastructure.

Achieving the goal of reducing greenhouse gas emissions involves the introduction of new legislative mechanisms on the climate. Thus, the European Commission has introduced the CBAM — Carbon Border Adjustment Mechanism, which presupposes charging for the carbon footprint of imported products. Such an initiative carries risks for Russia, significant exports from which to the EU may be affected by the new carbon regulation.

Also, in the Russian Federation, green legislation is at the stage of formation, in accordance with its commitment to reduce greenhouse gas emissions, as a part of the implementation of the Paris Climate Agreement. Summer saw the adoption of Federal Law No. 296-FZ dated July 2, 2021 "On limiting greenhouse gas emissions", which is the fundamental document for launching a carbon regulation system.

The law establishes:

- the introduction of the concept of a "carbon unit" as an object of law;
- the possibility of implementing climate projects;
- the introduction of mandatory reporting for enterprises.

A number of other documents were also approved in connection with the climate agenda:

- "The concept for the development of electric transport up to 2030", which will be implemented in two stages: from 2021 to 2024 and from 2025 to 2030;
- "The concept for the development of hydrogen energy", aimed at increasing production and expanding the scope of the use of hydrogen as an environmentally friendly energy carrier.

The Ministry of Economic Development of the Russian Federation is developing a "Strategy for the long-term development of the Russian Federation with low greenhouse gas emissions up to 2050", which will contribute to the formation of an integrated observation system for estimating CO_2 emissions.

AEB is in favor of finding a balanced approach in the interaction of business and government and approves the concept of the carbon regulation initiative. The Committee is ready to actively share the best practices of the European companies operating in the Russian Federation on adaptation to European climate initiatives.

In order to develop effective tools and incentives for decarbonization the Workstream is ready to take all necessary actions such as:

- interacting with the regulator at the early stages of law formation;
- creating occasions for discussion, such as events and forums, to exchange best practices and define ways to decarbonize the economy with the involvement of "hard-to-abate" sectors and the energy sector;
- to promote financial initiatives that stimulate R&D and investment activities on projects aimed at decarbonization.

FUTURE OF ENERGY

Renewable energy plays an important role in decarbonization within the global energy agenda. In Russia, 2021 has already become a defining year in terms of the formation of new trends in the long-term development of green energy. A new national program for the development of renewable energy for the period 2025-2035 has been approved, which sets new goals for the development of green generation and forms mechanisms for their achievement.

In addition, the results of the country's latest renewable energy tender, which took place in September 2021, set a new vector for the development and assessment of the cost of electricity produced from wind and solar generation.

In particular, prices for wind projects fell to record levels, by up to 70% of the limit values set by the Government of the Russian Federation. In turn, prices for solar generation fell by up to 60% below the limit values.

Certainly, in the medium term, there will be more understanding about the sustainability and viability of the new price parameters. However, in any case, there are new investment signals and price targets, confirming the importance and relevance of the development of green energy and its applicability in creating a low-carbon economy.

More and more companies from various industries are paying special attention to the implementation of strategies for sustainable development and are interested in reducing their carbon footprint along the entire value chain of their products and services. Green energy is a necessary tool for realizing these goals.

Further development of renewable energy sources and low-carbon technologies, taking government support measures into account, are important for creating and developing a low-carbon economy.

Taking the special role of renewables into account when approving the national low-carbon development strategy will help to achieve significant results in the foreseeable future.

Another promising area is the creation of conditions for growth in the low-carbon economy by using hydrogen technologies. Russia has significant natural resources potential for the development of hydrogen energy. Hydrogen technologies can be seen as an additional element in achieving the goal of reducing GHG emissions and reducing the carbon footprint in the value chain of manufacturing companies.

In the near future, it is expected that a regulatory legal framework will be adopted, streamlining the mechanisms for the development of the hydrogen economy. A special role in this process should be assigned to the creation of conditions for the production and consumption of the so-called "green hydrogen", produced from electricity generated by renewables.

REFORM OF THE EXTENDED PRODUCER RESPONSIBILITY INSTITUTION IN RUSSIA

Over the past year, the Concept for Improving the Institution of Extended Responsibility of Product and Packaging Manufacturers and Importers No. 12888p-P1 dated December 28, 2020, approved by Deputy Chairman of the Government of the Russian Federation V. V. Abramchenko (hereinafter referred to as the "EPR Concept"), has been actively implemented. The most significant measures included the Draft Federal Law "On Introducing Amendments to the Federal Law on Production and Consumption Wastes and Article 8 of the Federal Law on the Principles of State Regulation of Trade Activities in the Russian Federation" and related by-laws, developed by the Ministry of Natural Resources of Russia.

It is worth mentioning that the purpose of the EPR mechanism is to reduce the amount of waste reaching landfills (by 50% by 2030), to increase the amount of recycled waste and recycled materials involved in the economic turnover. To do this, it seems necessary to set country-wide targets for the disposal of product waste and to introduce waste sorting since otherwise, it is impossible to extract packaging waste from municipal solid waste (MSW) without sorting (~ 40% of MSW) and recycling them, as well as providing for incentive mechanisms to increase the use of recyclable materials in packaging and goods. The current regulation does not allow such goals to be achieved, since no persons have been made responsible for achieving country-wide targets for waste disposal and sorting. The lack of any targets for product waste disposal and waste sorting for constituent territories of the Russian Federation, municipalities, and regional operators hampers the establishment of waste sorting. There is no legal and/or economic incentives for the population to sort waste. The population does not have access to the relevant infrastructure and is not motivated to sort waste. The more funding regional operators receive, the greater the volume of MSW they remove from the site (remuneration per volume), so there is practically no waste sorting in Russia.

In addition, the amendments to the legislation proposed by the Ministry of Natural Resources of Russia impose a prohibition on the sale of goods, for which no information is available in the Unified State Information System for Accounting Product Waste (EGIS UOIT). In practice, such a prohibition can destroy the existing system of product circulation in Russia, since the mechanics of its application are ambiguous, no estimates have been provided for the costs of its creation, no alternative solutions have been analyzed to use the existing product labeling and traceability systems.

In addition, creating another state information system containing information about the entire range of products sold in the market will require huge costs, and the system itself will mirror the functionality of existing systems.

AEB member companies have repeatedly drawn attention to the fact that the draft regulations provide for independent implementation of the EPR principle, with a priori unrealizable recycling targets being set for packaging — 100%. Additionally, it is envisaged to apply a double coefficient to all the entities falling within the regulation — a twofold difference between the disposal target and the volume of waste disposal reached — in the event of a failure to reach the disposal targets. Such a requirement means that, for packaging, given 100% disposal targets, the costs can reach 200% of the volume of the released packaging.

Increasing coefficients are also envisaged when calculating the rate of the environmental fee for using packaging that is "hard to dispose of", which can increase the environmental fee by another 5 times, that is, by 500%. At the same time, the method of introducing such increasing coefficients does not rely on any calculation or practical justification.

As a result, the increase in the size of the environmental fee for packaging will rise to 1,000% of the basic rates of the environmental fee, which will undoubtedly have a negative impact on the cost of products.

In the opinion of businesses, the above-mentioned circumstances are critical, therefore it is important to abandon the use of a double coefficient and other increasing coefficients to the disposal target in the event of a failure to achieve the disposal targets. This would be more reasonable to be done gradually, rather than immediately increasing the disposal target for packaging by no more than 10% per year. In order to motivate the independent implementation of the EPR, for those who implement it independently, it would be advisable to establish a 35% disposal target for packaging, and 100% for payers.

In addition, the problem is exacerbated by the exclusion from the draft regulations of a provision stipulating the application of a decreasing coefficient to the scope of liability for the entities when using packaging containing secondary raw materials. At the same time, the EPR Concept directly determines the need to establish incentives to increase the use of recyclable materials for the production of products and return of packaging waste into circulation. To do this, an entity falling within the EPR shall have an economic interest in purchasing and using packaging with an increased share of recyclable materials for the production of its products.

The EPR Concept determines that the waste, the disposal of which shall be ensured within the EPR, is mainly generated by the population. Therefore, the EPR shall not include any packaging, which, in the process of moving along the distribution chain, remains and is collected by legal entities and/or self-employed entrepreneurs, is not product waste, but is disposed of as waste from their activities (production) in accordance with the applicable law. Such packaging is converted by the owner into secondary materials or sold for further disposal.

Extension of the EPR to such packaging will lead to an unjustified increase in the manufacturer's costs without a positive effect on the development of the packaging waste recycling system.

To resolve the situation, it seems appropriate to enable product manufacturers (importers) using such packaging to identify it upon declaration in accordance with GOST 17527-2020 "Packaging. Terms and Definitions" as "industrial packaging" — packaging intended to pack raw materials, semi-finished parts, or finished products, intended for delivery from the manufacturer to the consumer and/or other intermediaries such as processing or assembly plants, which also complies with international standard ISO 21067-1: 2016 "Packaging — Vocabulary — Part 1: General terms", and exempt product manufacturers (importers) using industrial packaging from the obligation to dispose of it or to pay the environmental fee, provided that the disposal of the industrial packaging is confirmed by the buyers.

To simplify administration, it is required to separate certain subcategories in Classifier OK 034-2014 (KPES 2008) "All-Russian Classifier of Products by Economic Activity (OKPD 2)" for industrial packaging.

The AEB has been actively collaborating with the authorities and other associations to ensure a continuous dialogue and consideration of the position of the industry when introducing amendments to the legislation on waste disposal.

The EPR Concept directly determines the need to establish incentives to increase the use of recyclable materials for the production of products and return of packaging waste into circulation.

MEASURES TO REVIVE INTERNATIONAL BUSINESS ACTIVITIES AMID THE COVID-19 PANDEMIC

The international business community, represented by European associations and chambers of commerce working in Russia, is concerned about the situation related to the COVID-19 pandemic.

The AEB, like other business associations, advocates the need to resolve the issue of mutual recognition of vaccination against the novel coronavirus with all the vaccines available to citizens of the Russian Federation and EU countries, as well as the relevant supporting documents.

Ensuring the free and safe trans-border movement of business representatives is vital in maintaining business activity between Russia and the European Union, which are mutual key trade and economic partners.

Mutual quarantine restrictions for entrants cause particular damage to export-oriented businesses, creating obstacles to the fulfillment of contractual obligations to customers and suppliers, timely implementation of joint projects, and the conclusion of new transactions. The business also incurs significant costs to administer the process of issuing permits for the limited number of work and business trips conducted by certain categories of individuals (senior managers and technicians).

The crisis in the interaction between Russia and the European Union in terms of business communication and movement of labor resources may be confirmed by the following figures:

- in 2020, foreign citizens were issued 62,686 work permits in the Russian Federation, which is more than 2 times less than in 2019;[1]
- among these, in 2020, foreign qualified and highly qualified specialists were issued 28,137 work permits, which is 1.85 times less than in 2019;[2]
- the need for foreign specialists was determined to be 104,993 people in 2020;[3]
- the number of migration registrations of EU citizens entering the Russian Federation for the purpose of "work" in 2020 was 52,246, which is almost 2 times less than in 2019.[4]

International cooperation is a prerequisite for an effective response to today's global challenges, which include the novel coronavirus pandemic.

[1] According to the Ministry of Internal Affairs of the Russian Federation: https://xn--b1aew.xn--p1ai/Deljatelnost/statistics/migracionnaya/item/22689548/

[2] Ibid.

[3] Decree of the Government of the Russian Federation No. 1579 dated December 3, 2019 "On determining the need to attract foreign workers arriving in the Russian Federation with a visa, including those among priority professional and qualification groups, and on approving quotas for 2020"

[4] According to the Ministry of Internal Affairs of the Russian Federation: https://xn--b1aew.xn--p1ai/Deljatelnost/statistics/migracionnaya/item/19365693; https://xn--b1aew.xn--p1ai/Deljatelnost/statistics/migracionnaya/item/22689602

According to the European business community, initiation of a constructive negotiation process between the European Commission and the Government of the Russian Federation on the issue of mutual recognition of all the vaccines against the new coronavirus infection available to the citizens of the Russian Federation and EU countries, and the relevant supporting documents, is an important step towards economic recovery and adaptation to the new conditions of interaction.

