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What is “Regulatory Path” for Russia?



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Abstract

The article discusses how exactly artificial intelligence technologies are regulated in Russia with analysis of key regulatory trends observed internationally, including stepping up of international cooperation, prevalence of flexible, adaptive regulatory options over one-size-fits-all approach, as well as regulatory focus on generative artificial intelligence and ethical issues. A special emphasis is made on exploration of the Russian regulatory model for artificial intelligence. Rather than following in the wake of the European Union with its universal, comprehensive Artificial Intelligence Act, Russia has opted for a horizontal regulatory approach covering different economic and social sectors. The article present discusses a set of regulations governing the relationships associated with artificial intelligence including strategic documents, legal acts on regulatory sandboxes, regulation of medical AI applications, data access mechanisms, etc. It is argued that Russia follows the path of building a comprehensive regulatory system for AI based on a hybrid approach combining statutory, ethical and technical regulation for a balance between supporting innovation and protecting public interests.



Keywords

artificial intelligence; state regulation; Russia; trends; regulatory framework; hybrid approach.

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The explosive progress of artificial intelligence (hereinafter AI) is changing the world around us by opening new horizons of opportunities in economy, science, learning and everyday life. Meanwhile, AI potential is fraught with risks requiring careful scrutiny and regulation in moving forward. Many countries, intergovernmental and international organizations prioritize the introduction of standards and rules for AI regulation since how much the society will benefit from AI technologies depends on the right regulatory approach. Countries differ considerably in their approaches to AI regulation [Bodini M., 2024: 569–570]. Where some strive to introduce rigid legal constraints on AI in areas of likely risk, others stake on supporting innovation and minimizing state intervention. A diversity of opinions is explained by cultural nuances, economic interests and political outlook of each state.

With a watchful eye on AI, international organizations produce documents calling for responsible and ethical use. Thus, in March 2024 the United Nations General Assembly has passed the resolution “Seizing the opportunities of safe, secure and trustworthy AI systems for sustainable development”¹. While not describing regulatory approaches to AI, it encouraged countries to develop national regulatory frameworks and international cooperation. Moreover, in July 2024 the resolution “Enhancing capacity-building of AI” was approved unanimously². The document initiated by China has encouraged the international community to put in place “a fair, open, inclusive and non-discriminatory business environment” for AI design and implementation in both developed and developing countries.

The UNESCO is also working towards ethical regulation, with the first ever global ethical standard, “Recommendations on the Ethics of Artificial Intelligence”, passed in November 2021 by 193 UN member states³ as non-binding, “soft law” instrument. Apart from the UNESCO, the

¹ Available at: <https://docs.un.org/en/A/78/L.49> (accessed: 17.07.2025)

² Available at: https://english.www.gov.cn/news/202407/02/content_WS-668394a7c6d0868f4e8e8c58.html#:~:text=The%20resolution%20on%20%22Enhancing%20International,beneficial%20intelligence%2C%20and%20benefiting%20humanity (accessed: 20.07.2025)

³ Recommendation on the Ethics of Artificial Intelligence // Available at: URL: <https://www.unesco.org/en/articles/recommendation-ethics-artificial-intelligence> (accessed: 18.07.2025)

OECD has addressed AI ethics in 2019 by issuing the AI Principles⁴ with the main purpose to promote positive development of AI technologies and assist governments, developers and private individuals with ethical development and use.

Likewise, the Council of Europe has long been dealing with issues faced by humanity as a result of progress in information and digital technologies, with the Framework Convention on AI, human rights, democracy and the rule of law passed on 17 May 2024⁵ as the first binding international AI treaty [Martynova E.A., Sushkov S.P., 2024: 64–69] subject to endorsement and ratification by member states and governing both public and private sectors.

The G7 also deals with AI regulation, with 11 guiding principles and a Code of Conduct developed for organizations designing advanced AI systems as part of the Hiroshima AI Process initiative⁶. These documents were drafted to address the development of advanced AI systems—foundation models and generative AI.

Different international organizations and associations — CIS, SCO, VIOS, BRICS, G20 and OSCE — are also intensifying work on artificial intelligence and relevant regulation with a special focus on this area.

Growing international cooperation to develop common AI standards brings to light the key regulatory trends designed to support secure and ethical use and sustainable technological development.

The first regulatory trend that could be identified is closer cooperation for AI governance with a special focus on international cooperation under the overarching agenda of regulating AI-related relationships [Buryaga V.O. et al., 2025: 75–77] as suggested, in particular, in recent UN resolutions. International cooperation is key to promoting a fair, open, inclusive and non-discriminatory business environment for AI development and implementation in both developed and developing countries.

As another trend, the world is cautious about the idea of universal horizontal legislation [Baturin Yu.M., 2022: 142–148] with a preference

⁴ OECD AI Principles overview // Available at: URL: <https://oecd.ai/en/ai-principles>. (accessed: 28.07.2025)

⁵ Available at: https://rm.coe.int/20240704ecn9–2024webinar_huderia/1680b0d26c (accessed: 17.07.