The unavailability of certain vaccines in the Russian Federation or in the European Union must not restrict the freedom of an individual's movement or become an obstacle to the exercise of one's labor functions. The process of approving the Russian Sputnik V vaccine for use in the EU has not yet been completed. The issue of registering foreign vaccines in Russia falls within the commercial interests of the relevant companies. Everyone should be provided a free and inalienable choice of any available vaccine. Not all EU citizens working and living in Russia are eligible to receive the COVID-19 vaccine in their home country. A citizen vaccinated with any vaccine available expresses his/her care for his/her personal health and contributes to the protection of others and the formation of collective immunity. Under such conditions, those vaccines that are registered and approved for use in Russian Federation should be recognized in the EU countries as conferring the right to enter the EU without the need to comply with quarantine measures. Likewise, those vaccines approved for use by the European Medicines Agency should be recognized in Russia for persons entering the Russian territory.

Undoubtedly, any business interested in normalizing business activities is ready to take measures to organize vaccination for its employees, thereby contributing to the achievement of the goals set by the Government of the Russian Federation and the governments of the EU member states to achieve the level of vaccination coverage required to ensure collective immunity.

In addition to the issue of vaccine recognition, the issue of lifting quarantine requirements for foreign specialists arriving in Russia for work purposes has been in the focus of the AEB member companies for a long time, in particular with respect to highly qualified specialists.

According to the information posted on the official website of the Russian Federal State Agency for Health and Consumer Rights (Rospotrebnadzor) on October 19, 2021,[5] the 14-day isolation provided for by Decree of the Russia's Chief Public Health Officer No. 9 dated March 30, 2020 "On additional measures to prevent the spread of COVID-2019" applies only to foreign citizens arriving in the territory of the Russian Federation for work purposes *within organized groups* involved in labor activities in accordance with the algorithm of attracting foreign citizens to the economy of the Russian Federation.

In addition, a *differentiated approach* to the isolation period of foreign citizens arriving in the Russian Federation for work purposes is provided. In accordance with such an approach, when attracting foreign citizens to work, biological material is collected from workers and is tested for COVID-19 by the polymerase chain reaction method or EIA and LFIA methods for the presence of IgG and IgM.

After that, *"other categories of foreign citizens arriving in the Russian Federation for work purposes"* are distinguished, for whom *only a medical document (in Russian or English)* is required confirming a negative result of a PCR laboratory test for COVID-19.

At the same time, no relevant changes have been made to the corresponding decrees of Russia's Chief Public Health Officer.

Despite the positive trend in our requirement to lift quarantine measures over the past year, it seems important to introduce the necessary amendments to the current sanitary requirements in order to completely resolve this issue.

Such steps are neutral as to the level of epidemiological security of the population, but can greatly facilitate the conditions for doing business for European and Russian economic entities, meet the economic need for qualified human resources, and in the long term, contribute to the recovery of certain economic sectors most affected by the economic downturn as a result of the global COVID-19 pandemic.

Any business interested in normalizing business activities is ready to take measures to organize vaccination for its employees.

[5] https://www.rospotrebnadzor.ru/about/info/news/news_details.php?ELEMENT_ID=19447

CURRENT MIGRATION ISSUES

For more than two years now, special attention has been paid to the application of migration legislation, the requirements of which have changed as often as the epidemiological situation in Russia and around the world has changed.

The Operational Headquarters under the Government of the Russian Federation has developed a number of measures that allow foreign citizens — highly qualified and technical specialists — to enter Russia for work purposes despite the restrictions imposed. In this regard, the AEB has done a great job at returning foreign highly-qualified specialists to the Russian Federation, communicating directly with the Government and the ministries involved. With the assistance of the Association of European Businesses, over 2,000 highly qualified specialists, as well as their family members, have been able to return to Russia and continue their professional activities here.

It shall be noted that a gradual weakening of requirements and a partial removal of restrictions have been seen regarding the entry of foreign citizens into the Russian Federation, which is confirmed by the expanding list of countries included in Appendix 1 to Order of the Government of the Russian Federation No. 635-r dated March 16, 2020.

In the context of such changes dictated by the situation related to the spread of COVID-19, the new legislation on migration is being developed, which will enter into force in 2024 and which completely amends the current migration procedures, introducing new legal instruments to control and improve migration processes.

Of the most important changes, the following are worth mentioning:

- There is no category of highly qualified specialist, that is, there is no clear definition of such a status for foreign workers.
- A validity period is introduced for a business visa, limited to 90 days in a calendar year (the current term is 90 days in each 180-day period).
- A Register of Unscrupulous Inviting Entities is established, where those companies can be included that do not ensure compliance with the declared purpose of the business trip or timely departure of the foreign citizen.
- A requirement is introduced to undergo annual medical examinations, exclusively in medical organizations included in the list established by the highest body of the regional executive.
- To attract foreign workers to the Russian Federation for work purposes, both employers and job seekers shall be included in the Register of Employers and the Register of Foreign Workers, respectively. To be included in the above registers, both companies and employees shall undergo a number of procedures that will replace the current migration procedures, including obtaining quotas and permits.
- A system of advance payments of the personal income tax is currently under discussion, which, if adopted, is equally applicable to all foreigh workers.
- A requirement is established for foreign citizens to notify of their departure from their place of stay.

Of course, the system for regulating migration processes now being developed by the legislator is aimed at creating more favorable administrative conditions and at establishing transparent and equal requirements and procedures for all participants.

At the same time, it is worth emphasizing that preserving a separate category of highly qualified specialists for foreign workers is very important, with the preservation of preferences for them and their families. The simplified migration procedure for highly qualified foreign specialists was highly appreciated by Russian and foreign business, and helped to attract foreign investors to Russia, and proved to be an effective tool for motivating foreign workers and their employers — large international companies — to establish new projects in Russia, develop business, and invest.

The AEB Migration Committee continues its work, actively interacting and conducting a constructive dialogue with the Government of Russia, the Ministry of Economic Development of the Russian Federation, and the Ministry of Internal Affairs of the Russian Federation, to develop prompt solutions for practical problems and improve the legislation on migration.

ISSUES OF PRODUCTION LOCALIZATION IN RUSSIA

Localization of production in Russia is usually driven either by market growth, competition, low production costs, or by the regulatory environment. Since there are different types of market entry and localization strategies that vary depending on the market, the amount of investment required, market regulation, etc., localization always requires a tailor-made approach.

That being said, there are still a number of general localization issues that companies will have to address when thinking about localization.

Along with the traditional review of the possibility to reduce production costs or increase sales due to growing demand in case of production setup in Russia, the opportunity for business growth shall also be reviewed considering the possibility to gain additional market share using industrial support measures for local production or vice versa the risk to lose market share in the event of further import and strengthening of localization regulations establishing certain restrictions on non-Russian made products. A successful investment decision requires not only a substantiated financial calculation and market review but also a deep analysis of the legal and tax frameworks to make the investment project more suitable and profitable.

Nowadays, investors have all but abandoned the "local for local" strategy and are looking at export opportunities instead. Therefore, the question of possible supply markets takes on key importance. When talking about such markets, logistics and certification issues, the absence of protective customs duties, and government measures to support exports have a material impact on the investor's localization strategy.

Furthermore, the competitive situation in the market is also of great importance. An investor must understand who its competitors are on the market and how their presence is expressed, as well as their localization plans. The "first come, first served" rule usually applies, meaning that the company that is first to localize takes it all.

However, the most burning issue that companies must address is still the localization requirements themselves. In certain branches, even if the company decides to localize, it still cannot meet the localization requirements due to their impracticality and other reasons beyond the company's control. Stringent localization requirements are probably justified when considering products of strategic importance for the state, but there are many products that are not covered by the provisions on strategic importance. Localization would still be ambitious for these products, but the chances of developing a win-win approach for business and

the state would be more realistic. In general, finding an appropriate localization strategy that fits the expectations of the state, on the one hand, and business, on the other hand, is one of the most challenging localization issues.

Unfortunately, another challenge encountered nowadays is political risks. In this regard, an investor needs to understand at least what guarantees the state provides in case of political risks, what guarantees of the stability of the investment framework are valid and for how long. Due to the existing uncertainty, there is often a "vacuum" when it comes to making investment decisions on the setup or expansion of production in Russia. In this situation, it helps if the investor understands how the state can share potential financial risks (for example, by providing investment grants for the project, special government guarantees, etc.).

Last but not least is the image aspect. Nothing has more of a positive impact on investment decisions on localization than success stories and examples of market presence. An investor is much more likely to invest in production in Russia if there is a wide range of international players on the market. Therefore, it is very important for the state to support existing investment projects and industrial business initiatives. This is important not only in terms of specific investments in production, but also in terms of image and future successful projects.

CURRENT TAXATION ISSUES

TAXATION OF INTRAGROUP SERVICES

To reduce costs, transnational corporations use so-called service companies, which service group members or accumulate specific functions related to the business processes of a corporation at the level of the parent company. Such activity of a contractor company brings benefit to the recipient companies because they do not need to purchase similar services from third parties or organize the performance of necessary functions using their own resources. In recent years, the practices of the tax administration were a hindrance on the taxpayers. In fact, they made it practically impossible for Russian taxpayers to have their expenses on the acquisition of services from the companies of the group recognized by the tax authorities. By issuing Letter No. ShYu-4-13/12599@ dated 6 August 2020, the Federal Tax Service took the first step toward establishing uniform approaches to tax audits over that type of expenses. As a follow-up to this letter, on 2 February 2021, the Federal Tax Service issued Letter No. ShYu-4-13/1749@, which, however, caused concern in the business community because the territorial tax inspectorates could interpret the examples given in the letter narrowly, as examples of exclusively shareholder activities, without taking into account the criterion of whether there is a benefit from it for the Russian taxpayer. Also, to date, the regulation does not cover the important methodological issue of applying distribution keys (allocation keys) to costs incurred by a contractor when using an indirect pricing mechanism.

To solve this issue, the AEB experts recommend the priority of the general provisions of the FTS letter dated 6 August 2020 be directly codified given the fact that the determining criterion for any services to be accounted as expenses should be the criterion of benefit for the taxpayer. That is, if the activities listed in the FTS letter dated 21 February 2021 are aimed at obtaining benefits for a Russian member company of the international group of companies, then the benefit test is met.

It is also necessary to continue the work on establishing uniform approaches to recognizing expenses for the acquisition of intragroup services, including the establishment of reasonable approaches in terms of conformity with the provisions of the Transfer Pricing Guidelines of the Organization for Economic Cooperation, toward:

- determining the price of services with the use of the substantiated allocation keys;
- limiting the power of the local tax authorities to make detailed analyses of contractual pricing under the guise of checking the economic justification of expenses;
- receiving information about a foreign contractor through the international exchange of information between tax authorities.

VAT TAXATION OF ELECTRONIC SERVICES

Since 1 January 2019, all foreign companies supplying electronic services to Russian customers (foreign ESS vendors) shall be registered with the Russian tax authorities and directly report and pay VAT to the Russian budget. These requirements have no exceptions and apply even to one-off, intra-group and low-value transactions.

Moreover, according to the Russian Ministry of Finance and the Federal Tax Service, tax-registered foreign ESS vendors shall directly report and pay Russian VAT on all sales attracting this VAT (other sales), rather than only on electronic services. This requirement creates a number of technical issues, including input-VAT recovery by the Russian customers on such transactions.

The current regime contravenes global tax policy trends and creates unreasonable administrative burden for the foreign ESS vendors. Compliance with this regime requires expert knowledge of the Russian tax legislation and complicated and expensive changes to the companies' IT systems. For many companies, these rules are a barrier to the Russian market. Russian taxpayers also suffer, as they either lose access to the new technologies or bear tax risks associated with non-compliance by the foreign vendor.

These issues were partially mitigated by the FTS Letter No. SD-4-3/7937@ (СД-4-3/7937@) dated 24 April 2019. In this Letter, drafted with the active participation of AEB, the FTS essentially 'allowed' the Russian customers to voluntarily withhold and pay VAT on electronic services and other sales and to recover this VAT. However, this mechanism directly contradicts the Tax Code of the Russian Federation and may be applied only if a foreign provider has sufficient control over the Russian customer.

One of the possible ways out of this situation could be limiting the scope of the regime to foreign ESS vendors selling services to the Russian individuals and individual entrepreneurs. As an interim measure, it is good to exclude the intercompany transactions from the scope of the regime (AEB has developed the relevant draft law). Also it is important to address the technical gaps in the current regime.

TAX CLAUSE

The mechanism of the tax clause shifts the function of tax control from the tax authorities to the companies purchasing services, and with it the objective to force unscrupulous contractors in the supply chain to pay their taxes in most cases is not achieved as the tax liability for the payment of taxes by counterparties is actually imposed on the customers of services, which does not comply with the tax legislation. Furthermore, this mechanism imposes a significant additional administrative burden on the business, that of performing functions that are not typical for business.

This mechanism entails restriction of the freedom of civil turnover, forcing businesses to make commercially unjustified decisions. For example, when choosing a contractor, a company must first consider the contractor's compliance with the requirements of the tax clause and not the contractor's experience of successful operation and representation in the market.

Many taxpayers report being forced to use the tax clause mechanism by their local tax authorities under the threat of additional tax audits. This does not correspond with the declared goal of the Federal Tax Service to create a model convenient for all participants to "whitewash" the market. Business participation in this initiative of the Federal Tax Service should be exclusively voluntary and not compulsory.

The mechanism of the tax clause regarding the imposition of tax control functions and the burden of the VAT payment on the business contradicts a number of fundamental principles of the tax legislation, including Article 57 of the Constitution of the Russian Federation and Article 3 of the Tax Code of the Russian Federation.

The tax clause provision requiring a contractor to be listed in the so-called registers of diligent suppliers contradicts the requirements of antimonopoly legislation, which is confirmed by the available court cases.

The representatives of the AEB member companies suggest that the inclusion of a tax clause in commercial contracts should be exclusively voluntary. The public-legal task of "whitewashing" the market should be solved not at the level of judicial acts on individual civil cases, but by making appropriate changes to the legislation on taxes and fees, mandatory for all participants of tax relations. It is necessary to consider alternative options for effective control over the payment of taxes by counterparties, ones that would not create such a significant administrative cost for business.

ISSUES OF CUSTOMS VALUATION

The issue of accurate customs valuation is currently the most significant issue for all participants in foreign trade due to the conservative approach applied by the customs authorities. The latest hot topics include tabulating the customs value to include the amounts of royalties and intra-group payments, dividends, and VAT amounts paid by importers as tax agents in connection with the transfer of royalties to foreign rightsholders. The above issues have increasingly arisen in customs inspections conducted after the release of goods.

The active application of a conservative approach in 2021 was undoubtedly associated with the publication of the Accounts Chamber's Report announcing an understatement of customs payments by 98.5 billion roubles, which motivated customs authorities to include royalties in the customs value, to meet the planned targets. In the period from February to August 2021, the FCS of Russia initiated and conducted dozens of customs inspections after the release of goods. At the same time, judicial practice provides for both positive and negative decisions for companies. In connection therewith, assessing the risks of including additional charges is required, particularly to minimize customs risks in the past and future periods.

Let us hereby note that customs authorities pay special attention to all licensing and contract structures, and carefully study their features. In particular, the problematic aspects are: 1) classification of intellectual property items, such as the know-how used in the manufacture of finished products in Russia or in administrative and economic activities in general, as imported goods and the need to include royalties for the specified items of intellectual property in the customs value of such goods, and 2) inclusion of royalties payable for manufactured products in the customs value of raw materials imported for the manufacture of such products.

The necessity to develop unambiguous provisions regulating this issue at the supranational level must be emphasized, as this will provide businesses with an opportunity to apply a unified approach to customs valuation, and will positively affect the activities of both manufacturers and importers, as well as government agencies.

In addition to including additional payments in the customs valuation structure, it shall be noted that customs authorities often request confirmation that there is no dependence between the counterparties and the transaction price. In particular, they ask for verification values. Since Decision of the EEC Board No. 160 dated October 16, 2018 "On cases where a customs value declaration is required, on approving customs value declaration forms and on the procedure for filling the customs value declaration" came into force in 2019, control on the part of customs authorities has only intensified. At the same time, when declaring goods, it is not enough to submit an explanatory letter about the lack of interconnection or intra-group price lists.

In practice, importing companies always declare that the customs value is close to the verification values, but in actuality, they do not calculate such values. Obviously, the statement in the customs value declaration that the customs value is close to one of the verification values should be justified and documented, since customs authorities may request the appropriate supporting documents and information. At the same time, importing companies may, independently, without waiting for any requests from customs authorities, use the mechanism for submitting information on verification values as an effective way of proving the absence of any influence of the relationship on the customs value, both at the time of declaration and during post-release customs inspections.

As practical experience shows, the verification value determined by the subtraction method is the most accessible value for calculation. Information for other types of verification values is difficult to obtain due to (i) the confidential nature of the information on the value structure of the goods and on transactions between the supplier and third unrelated parties, or (ii) the lack of information about such transactions.

However, due to the lack of a methodology for calculating such values, business representatives often face difficulties in preparing the body of evidence.

In the second half of 2021, especially upon publication of Letter of the Ministry of Finance of the Russian Federation No. 27-01-21/82729 dated October 13, 2021 "On inclusion in the customs value of goods of taxes, including VAT paid by the declarant in relation to royalties or other payments for the use of intellectual property and accrued in favor of a foreign entity", based on the results of control measures, customs authorities have made a number of decisions that such amounts shall be included in the customs value of imported goods. Despite the fact that letters of the Ministry of Finance are only advisory in nature, and there is no clear regulatory framework, practice on this issue has been rapidly advancing.

Thus, Russian corporate licensees act as tax agents obliged to calculate, withhold and pay the relevant amount of VAT to the budget, if the conditions stipulated by the Tax Code of the Russian Federation are met with respect to the foreign licensor. And despite VAT being charged only from those transactions related to the payment of royalties that are carried out in the domestic market, the FCS of Russia interprets such VAT amounts as those subject to inclusion in the customs value based on the provisions of the international customs legislation (Recommended Opinions 4.16 and 4.18 of the Technical Customs Valuation Committee of the World Customs Organization) and the aforementioned letter from the Ministry of Finance of the Russian Federation.

In this connection, there is an urgent need to regulate the issue at the legislative level on the need to include (exclude) VAT amounts paid by Russian legal entities as tax agents in connection with the transfer of royalties to foreign rightsholders in the customs value of goods, as the lack of recommended examples and techniques leads to an excessively broad interpretation of these aspects by the customs authorities.

As to the prospects for judicial review of the negative decisions taken by customs authorities against importing companies based on the results of control measures on the issue of including royalties in the customs value of imported goods, the statistics are ambiguous and forms a ratio of 50:50.

We believe that the trends in terms of the subjects of inspection and the scope of control measures will remain unchanged in 2022. Regulatory and judicial practice is expected to develop further regarding the inclusion in the customs value of imported goods of additional payments and VAT amounts paid by foreign trade participants as royalties for the use of intellectual property accrued in favor of a foreign entity.

In addition, it is worth emphasizing that the Federal Customs Service and the Federal Tax Service have been actively engaged in the mutual exchange of information during in-house audits. In this regard, there is a high probability that the Federal Customs Service and the Federal Tax Service will take transfer pricing documentation into account in the future. Thus, the business community is to follow uniform approaches in determining the customs value of imported goods, taking the provisions of both the customs legislation and transfer pricing regulations into account.

To crown it all, in order to prevent possible negative consequences, the business community is to be proactive, conduct a preliminary comprehensive analysis of the need to include additional payments in the customs value structure, and conduct an ongoing analysis of current judicial practice, which will bring an awareness of the positive argumentation supported by courts, and may later be used when appealing decisions of the customs authority. It will also help adapt the licensing structure to current trends and work out a protective legal position to be defended when facing the customs authorities.

INCLUSION OF VAT ON ROYALTIES IN THE CUSTOMS VALUE OF IMPORTED GOODS: WHO IS RIGHT AND WHAT TO DO

This article examines the general issues of lawfulness of including VAT on royalties in the customs value of goods and the emerging risks for Russian participants in international licensing structures.

Comprehensive inspections on the issue of inclusion of license payments (royalties) (hereinafter also referred to as *"royalties"*), as well as other various "intra-group" payments in the customs value of imported goods may be considered a trend of the last year and the nearest future in the field of customs practice. Such inspections have resulted from the implementation by customs authorities of the instructions of the Accounts Chamber[1] in relation to companies bearing intra-group licensing obligations. The above customs control measures have resulted in the collection of several billion roubles of unpaid customs duties and penalties to the budget of the Russian Federation, as well as in serious risks of administrative and criminal liability. At the same time, a new feature of inspection measures in 2021 has been inclusion not only of royalties in the customs value of imported goods but also of VAT amounts withheld when such royalties were paid to a foreign licensor (hereinafter referred to as *"VAT on royalties"*), which has further increased the risks for companies.

[1] Report on the results of the control measure "Checking the completeness of customs payments to the federal budget in the period from 2018 to 2019 and the expired period of 2020, in relation to the goods imported into the territory of the Eurasian Economic Union and classified as intellectual property items (including patents, trademarks, copyright)" (https://ach.gov.ru/upload/iblock/1bb/1bbb4139914f4f2e51e0edb565f19647.pdf)

The position of customs authorities regarding VAT on royalties is based on the Guidance issued by the Ministry of Finance of the Russian Federation (hereinafter referred to as the *"Ministry of Finance of Russia"*).[2] So, the Ministry of Finance of Russia has recently repeatedly pointed out the need to include VAT on royalties in the customs value of imported goods as part of the additional charges on the price actually paid or payable for imported goods (hereinafter referred to as the *"Actually Paid Price"*) referring to Recommended Opinions 4.16 and 4.18 (hereinafter referred to as *"Opinions 4.16 and 4.18"*) adopted by the Technical Committee for Customs Valuation of the World Customs Organization (hereinafter referred to as the *"Technical Committee", "WCO"*).[3]

Undoubtedly, the availability of grounds for including certain types of royalties in the customs value of goods, based on specific characteristics of a certain licensing structure, shall be assessed on the basis of a competent legal analysis. Meanwhile, taking into account our practical experience, below we will briefly state the main arguments evidencing our opinion that the decision of customs authorities to include VAT on royalties in the customs value of goods shall be deemed unjustified.

ADDITIONAL CHARGES TO THE PRICE OF IMPORTED GOODS WITHIN THE MEANING OF CLAUSE 1 OF ART. 40 OF THE CC EAEU

According to the provisions of the Customs Code of the Eurasian Economic Union (hereinafter referred to as the *"CC EAEU"*), VAT on royalties shall not be deemed as one of the additional charges to the Actually Paid Price. Due to the fact that the list of additional charges is exhaustive, the inclusion of any other payments in the customs value of imported goods, other than those provided for by law, is contrary to the customs legislation.

Additionally, this thesis is confirmed by the fact that mentioning duties, taxes, and fees in Clause 2 of Art. 40 of the CC EAEU, the legislator clearly defined them as an independent category of charges, different from other expenses, including royalties.

In our opinion, the position of the Ministry of Finance of Russia that VAT on royalties may not be considered as a deduction under Clause 2 of Art. 40 of the CC EAEU as a tax paid in connection with the import of goods is erroneous: the importer pays royalties in relation to imported goods as a precondition for their entry into circulation in the EAEU; royalties are included in the customs value of goods precisely in connection with the import and sale of such products; in addition, a royalty is most often defined in practice as a percentage of net proceeds from the sale of goods, which also indicates the relationship between royalties and the sale of imported goods. Accordingly, VAT on royalties shall not be included in the customs value as a tax that is paid in connection with the import and further sale of imported goods in the EAEU.

It shall also be borne in mind that, by its nature, VAT is an indirect tax, the burden of which falls on end users. In this regard, VAT on royalties may not be considered an integral part of the licensor's income or be included in the customs value of goods as an additional charge on the Actually Paid Price in the form of royalties, as suggested by the Ministry of Finance of Russia.

WCO TECHNICAL COMMITTEE'S OPINIONS 4.16 AND 4.18

The position of the Technical Committee expressed in its Opinions 4.16 and 4.18 appears to be inapplicable to VAT on royalties on cases of income tax.

First of all, in its Opinions 4.16 and 4.18, the Technical Committee answered the question of the need to include the amount of income tax withheld from royalties in the country of importation in the customs value of imported goods (withholding tax). At the same time, VAT or other taxes are not mentioned in Opinions 4.16 and 4.18, and there are no conclusions thereon.

In addition, the Technical Committee gave its comments in relation to specific factual circumstances, and a broader interpretation and application of its position appears unfounded.

Thus, Opinion 4.16 considers a situation when the procedure for charging income tax from royalties is not directly regulated by the provisions of the license agreement and the amount of income tax is actually withheld from the amount of royalties payable, thus reducing the licensor's amount of royalty proceeds provided for in the license agreement. It seems that the conclusion of the Technical Committee does not apply to situations where the tax is "separated from the price", i.e., the license agreement explicitly provides for an increase in the amount of royalties payable to the licensor by the amount of tax (the so-called *gross-up clause*).

In turn, Opinion 4.18[4], which has not yet been approved by the WCO Council as of the date hereof, refers to a situation where the legislation of the country of importation provides for the withholding of income tax (withholding tax) from the gross amount of the licensor's income in the form of royalties, including the amount of the tax itself. Extrapolation of the conclusions of the Technical Committee specified in Opinion 4.18, to the Russian VAT seems to be ambiguous, since the Tax Code of the Russian Federation provides for a different procedure for calculating VAT.

[2] Letters of the Ministry of Finance of Russia No. 03-10-11/45719 dated August 04, 2016, No. 03-10-08/66933 dated November 19, 2015

[3] Letter of the Ministry of Finance of Russia No. 27-01-21/82729 dated October 13, 2021

[4] Opinion 4.18 has not been approved by the WCO Council, and therefore it has not yet entered into force and has not been officially published — http://www.wcoomd.org/en/media/newsroom/2021/may/two-new-instruments-adopted-by-the -technical-committee-on-customs-valuation.aspx

INCLUSION OF VAT IN SEVERAL ECONOMIC TRANSACTIONS

Additionally, it shall be noted that inclusion of VAT on royalties in the customs value of goods leads to a situation where the same amount of VAT on royalties is firstly paid and reimbursed in internal transactions (transactions related to granting a license for trademarks), and is then taken into account when calculating a basis for import VAT in external transactions (transactions related to the import of goods). Thus, one and the same VAT amount, with a single economic basis, the only added value it creates, is accounted twice in different economic transactions from the economic point of view. This approach, however, contradicts a number of basic taxation principles and the position of the Constitutional Court of the Russian Federation.

Taking into account the intensity of customs inspections, we shall expect the emergence of judicial practice on specific disputes related to the inclusion of VAT on royalties in the customs value of goods in the foreseeable future.

As mandatory "homework" for those companies which have not yet been subjected to an inspection, we hereby recommend conducting a detailed assessment of the existing licensing structures in order to identify customs risks. Within such managerial work, it is required, inter alia, to weigh the consequences of including VAT on royalties in the customs value of goods in a broader context of the relevance of all existing licensing relations to the import.

In addition, it is important to analyze licensing agreements, inter alia, in terms of the "market" rate of license fees, and, in general, in terms of the relevance of royalties to the import of goods in complex licensed structures that provide for a split of royalties depending on the various powers of the Russian licensee.

Comprehensive inspections on the issue of inclusion of license payments (royalties), as well as other various "intra-group" payments in the customs value of imported goods may be considered a trend of the last year and the nearest future in the field of customs practice.

STATE AND TRENDS OF THE IT INDUSTRY DEVELOPMENT IN RUSSIA

Russia is striving for digital transformation and for an increased level of technological independence. Projects such as Information Society and Electronic Government have led to the creation of the national program titled Digital Economy. In the context of the pandemic, the need to uphold the work of authorities and the lives of citizens has further spurred the development of the electronic services, and widespread digitalization has become a national priority.

As a response to the economic and political sanctions imposed by Western states, in 2014, the Russian Government approved an import substitution program for a number of industries, including IT. As a result, several legislative acts aimed at protecting domestic companies and ensuring national interests and security have been adopted over the past seven years. However, these legislative acts have significantly reduced the market opportunities for foreign high-tech companies in the Russian market as well as the global competitiveness of domestic companies.

With the "tax maneuver" for the IT industry announced in 2020, the Russian Government has underscored that the creation of positive conditions designed to strengthen the desire of foreign IT companies to operate in Russia should be one of the priorities of the national program Digital Economy.

In December 2020, at the Artificial Intelligence Conference, which was attended by Russian President Vladimir Putin via videoconference, the head of Sberbank, German Gref, announced the creation of the first Artificial Intelligence Institute in Russia. Also, the German and Swiss scientist and specialist in artificial intelligence, Jurgen Schmidhuber, was appointed its scientific director.

In September 2021, Russia and the European Union began consultations within the framework of the World Trade Organization (WTO) on the protectionist measures previously introduced by the Russian Federation, that limit the participation of European organizations in the procurement processes of companies under partial state ownership.

We see that the State has not chosen a path of self-isolation; it remains open to the development of its digital industry. Nevertheless, the existing number of restrictions placed on foreign IT companies in the Russian market, as well as the ongoing promotion of the import substitution concept, hinder the development of the international cooperation and limit the access of the Russian companies to the best international practices. This in turn greatly complicates the joint development of high-tech products capable of competing on the international market.

RUSSIAN LEGISLATION ON PERSONAL DATA

On October 10, 2018, the Russian Federation signed a protocol amending the Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data of 1981, which should help align the legislation of the Russian Federation and the European Union regarding the processing of personal data. We believe that the process of harmonizing Russian and European legislation will have a positive impact on legal regulation in this area.

On December 2, 2019, a law introducing significant fines for non-compliance with requirements for the localization of databases containing personal data came into force. The fines range from 1 to 18 million roubles for companies and from 100,000 to 800,000 roubles for CEOs and other top managers. The court has imposed fines on Twitter and Facebook for repeated violations (17 million roubles and 15 million roubles, respectively), and, for the first time, violations — on Google (3 million roubles) and WhatsApp (4 million roubles). On July 21, 2020, the Russian Government

submitted a draft law to the State Duma (https://sozd.duma.gov.ru/bill/992331-7) on the procedure for depersonalizing personal data. The requirements and methods for depersonalizing such data will be approved by the Federal Service for the Supervision of Communications, Information Technology and Mass Media. Regarding personal data erasure within IT systems, the draft law prescribes using only security products that have been certified by the Federal Service for Technical and Export Control (FSTEC) or the Federal Security Service (FSS), which will create additional difficulties for the data operator in fulfilling the legal requirement for the timely erasure of personal data.

In 2021, special requirements were introduced regarding the dissemination of subjects' personal data. A data operator must obtain separate consent for the dissemination of personal data among an indefinite circle of persons and for the use of such data, the form of which is approved by Roskomnadzor. In practice, the mechanisms for obtaining consent cause a large number of difficulties and do not allow the data subjects to effectively control the use of information about themselves on the Internet.

DEVELOPMENT OF THE LABELING SYSTEM IN RUSSIA AND EAEU MEMBER STATES: KEY TOPICS

The system of product labeling by means of identification and tracking product movements remains one of the most discussed issues both in the business community and in the dialogue between business and authorities.

The system of product labeling with means of identification has been introduced or is planned to be introduced in such categories as tobacco products, shoes, medicines, fur coats, cameras, flash lamps, tires, light-industrial goods, perfumes, dairy products, packaged water, bicycles, and wheelchairs; experiments have been underway to introduce labeling for dietary supplements, beer, and low-alcohol drinks, as well as biocides and antibacterial cosmetic products intended for cleansing hands.

It is assumed that the introduction of a product labeling system is beneficial to consumers, businesses, and the state.

At the same time, the majority of participants in the turnover of labeled products have not received the declared business benefits: revenue growth and increased competitiveness of the "white business", process optimization, or cost reduction. In addition, the introduction of labeling leads to a significant complication of business processes at all stages of the supply chain and a significant financial burden for both, manufacturers and importers.

PROBLEM OF INTRODUCING LABELING IN NEW PRODUCT GROUPS

In the context of active development of the labeling institution, business is particularly concerned about the lack of transparency in the decisions made by authorities on the issue of extending the labeling requirement to new product groups.

In accordance with the Guidelines for the definition of new product groups in order to prepare proposals to the Government of the Russian Federation for a decision on inclusion in the list of individual goods subject to mandatory labeling with identification means, approved by order of the Ministry of Industry and Trade, the Department of the digital product labeling system and legalization of product turnover should rely on official statistics, information from federal executive bodies, including data on the implementation of state control (supervision), as well as the results of sociological research; information received from the public, scientific, human rights, industrial and other organizations and associations, as well as judicial practice.

When forming a list of products subject to mandatory labeling, the main parameters characterizing the markets of the selected product groups shall be taken into account: market volumes (both in value and in kind), the industry's focus on imports, the share of illegal traffic, including illegal imports, the unit cost of a product, the rate of import customs duties, the share of self-employed entrepreneurs in the turnover structure, sensitivity to the introduction of the labeling system, etc.

The above Guidelines provide that, based on the results of the assessment, a draft report on the assessment of the feasibility of introducing a labeling system shall be prepared and posted on the official website of the coordinator of the system on the Internet, leading to public consultations for 30 calendar days.

At the same time, the business community has been repeatedly applying to the Government with its proposals to increase the transparency of the decision-making process when making decisions to extend the labeling requirement to new product groups. This is indirect evidence that the above Guidelines may not be applied in practice, with the decision-making process remaining opaque.

Since the introduction of the labeling system is associated with high financial costs for businesses, it is extremely important for manufacturers and importers to understand the feasibility of introducing labeling, as well as the ratio of investment and benefits received. At the same time, the analysis of the ratio of investments and the benefits received will allow the authorities to avoid negative consequences for consumers in the form of price increases and reduction in the range of products on the market and focus specifically on industries or product categories evincing a high proportion of counterfeit products.

PROBLEM OF WHERE TO APPLY MEANS OF IDENTIFICATION ON IMPORTED PRODUCTS

Within the development of the institution of labeling and on the basis of practical experience accumulated, participants in the turnover of labeled goods have regularly proposed solutions to the federal authorities on how to improve the environment for the development of labeling.

In particular, importers consider the possibility of applying means of identification at importers' warehouses in order to optimize costs, without prejudice to the fulfillment of the issues to be resolved by the labeling system.

The labeling rules approved for certain product groups by the relevant Decrees of the Government of the Russian Federation require importers to physically apply means of identification on products abroad or in customs warehouses, which is one of the main difficulties faced by importers when implementing labeling.

Applying means of identification abroad is an expensive procedure due to the high costs of developing the IT infrastructure to obtain and physically apply means of identification to each product unit. In addition, the arrangement of Russian crypto-protected labeling abroad creates significant risks both for Russian importers, who cannot guarantee correct application thereof in foreign states, and for the state since the protective cryptographic elements of labeling codes are beyond the control of Russian state authorities.

Applying means of identification in customs warehouses will lead to a serious increase in the costs of financial imports due to the high cost of applying additional labels in customs warehouses in the Russian Federation, and will significantly increase the time imported goods spend undergoing customs clearance and lead to an increase in delivery deadlines. In addition, the labeling of certain product groups requires a special infrastructure, which is not available in each customs warehouse.

The EAEU agreements on labeling of imported goods after their release by customs authorities (Article 4) allow creating conditions in the Russian Federation for labeling imported goods after their customs clearance at importers' warehouses and make it possible to optimize importers' costs, support the interest of investments in the development of industries on the Russian market, as well as support the pricing policy.

PROBLEM OF MULTIPLE TRACEABILITY SYSTEMS

It is worth mentioning that in Russia and other EAEU member states, control over the illegal circulation of certain product groups is exercised with the help of national traceability systems. For example, in Russia, there is a traceability system for alcohol-containing products — EGAIS, and a traceability system for controlled veterinary products — Mercury AIS.

Labeling of the above categories of products is a significant burden for business, especially for companies operating in different product markets, due to the need to interact with several traceability systems that resolve, inter alia, the common objective of combating illegal traffic.

Managing such a plurality of traceability systems requires investments in expensive solutions for integrating such systems, and in technical improvements of internal information systems.

In this regard, trade participants advocate the need to develop a single interface to arrange interaction between trade participants and information systems implemented or planned to be implemented as per the single-window principle, in order to provide a simultaneous automatic data upload, automated distribution of information across all systems, to eliminate the duplication of information in paper form, and to facilitate the provision of data during market inspections.

THE PROBLEM OF LABELING IN THE EAEU MEMBER STATES

In 2021, the EAEU member states began to actively introduce labeling within their states: in Belarus, they introduced labeling for dairy products, light industry goods, footwear, tires, and other categories, in Kazakhstan — footwear, in Kyrgyzstan — tobacco and alcohol.

Despite the basic model of the product labeling system approved by the EEC Council, which prevents the emergence of barriers in the internal EAEU market, the introduction of labeling in the EAEU member states remains extremely difficult due to the lack of uniform requirements and standards for the product labeling system in the EAEU member states (Belarus, Kazakhstan, Armenia, and Kyrgyzstan), as well as the recognition of labeling codes in the EAEU member states.

Uniform requirements are planned for introduction only in 2023, and at present, the EAEU member states can use national standards.

In the above conditions, manufacturers and importers face serious difficulties with product turnover within the EAEU member states, and some of them make decisions to stop supplies, since the Russian code is not accepted in other EAEU countries, and obtaining a new code is associated with additional financial costs and technical difficulties.

Thus, it is advisable to introduce labeling in the EAEU states only when the requirements for the product labeling system will be unified, labeling systems in all EAEU member states will be integrated, labeling codes will be recognized, and the possibility of using several traceability systems for a particular product group will be excluded.

Within the development of the institution of labeling and on the basis of practical experience accumulated, participants in the turnover of labeled goods have regularly proposed solutions to the federal authorities on how to improve the environment for the development of labeling.

ISSUES OF ANTIMONOPOLY REGULATION

Antimonopoly regulation is an important tool for protecting competition, since it helps to directly and promptly address the threats to the restriction thereof, and prevents the emergence of such threats.

Conclusions as to the effectiveness of antimonopoly regulation in Russia can be drawn based on an analysis of the practical application of the terms and conditions of Federal Law on the Protection of Competition No. 135-FZ dated July 26, 2006 (hereinafter referred to as the "Competition Law") in terms of identifying and suppressing abuse of a dominant position, agreements and concerted action of business entities that restrict competition, anti-competitive actions of executive bodies, and unfair competition.

To do this, we hereby propose to consider several of the most notorious recent antimonopoly cases, and pay attention to the key activities of the FAS in terms of carrying out unscheduled on-site inspections.

Undoubtedly, anticompetitive agreements, in particular, bid rigging, have traditionally formed a significant proportion of antimonopoly violations. Nevertheless, the FAS has recently considered a number of interesting cases related to the abuse of a dominant position, which can rightfully be considered the most outstanding in the FAS's operations from 2020 to 2021.

For example, in April 2021, the FAS imposed a record turnover-based fine on Apple in the amount of 12 million dollars (approximately 906 million roubles) for violating antimonopoly laws by abusing its dominant position in the market for mobile device applications running the iOS operating system. The case was initiated back in 2019 on the complaint of Kaspersky Laboratory JSC. The FAS found out that the corporation provided competitive advantages to its products in the market for mobile applications running on the iOS platform, including parental control applications, while providing worse conditions for competitors' products, in particular those of Kaspersky Laboratory. The FAS issued an order to Apple aimed at eliminating discrimination against third-party developers. Apple has not yet complied with the order, as it has decided to appeal against the relevant FAS acts in court. In October 2021, another case was initiated against Apple in relation to the abuse of its dominant position — the corporation is accused of imposing unfavorable contractual conditions on third-party developers, depriving them of the ability to provide users with a purchase method other than in-app purchase in their mobile applications, and requiring them to change the functionality of their applications.

In December 2020, the FAS of Russia disposed the case on violation of the antimonopoly law initiated against Booking.com B.V., which abused its dominant position in the market for the provision of services by aggregators of information on accommodation facilities by imposing unfavorable contractual conditions on Russian hotels, obliging them to comply with the company's parity of prices policy, the availability of rooms and conditions in all of its sales and service distribution channels, meaning that the aggregator obliged them to provide their best booking conditions through the Booking.com website. For any violation of such an arrangement, the aggregator applied sanctions on hotels, which were forced to comply with unfavorable contractual conditions in order to preserve profits. It is worth noting that similar charges have been pending in many other jurisdictions, and the indictment against Booking.com B. V. issued by the FAS of Russia served as a logical continuation of the incriminating practice of foreign antimonopoly bodies. Booking.com B.V. was issued an order to terminate the violation, with a fine of 1.3 billion roubles imposed on the company.

Another notorious case related to the abuse of a dominant position in 2021 was that of initiated against the largest Russian metallurgical companies: PJSC Severstal, PJSC MMK, and PJSC NLMK. The FAS of Russia had received numerous allegations of an unjustified increase in prices for hot-rolled flat products, on which basis it conducted an investigation and concluded that the actions of the companies involved showed signs of establishing and maintaining monopoly high prices for hot-rolled products.

As of the date of this article, the case is still pending with the antimonopoly authority. Despite the fact that one of the parties to the litigation, PJSC Severstal, has already lowered the base prices for hot-rolled flat products, the FAS intends to check the validity of prices in previous periods. If the antimonopoly authority concludes that there is a violation, the metallurgical companies involved will face heavy fines and, possibly, an order aimed at ensuring competition.

Stabilizing prices in the market is a strategically important task, the solution of which will directly affect the reduction of prices in other economic sectors dependant on flat-rolled products: shipbuilding, mechanical engineering, residential and infrastructural construction, as well as the oil and gas industry. In this regard, the case is of particular importance for the FAS.

As noted above, an important role in the activities aimed at counteracting violations of antimonopoly legislation is played by unscheduled inspections ("Dawn Raids") carried out by the FAS of Russia, which are conducted in order to monitor the compliance of business entities and a number of state authorities with the antimonopoly legislation. As a rule, such inspections are conducted upon receipt of a complaint or another message about a violation of antimonopoly regulations from companies, citizens, the media, law enforcement agencies, public associations, local administrations, or other state bodies, or when such a violation is independently detected by the antimonopoly authority. According to Art. 11 and 16 of the Law on the Protection of Competition, Dawn Raids shall be conducted without notifying the inspected persons, since the element of surprise allows the FAS to efficiently obtain evidence, making it impossible for the inspected persons to destroy signs of their violation by the time the FAS inspection begins. The rather broad powers of the FAS in the field of inspections (the FAS inspection can examine documents and premises, copy documents and information from work computers, including correspondence from e-mail, interview employees, etc.) often allow the FAS to find irrefutable evidence of violations of the antimonopoly legislation during an unscheduled inspection.

Thus, on the basis of complaints filed by citizens with the FAS of Russia, which contained information about price increases at federal retail chains, in August 2021, the FAS of Russia conducted unscheduled on-site inspections of X5 Group (retail chains such as Pyaterochka, Perekrestok, Karusel), Lenta LLC and Tander JSC (the Magnit retail chain) to find evidence of anticompetitive collusion, which could result in an increase in prices and maintenance thereof at a heightened level. Based on the inspections carried out by the FAS of Russia, pricing by the largest retail chains will be assessed, and reasons for possible unjustified price increases will be studied.

In the context of the spread of the novel coronavirus (COVID-19), the FAS is expected to ensure stringent control over the prices for medical products. In August 2021, the FAS of Russia carried out on-site inspections of a number of official distributors of mechanical ventilation devices manufactured by Hamilton Medical AG. Based on the results of such inspections, it was established that Hamilton Medical AG had provided instructions to its distributors on how to participate in public and municipal procurement. As a result, competition between distributors was virtually eliminated, which led to the division of the product's market by territory and by the composition of the buyers, as well as to consistently high prices at tenders. As a result of the inspection, the antimonopoly authority initiated a case against Hamilton Medical AG on the grounds of illegal coordination of actions of the manufacturer's official distributors when participating in public and municipal procurement for the supply of ALVs.

Of course, control activities of the FAS are aimed not only at identifying antimonopoly violations and holding violators liable, but also at preventing new violations. Antimonopoly compliance is also expected to provide great support to the FAS in the prevention of antimonopoly violations — that is, a set of measures for identifying antimonopoly risks and preventing violations, which has been independently developed and implemented by business entities and the authorities.

Since 2014, Russia has been actively discussing the feasibility of introducing antimonopoly compliance. At that time, a number of companies (MTS PJSC, Baltika Breweries LLC, Promsvyazbank OJSC, Ural Mining and Metallurgical Company LLC, SIBUR PJSC, etc.) developed and implemented an antimonopoly compliance system, and have recently noted the effectiveness of the mechanism.

In recent years, the discussion about antimonopoly compliance has transformed from the issue of its feasibility to the issue of the thorough development of its mechanisms and implementation procedures. Thus, in the spring of 2020, a new article on antimonopoly compliance was included in the Law on the Protection of Competition, and in July 2021, the FAS of Russia published a guidance on antimonopoly compliance (hereinafter referred to as the "Guidance"). The Guidance notes that the decision to implement antimonopoly compliance shall be made voluntarily. At the same time, the introduction of the system will help the companies obtain a number of advantages, such as a reduced risk of violating the antimonopoly legislation and of the subsequent consequences; a reduced risk category and, as a consequence, reduced intensity of inspections by the FAS of Russia; the possibility of referring to the compliance system to mitigate administrative liability, etc. Moreover, the Guidance directly stipulates that "a business entity may not

be recognized as violating the antimonopoly legislation if its actions are carried out in accordance with the established rules of antimonopoly compliance (with the FAS of Russia)".

Companies may submit their internal instruments in the field of antimonopoly compliance to the FAS of Russia to check them for compliance with the antimonopoly legislation. The Service will examine the documents within 30 days and, based on the results of such an examination, issue a reasoned opinion on their compliance or non-compliance with the antimonopoly legislation. It is also permissable to reapply to the FAS of Russia in the event of receiving a negative opinion.

Thus, the antimonopoly regulation in Russia is not static; it is developing and kept up-to-date. It can conclusively be said that new mechanisms and tools to influence this environment will be developed, the old ones will be revised, and the results of such activities will not be long in coming.

"CONSUMER EXTREMISM" IN RUSSIA: FOREWARNED, FOREARMED

Consumer protection and its implementation have been one of the hottest topics discussed at the state level and in business. A specific feature of relations with the consumer consists in the fact that the Law of the Russian Federation on the Protection of Consumer Rights enshrines a number of preferences for consumers as a weaker party in the relevant legal relations, requiring additional guarantees for the protection of their rights and interests. A significant role in consumer protection is assigned to public organizations. Moreover, the Government of the Russian Federation has adopted the Strategy for State Policy of the Russian Federation in the Field of Consumer Protection for a period up to 2030. In addition, a number of bills have been submitted to the State Duma of the Russian Federation, which fix the already established practice on the one hand, and further increase the responsibility of business on the other.

Most companies have established practices for processing consumer claims and appeals, which minimize subsequent appeals of their customers to courts for the purpose of enforcing their rights and interests. In recent years, however, business has faced a surge in such behavior of consumers and public associations, which is aimed not at protecting consumer rights and interests, but at obtaining certain benefits and income. In such a case, legal mechanisms laid down in the Law are used. This phenomenon is called "consumer extremism".

It is worth noting that "consumer extremism" is an exception rather than a rule, since most consumers exercise their rights in good faith. However, even a small percentage of consumers abusing their rights causes significant damage to business, especially in areas where the product cost is high.

Given the increased social responsibility of business, companies shall be aware of which legal provisions can be used by unscrupulous customers.

For example, the Law on the Protection of Consumer Rights does not provide for any pre-trial dispute resolution procedure but does establish a company's right to conduct a quality check, sometimes called an expert review. Within such a check, the validity of the buyer's claims regarding product quality is established, the nature of the claimed defect is studied, etc. This measure was included to ensure that consumer claims can be resolved by companies out of

court to the maximum possible extent, thereby reducing the burden on the judicial system. However, the absence of the obligation to present the product for a quality check leads to the direct involvement of the court. At the same time, the consumer continues to use the alleged "low-quality" product during the trial, and the period for calculating penalties only increases.

It is the significant amounts of the penalties levied, which include forfeit and fines, that are attractive to unscrupulous consumers. According to the Law on the Protection of Consumer Rights, the consumer is awarded a penalty of 1% per day of the product value for the entire period of delay and a fine of 50% of the amount awarded to the consumer. If a public organization is involved in the protection of a consumer, it receives 25% of the fine amount imposed in favor of the consumer.

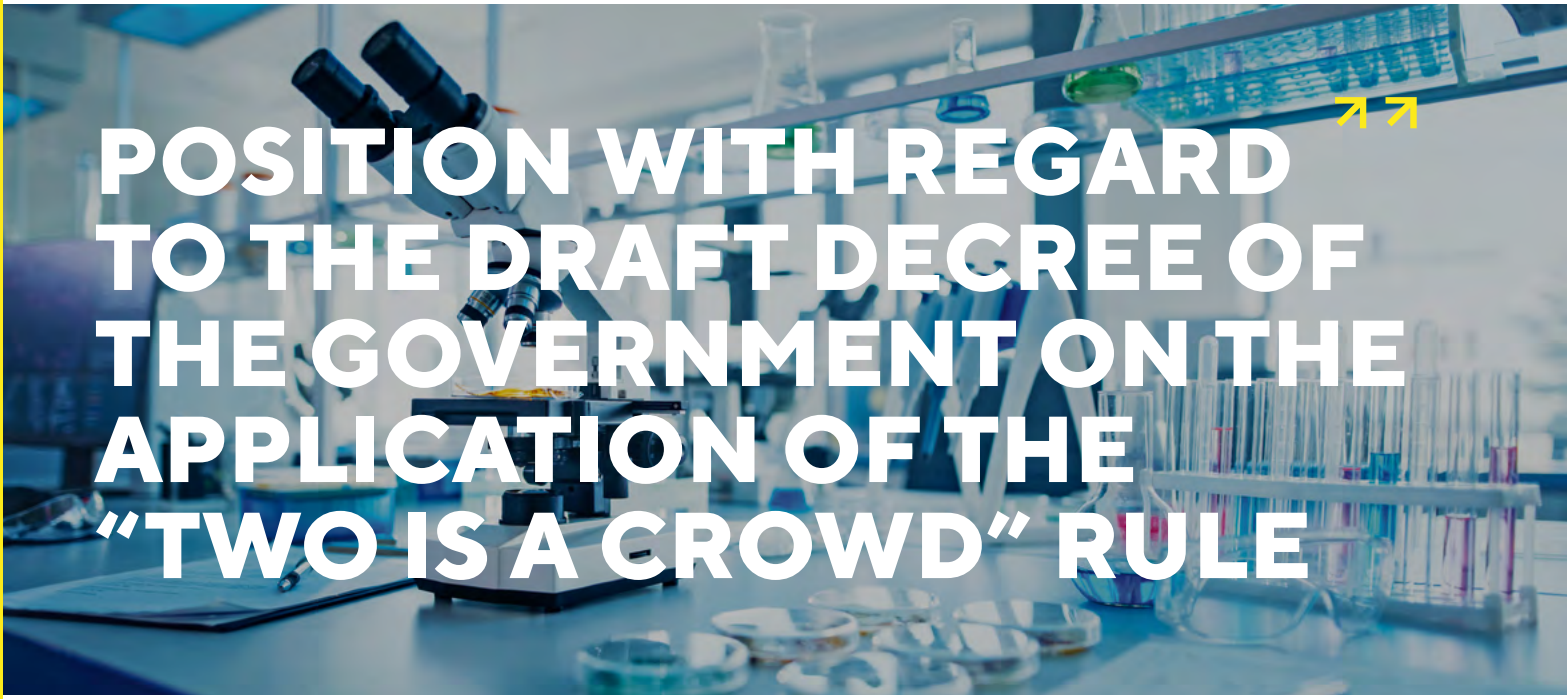
At the company's request, the court can reduce the amount of the forfeit and the fine if it finds such a request justified but only in exceptional cases. In practice, the amounts of the forfeit and the fines awarded in favor of consumers in relation to poor-quality goods, even upon their reduction by the court, can amount to 300–400% of the original cost of the products. Moreover, when the court awards a penalty in the amount of 1% per day of the product value from the effective date of the decision and until execution of such a decision, the amount to be paid increases manifold. After all, neither the bailiff, nor the bank has the right to reduce the amount of the penalty like a court but calculates it at the rate provided for by the Law. As a result, this leads to the fact that unscrupulous consumers deliberately refrain from providing their bank details for as long as possible, since they are entitled to receive a writ of execution within 3 years from the effective date of the decision and, as a result, receive a much larger amount than that awarded by the court.

Unlike the penalty for products, which is unlimited, the amount of the penalty for service provision is limited to the cost of the service, although the penalty rate is 3% of the service price per day.

We have recently noted a trend towards applying the provisions of the Law on the Protection of Consumer Rights in disputes between legal entities. The situation is as follows: a legal entity, often a public association, which previously represented the interests of a consumer in litigation, acquires a right of claim against a company under a rights of claims assignment contract, as a rule, in relation to the penalty of 1% per day from the effective date of the court decision and until its actual execution. After that, the legal entity applies to the arbitration court with a claim to collect penalties from the defendant. In such a case, the decision may already have been executed by the company voluntarily, but it could objectively take some time from the moment the decision entered into force until its execution, which is what the unscrupulous plaintiffs use. After all, in 3.5 months, the amount of the 1% penalty will be equal to the product price. Obviously, this practice does not lead to the restoration of consumer rights, but to abuse and collection of significant amounts from companies.

Therefore, a thorough review of the relevant legal provisions is necessary. It shall become the basis for equal relations between business representatives and consumers, with the responsibility of the former guaranteed, on the one hand, and protection from "consumer extremism" on the other.

> It is worth noting that "consumer extremism" is an exception rather than a rule, since most consumers exercise their rights in good faith. However, even a small percentage of consumers abusing their rights causes significant damage to business, especially in areas where the product cost is high.



POSITION WITH REGARD TO THE DRAFT DECREE OF THE GOVERNMENT ON THE APPLICATION OF THE "TWO IS A CROWD" RULE

The AEB Health and Pharmaceuticals Committee represents the interests of European pharmaceutical manufacturers, many of which have transferred to modern technologies, have localized their production in Russia, and have been producing a wide range of modern medicines in demand by the healthcare system.

In connection with the draft Decree of the Government of the Russian Federation on Amending Decree of the Government of the Russian Federation No. 1289 dated November 30, 2015, as well as in the context of adopting a Pharmaceutical Industry Development Strategy for a period until 2030, it shall be noted that the "two is a crowd" rule will significantly affect the strategy of pharmaceutical manufacturers in terms of the further investment and development of production in Russia.

At the moment, a dialogue with government authorities, in particular, with the Ministry of Industry and Trade of Russia, is vital within the framework of further elaboration of the above Decree of the Government of the Russian Federation, as is ensuring the uninterrupted circulation of medicines on the market, in particular, those included in the list of strategically important medicines (LSIM), the production of which must be ensured within the Russian Federation.

AEB member companies consider it necessary to discuss potential risks for further development of the pharmaceutical industry, the patient community, the healthcare infrastructure, and those risks associated with the introduction of the "two is a crowd" rule, and to jointly develop a balanced solution.

POSITION OF THE AEB HEALTH AND PHARMACEUTICALS COMMITTEE ON THE DRAFT DECREE OF THE GOVERNMENT OF THE RUSSIAN FEDERATION ON THE APPLICATION OF THE "TWO IS A CROWD" RULE[1]

According to the State Register of Medicines (GRLS), out of 215 international non-proprietary names included in the List of Strategically Important Medicines, for 80 INNs, there are no ingredients produced in the Russian Federation, and for 31 INNs, there are no finished dosage forms produced in the Russian Federation. This means that almost half of the medicines included in the List of Strategically Important Medicines are produced by both Russian and international pharmaceutical companies using foreign pharmaceutical ingredients. Thus, upon *the introduction of the "two is a crowd" principle, the majority of Russian pharmaceutical manufacturers will not be able to participate in state auctions.* The above situation cannot but affect the further development of the industry and the healthcare system as a whole.

The time factor is of great importance in the production of pharmaceutical ingredients: considering all the procedures involved, the transition to a new system may take 5–7 years. At present, the Russian Federation has not yet ensured the production volumes of active pharmaceutical ingredients (API) required to fully satisfy the needs of the healthcare system. The "two is a crowd" rule can lead to the *dependence of the healthcare system on a limited number of API manufacturers.* In their turn, such results can provoke an increase in prices on the drug market, reduce the availability of

[1] As of December 2021

medicines and reduce the available choices of effective therapy for patients. According to the most dramatic scenario, the "two is a crowd" rule can lead to the further withdrawal of a number of socially important medicines from the market, with negative consequences for patients and, as a consequence, to increased social tension.

AEB member companies have been expressing concern about function of the "two is a crowd" mechanism. For example, will there be a need to obtain *special permits in all cases of procuring foreign medicines, regardless of the actual presence/absence of analogues and the actual possibility of their production and/or delivery by local manufacturers?*

The introduction of the "second is a crowd" principle in the procurement of medicines may also have a *negative impact on the investment attractiveness of the pharmaceutical industry.* To fulfill the tasks set by the Pharma-2020 state program, international pharmaceutical companies have been implementing large investment projects to localize the production of medicines in the Russian Federation. These have had a positive impact on the development of the industry through new technologies and know-how being transferred to Russia, new jobs being created, industrial production volumes growing, and expertise-exchange programs being implemented between Russian and foreign specialists. A significant part of such projects has been implemented within the framework of special investment contracts (SPIC), the essential condition of which is to guarantee invariability of the business environment for investors. Adoption of the "two is a crowd" rule will fundamentally change the conditions of the business environment and challenge the feasibility of implementing investment projects in the pharmaceutical industry.

It is also important to note a *possible violation of the priority healthcare principle of patient orientation* — the provision of equal opportunities for each patient to receive a medicine prescribed by a doctor. The patient will be limited in his/her choice of the required therapy since a medicine purchased according to the "two is a crowd" rule may simply not suit a number of patients according to their indications.

We believe that achieving the strategic goal of ensuring medicine safety and the nation's self-sufficiency requires an integrated approach, primarily including measures neither restrictive nor prohibitive, but of a stimulating nature (such as subsidizing the synthesis of pharmaceutical ingredients, supporting the chemical industry, tax incentives, etc.). State instruments are required to maintain a favorable investment climate, stability of the legislation and conditions of access to the market, and support for innovation, especially given the long planning and launch period of technology transfer projects in the pharmaceutical industry.

To stimulate the production of ingredients, measures have already been implemented forming a preferential regime for the purchase of medicines produced in the EAEU: the "three is a crowd" rule (Decree of the Government of the Russian Federation No. 1289 dated November 30, 2015), as well as a mechanism establishing a price preference of 25% when purchasing medicines, for which ingredients are produced in the EAEU countries (Order of the Ministry of Finance of Russia No. 126n dated June 4, 2018). We propose that the application of such mechanisms be analyzed and, if necessary, modified.

In terms of the state policy of the Russian Federation in the field of import substitution, in relation to the high-tech medical equipment industry, serious concerns among the AEB members constituting major international medical equipment manufacturers, are caused by the amendments introduced by Decree of the Government of the Russian Federation No. 1432 dated August 28, 2021, to Decree of the Government of the Russian Federation No. 878 dated July 10, 2019. Under it, 30 types of medical devices, including computer and magnetic resonance tomographs, ultrasound diagnostic devices, neonatal equipment, and endoscopic equipment were removed from the scope of Decree of the Government of the Russian Federation No. 102 dated February 5, 2015 (the "three is a crowd" rule) and included in the register of radio-electronic products, for which more stringent procurement requirements are established (the "second is a crowd" rule).

We believe that achieving the strategic goal of ensuring medicine safety and the nation's self-sufficiency requires an integrated approach, primarily including measures neither restrictive nor prohibitive, but of a stimulating nature (such as subsidizing the synthesis of pharmaceutical ingredients, supporting the chemical industry, tax incentives, etc.).

In order to prevent negative consequences, the decision to classify high-tech medical equipment (OKVED-2 code 26.60) as radio-electronic products should be withdrawn, and appropriate amendments to the List of Radio-Electronic Products, approved by Decree of the Government of the Russian Federation No. 878 dated July 10, 2019, should be made (as amended by Decree of the Government of the Russian Federation No. 1432 dated August 28, 2021).

Moreover, in order to develop the Russian medical industry, it is proposed to organize a discussion of positive measures to stimulate localization and establish achievable criteria for classifying production as Russian, at the level of the Government of the Russian Federation, with the involvement of high-tech medical device manufacturers.

POSITION OF THE AEB WORKING GROUP OF MEDICAL EQUIPMENT MANUFACTURERS ON THE ADOPTION OF DECREE OF THE GOVERNMENT OF THE RUSSIAN FEDERATION NO. 1432 DATED AUGUST 28, 2021 (THE "TWO IS A CROWD" RULE)

On August 28, 2021 the Government of the Russian Federation adopted Decree on Amendments to Certain Acts of the Government of the Russian Federation No. 1432 (hereinafter referred to as "Decree No. 1432").

As a result, 30 types of medical devices, including but not limited to: computer and magnetic resonance tomographs, ultrasound diagnostic devices, neonatal equipment, endoscopic equipment (hereinafter referred to as "medical equipment") were removed from the scope of Decree of the Government of the Russian Federation No. 102 dated February 5, 2015 (the "three is a crowd" rule), and included in the register of radio-electronic products, which are subject to more stringent procurement requirements (the "two is a crowd" rule) established by Decree of the Government of the Russian Federation No. 878 dated July 10, 2019 (hereinafter referred to as "Decree No. 878").

In practice, the new requirements include obtaining a special permit for any instance of purchasing foreign-made medical equipment, regardless of the actual presence/absence of domestic analogs or the actual possibility of their production and/or delivery by local manufacturers.

In addition, attention is to be drawn to the fact that the presence of domestic analogs or the actual possibility of their production by a local manufacturer will not automatically imply the participation of a local manufacturer in the procurement process. This can lead to a significant increase in the procurement time, and, as a result, negatively affect the timeframe for the delivery of equipment to medical organizations.

In addition, in the absence of a medical device in the radio-electronic industrial register or in the presence of such a device, the functional characteristics of which differ from those specified in the procurement requirements, Decree No. 1432 provides for the issuance of a special permit in the manner determined by the Ministry of Industry and Trade.

This means that if several customers simultaneously decide (for example, within the framework of a joint auction) to purchase the same product, each of them will need to independently apply to the Ministry of Industry and Trade for such a permit. For example, the deadline for issuance by the Ministry of Industry and Trade of Russia of a decision on an application for the purchase of foreign products within the framework of Decree of the Government of the Russian Federation No. 616 dated April 30, 2020, is twenty-seven business days from the registration date of such an application.

The above significant amendment to the medical equipment procurement approach was adopted without any public discussions or consultations with associations of international high-tech medical equipment manufacturers. These have been present in the Russian market for many years, ensuring continuing supplies to medical organizations in Russia, partly within the framework of national projects such as Healthcare and Demography, implementing projects to localize production, and promoting the introduction of innovations and development of local technological competencies.

Moreover, on September 8, 2021, draft amendments to Decree No. 878 (ID - 02/07/09-21/00120082) were posted on the legal portal www.regulation.gov.ru, which completely excludes the possibility of supplying medical equipment, even in the absence of analogous products in the registers of radio-electronic products and Eurasian industrial goods (exclusion of Clause 4 of Decree No. 878), and removes the possibility of obtaining a permit to purchase medical equipment originating from a foreign country (exclusion of Clause 5 of Decree No. 878), which will lead to an even worsened situation in the market for the public procurement of medical equipment.

This means, that, before Decree No. 1432 came into effect, when announcing a procurement, the Customer had to write a justification therefor (notification procedure). However, after Decree No. 1432 came into effect, it became necessary to obtain a permit from the Ministry of Industry and Trade, and given that any new changes are planned, the Customer will not be able to use any additional characteristics of medical equipment in the required procurement, but can only use such items from the Catalog of Goods, Works and Services, which have common characteristics (for example, for a CT, this means the gantry aperture, table load capacity, and the number of slices). As an example, we hereby inform you that given the lack of the possibility to specify additional characteristics, the Customer can receive expensive equipment that does not meet its needs, for example, a CT with the specified characteristics, but without any software support or workplace equipment, making it impossible to operate the device.

The exclusion of Clause 4 from Decree No. 878 will make it completely impossible to purchase foreign equipment, since it was this clause that regulated the possibility of purchasing foreign medical equipment, provided that there were no analogous medical devices in the registers.

At the same time, we hereby note that the current requirements for confirming production of industrial products within the Russian Federation, established by Decree of the Government of the Russian Federation No. 719 dated July 7, 2015 (hereinafter referred to as "Decree No. 719"), cannot be fulfilled due to the lack of local component manufacturers capable of ensuring an appropriate level of quality and compliance with technological requirements for modern, high-tech and safe medical equipment, the long periods of testing before introducing components into production, the long periods for introducing changes to the marketing authorization for a medical device when replacing a component or component supplier. In such a context, both Russian and international manufacturers have been facing the impossibility of obtaining a conclusive production confirmation issued by the Ministry of Industry and Trade of Russia in accordance with Decree No. 719 or getting included in the relevant register. The Ministry of Industry and Trade of Russia has been working on preparing amendments to Decree No. 719, which will further tighten the criteria for obtaining "Russian" status for medical devices.

Medical equipment manufacturers have been seriously concerned about the current situation and fear that there will be negative consequences from applying the "two is a crowd" principle, including:

- artificial monopolization of the market/restriction of competition, as well as the creation of the artificial dependence of the entire healthcare system on a limited number of manufacturers (for certain types of medical equipment, there is only one manufacturer in the register of electronic products);
- an unpredictable increase in the timing of public procurement, which significantly complicates planning of the medical equipment production process by manufacturers, and, as a result, negatively affects the delivery deadlines of medical equipment to medical organizations;
- increased prices for medical equipment and ineffective spending of state budgetary funds;
- lack of motivation among the manufacturers included in the register of radio-electronic products to further innovate or technologically modernize/renew the medical equipment manufactured;
- a deteriorated investment climate in the medical industry, forced termination of localization and technology transfer projects for the following reasons:
  - no transitional period is provided to transfer medical technologies to Russia and ensure compliance with the requirements of Decree No. 719 (5–7 years from the start date of the localization project);
  - there is no local production of components/spare parts for medical equipment;
- the threat of disrupting the implementation of national projects such as "Healthcare" and "Demography", which have already been seriously hampered by the negative impact of the COVID-19 pandemic;
- limiting patients' access to modern/innovative types of high-tech medical care;
- the inability for medical organizations to purchase equipment in accordance with their clinical needs;
- violation of procurement processes/suspension of tender procedures (considering the requirements provided for by Decrees No. 2013, 2014, and 1432), since the procedure for issuing permits by the Ministry of Industry and Trade of Russia for the purchase of foreign medical equipment is not regulated within Decree of the Government of the Russian Federation No. 878 dated July 10, 2019. Thus, it is not clear who evaluates the medical organizations' justifications for the impossibility of purchasing locally produced medical equipment or on what basis they do so. The lack of any regulations defining the procedure for obtaining permits significantly increases the risk of challenging the medical equipment procurement procedures, and, as a result, negatively affects the confidence of market participants in the public procurement system.

To prevent negative consequences, we hereby propose to revise (cancel) the decision to classify high-tech medical equipment (code 26.60) as radio-electronic products due to specific characteristics of medical equipment circulation (development, production, registration, use, service), and in view of its high social significance:

- by designation, medical equipment classified as radio-electronic products does not differ from any other medical-industrial products, and approaches to its regulation should not differ;
- the specific characteristics of using medical equipment differ from those of using other products classified as radio-electronic products;
- medical equipment is used only in medical organizations and, accordingly, its use should be regulated and monitored by a specialized federal executive body (the Ministry of Health of the Russian Federation).

PARALLEL IMPORTS AND DUAL QUALITY

For a significant period of time, the AEB has consistently defended its position as to the fact that liberalization of parallel imports will have numerous negative consequences for the social and economic development of Russia. This, the current Russian legislation governing the exhaustion of the right to a trademark does not require any changes.

In this regard, the business community is concerned about various legislative initiatives in terms of clarifying the limits on exercising exclusive rights when importing goods containing the results of intellectual activity and means of individualization.

To balance the interests of the rightsholder and the rights of others, the law establishes the principle of the exhaustion of trademark rights. Part 4 of the Civil Code of the Russian Federation establishes a "national" principle of the exhaustion of trademark rights, which presumes that right holders may not prohibit other persons from using their trademarks in respect of other products that were put into civil circulation in the Russian Federation directly by or with the consent of their right holders.

Similar provisions concerning the exhaustion of trademark rights are also contained in the Customs Union Agreement on the Common Principles of Regulation in the Field of Intellectual Property Protection as well as in the Treaty on the Eurasian Economic Union. The Agreement and the Treaty establish a regional principle for the exhaustion of trademark rights for the member states of the Customs Union and the Eurasian Economic Union (the Republic of Belarus, the Republic of Kazakhstan, the Russian Federation, the Republic of Armenia, and the Republic of Kyrgyzstan). A largely similar model of the regional principle of the exhaustion of trademark rights is also used in the European Union[1]. In general, in the overwhelming number of states, parallel imports are not unconditionally allowed.

The import of products into Russia with a trademark applied thereto for the purpose of introducing such products into economic circulation is an independent method of using such a trademark. At the same time, the prohibition on such use of a trademark without the rightsholder's consent, as provided by the current legislation, is aimed at observing Russia's international obligations in the field of intellectual property protection in accordance with the Constitution of the Russian Federation[2].

In connection therewith, the transition to the international principle of exhaustion of rights will mean a return to the past, will become a negative example reflecting the instability of the Russian legislation and the investment climate for international rightsholders and investors, many of whom have localized their manufacture in Russia and counted on a high level of protection of their intellectual rights when adopting the corresponding decisions.

The AEB is convinced that parallel imports contradict the long-term interests of Russia, do not contribute to an increase in investment attractiveness, further development of Russian industry, import substitution, and manufacturing localization, do not meet the interests of consumers of Russian products, and, when considering the issue of parallel imports, it is necessary to apply a balanced and objective approach, comprehensively assessing a variety of significant aspects.

The discussion over many about the legalization of parallel imports has resulted in a discussion of dual quality.

An ambiguous approach has taken shape regarding the issue of so-called "dual quality", which supposes conducting comparisons of products of international brands circulating in Russia and similar goods circulating in other countries. If differences are identified and if sales in Russia are arranged without informing consumers about the target to manufacture such products for the Russian Federation, the actions of such Russian manufacturers may be regarded as unfair competition.

In fact, the issue of "dual quality" presents the possibility of comparing products under one and the same trademark

[1] Article 7 of First Council Directive 89/104/EEC of December 21, 1988 to Approximate the Laws of the Member States Relating to Trademarks

[2] See: Determination of the Constitutional Court of the Russian Federation No. 171-O dated April 22, 2004

circulating in arbitrarily selected markets having a priori different conditions (without considering the fact that the manufacturer has made no representations as to identity or similarity of such products).

As a rule, products manufactured by international companies are similar to the greatest possible extent in their properties and characteristics, regardless of where they are produced and for which country they are intended. Sometimes, the differences arise due to objective reasons, such as consumer preferences, manufacturing conditions, the use of such products, and, above all, differences in legal regulations enacted in a particular country and the need to adapt to them.

Thus, the differences between the mandatory requirements for products in Russia and in other countries often lead to the need to modify the global product design before entering the Russian market. At the same time, the products sold in Russia correspond to their foreign counterparts in terms of consumer properties and quality characteristics to the greatest possible extent.

The proposal to additionally inform consumers about the targeted manufacture of the products for their sale in the Russian Federation by means of appropriate labeling seems to be redundant from the point of view of the current legislation in force in Russia and the EAEU. The uniform circulation mark and Russian labeling already indicate that such products have passed all the conformity assessment procedures established in the technical regulations of the EAEU and have been put into circulation in this market.

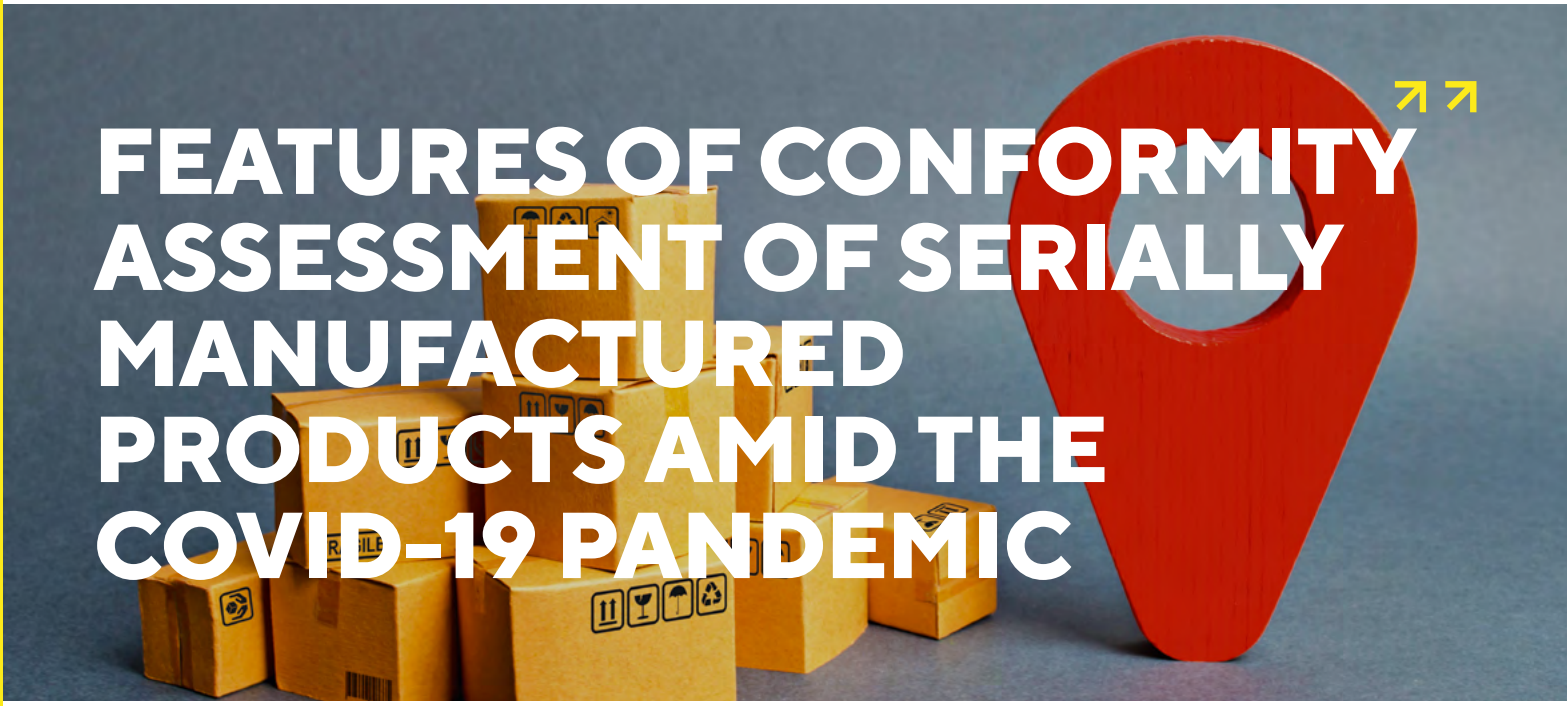
Any attempts to find problems of "dual quality" in relation to products that fully comply with the requirements of the legislation of the Russian Federation and the EAEU, but have some minor differences from their analogs circulating in the far abroad, cast doubt on the effectiveness of the product conformity assessment system adopted in Russia (and the EAEU) and the validity of the established requirements in the field of quality and safety.

Such attempts form an unjustified prejudice among Russian consumers in relation to the products produced in the Russian Federation under international trademarks cause not only reputational damage to product manufacturers but also material damage in the form of reduced sales. This may adversely affect the investment climate and the rate of localization of manufacturing in Russia.

The solution to the problem will be the refusal to form a policy of discrimination against products produced in Russia under international trademarks in relation to their foreign counterparts. A decisive, fundamental step could be the harmonization of regulatory requirements between Russia and the EAEU and other states, including mutual recognition of test results based on aligned approaches to product conformity assessment and methods of performing laboratory testing on them. This would not only allow international manufacturers to produce completely identical products in Russia and other countries but would also increase the export potential of the Russian Federation.

It seems necessary to continue active cooperation, participation in discussions, and consultations at all levels and platforms to convey the position of business to all the stakeholders and government agencies involved in the decision-making process on the issues considered.

The AEB is convinced that parallel imports contradict the long-term interests of Russia, do not contribute to an increase in investment attractiveness, further development of Russian industry, import substitution, and manufacturing localization, do not meet the interests of consumers of Russian products, and, when considering the issue of parallel imports, it is necessary to apply a balanced and objective approach, comprehensively assessing a variety of significant aspects.



FEATURES OF CONFORMITY ASSESSMENT OF SERIALLY MANUFACTURED PRODUCTS AMID THE COVID-19 PANDEMIC

At the end of 2020, the Eurasian Economic Commission approved the Interim Measures applied during the certification of serially manufactured products in an unfavorable epidemiological situation caused by the spread of COVID-19 (hereinafter referred to as the "Interim Measures"), which, inter alia, provide for the possibility of analyzing manufacturing status by remote assessment using means of remote interaction (audio and video communication). The adoption of the Interim Measures has allowed the conformity assessment procedures to be conducted in the new conditions when one cannot visit manufacturing locations. During the period in which the Interim Measures are in effect, the certification subjects, including manufacturers and accredited persons, have accumulated extensive experience facilitating the assessment not only of the benefits but also the difficulties in the implementation of the new approach.

During remote assessment, the requirement for continuous transmission of clear video images from the start till the end of the audit is the most challenging aspect. It turned out to be very difficult, and in some cases, even impossible to ensure the continuous transmission of video images when manufacturing sites are large and when it is necessary to visit several workshops or take samples in an open warehouse. In addition to that, it is quite problematic to ensure continuous videoconferencing of participants located in different time zones (USA, Australia, China) as working hours do not overlap for the period conducive to conducting the audit. The COVID-19 pandemic also creates difficulties for the functioning of supply chains; due to which, additional inspection control mechanisms are required, e.g. in the form of remote assessment.

It is important, that the originally established period of Interim Measures expired on January 9, 2022. However, various pandemic-related bans and restrictions remain in effect in many countries worldwide. Moreover, the lack of a clear definition of the concept of "lifting restrictions" leads to divergence in the approaches to the conformity assessment procedure by different certification authorities. Taking into account the current situation and the uncertainty about the pandemic progress, we believe that these measures should not be limited in time. It is necessary to identify criteria that allow the decision on lifting of restrictions to be made for the purpose of carrying out the conformity assessment procedure.

RECOMMENDATIONS

- Extend the effective period of the Interim Measures applied during the certification of serially manufactured products in the unfavorable epidemiological situation caused by the spread of COVID-19.
- Provide for the possibility of conducting remote assessments over several days with breaks.
- Provide for the possibility of identifying and selecting samples of products during the certification of products (including new ones) or scheduled periodic assessment of certified products both at the finished product warehouse of the manufacturer as part of the remote selection and at the finished product warehouse of an authorized representative of the manufacturer in accordance with the Typical Conformity Assessment Procedure Schemes.

- Provide for the possibility of conducting periodic assessments (inspection control) of certified products in the form of the remote analysis of the manufacturing status.
- Set clear criteria for determining when restrictions will cease to be effective for the purpose of applying the Interim Measures.
- Provide transitional provisions for work in progress, if the analysis of the manufacturing status in relation to the selected and identified samples was conducted during the effective period of the current Interim Measures, but the certification procedure was not completed at their expiry.

The adoption of the Interim Measures has allowed the conformity assessment procedures to be conducted in the new conditions when one cannot visit manufacturing locations. During the period in which the Interim Measures are in effect, the certification subjects, including manufacturers and accredited persons, have accumulated extensive experience facilitating the assessment not only of the benefits but also the difficulties in the implementation of the new approach.

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AEB MEMBERSHIP APPLICATION FORM / ЗАЯВЛЕНИЕ НА ЧЛЕНСТВО В АЕБ

Please, email a scan of completed and signed application form to: membership.application@aebrus.ru**, and send the original document by post /** Пожалуйста, вышлите скан заполненного и подписанного заявления на адрес: **membership.application@aebrus.ru**, а оригинал направьте почтой.

Calendar year/Календарный год: 2022

Name of your AEB Contact / Ваше контактное лицо в АЕБ:

1. COMPANY / СВЕДЕНИЯ О КОМПАНИИ

Company name in full, according to company charter in English & Russian. (Individual applicants: please indicate your business activities or the employer / Название компании в соответствии с уставом на русском и английском языках. (Для индивидуальных участников – описание предпринимательской деятельности или работодателя):

Legal address (and postal address, if different from legal address) / Юридический адрес (и фактический адрес, если он отличается от юридического):	**INN/KPP** / ИНН/КПП:	
	Phone Number / Номер:	**Fax number** / Номер факса:
	Website address / Страница в Интернете:	

2. CATEGORY: THE CATEGORY IS DETERMINED ACCORDING TO THE GLOBAL TURNOVER OF THE COMPANY/ КАТЕГОРИЯ: КАТЕГОРИЯ ОПРЕДЕЛЯЕТСЯ ГЛОБАЛЬНЫМ ОБОРОТОМ КОМПАНИИ

Please attach the signed letter on the company activities and its global annual turnover on the company letterhead / Просьба приложить официальное письмо на бланке организации с описанием деятельности компании и указанием ее глобального оборота, заверенное подписью.

	Please indicate the corresponding AEB Category/ Отметьте, пожалуйста, соответствующую категорию:	**Company's global annual turnover (EUR) /** Глобальный оборот компании (евро)	**AEB Membership Fee /** Членский взнос АЕБ
☐	**SPONSORSHIP** / Спонсорство	**--**	**12,000 EUR /евро**
☐	**CATEGORY A** / Категория А	**>500 million/миллионов**	**6,500 EUR /евро**
☐	**CATEGORY B** / Категория Б	**100-499 million/миллионов**	**4,000 EUR /евро**
☐	**CATEGORY C** / Категория С	**1-99 million/миллионов**	**2,500 EUR /евро**
☐	**CATEGORY D** / Категория Д	**<1 million/миллиона**	**800 EUR /евро**
☐	**CATEGORY I (EU/EFTA citizens only)**/ Индивидуальное (только для граждан Евросоюза/ ЕАСТ)	**--**	**1,000 EUR /евро**
☐	**CATEGORY R (rep. offices)** / Категория Р (companies registered in Russia by a rep. office only may join for the first two years with an adequate upgrade to follow) / компании, зарегистрированные в России только в качестве представительств, могут вступить на первые два года с последующим повышением категории до актуальной)	**--**	**3,000 EUR / евро**

Any non-EU/non-EFTA Legal Entities applying to become Associate Members must be endorsed by two Ordinary Members (AEB members that are Legal Entities registered in an EU/EFTA member state or Individual Members – EU/EFTA citizens) in writing / Заявление о вступлении в Ассоциацию любого юридического лица из страны, не входящей в Евросоюз/ЕАСТ, должно быть письменно подтверждено двумя юридическими лицами из Евросоюза/ЕАСТ или индивидуальными участниками-гражданами в Евросоюзе/ЕАСТ.

Individual AEB Membership is restricted to EU/EFTA member state citizens, who are individual entrepreneurs or who are employed by a company, which cannot join the AEB for the internal regulations / К рассмотрению принимаются заявления на индивидуальное членство от граждан Евросоюза/ЕАСТ, занимающихся индивидуальным предпринимательством или работающих в неевропейских компаниях, внутренняя политика которых не предполагает членство в АЕБ.

All applications are subject to the AEB Board approval / Все заявления утверждаются Правлением АЕБ.

3. CONTACT PERSON / КОНТАКТНОЕ ЛИЦО	
Title, first name, surname / ФИО:	
Position in company / Должность:	
E-mail address / Адрес эл. почты:	

4. COUNTRY OF ORIGIN / СТРАНА ПРОИСХОЖДЕНИЯ	
A. For a company / Компаниям: **Please specify the country of origin** / Указать страну происхождения компании[1]	
or B. For an individual applicant / Индивидуальным заявителям: **Please specify the country of which you hold CITIZENSHIP** / Указать гражданство	
Please fill in either A or B above / Заполните только графу А или В.	

5. COMPANY DETAILS / ИНФОРМАЦИЯ О КОМПАНИИ			
Company present in Russia since: _____ / Компания присутствует на российском рынке с:_____ г.			
Company activities / Деятельность компании	**Primary** / Основная:		**Secondary** / Второстепенная:
Company turnover (euro) / Оборот компании (в евро)	**In Russia** / в России:	**Worldwide** / в мире:	☐ **Please do not include this in the AEB Member Database** / Не включайте это в справочник АЕБ
Number of employees / Количество сотрудников	**In Russia** / в России:	**Worldwide** / в мире:	☐ **Please do not include this in the AEB Member Database** / Не включайте это в справочник АЕБ
Please briefly describe your company's activities (for inclusion in the AEB Database and in the AEB Newsletter) / Краткое описание деятельности Вашей компании (для включения в базу данных АЕБ и публикаций АЕБ)			

6. HOW DID YOU LEARN ABOUT THE AEB / КАК ВЫ УЗНАЛИ ОБ АЕБ?		
☐ **Personal Contact** / Личный контакт	☐ **Internet** / Интернет	☐ **Event** / Мероприятие
☐ **Media** / СМИ	☐ **Advertising Source** / Реклама	☐ **Other** / Другое

Signature of Authorised Representative of Applicant Company /
Подпись уполномоченного лица заявителя:

_____

_____

Date / Дата:

Signature of Authorised Representative of the AEB /
Подпись Руководителя АЕБ:

_____

_____

Date / Дата:

[1] In accordance with the country of registration and citizenship of the major owner / В соответствии со страной регистрации и гражданством мажоритарного собственника.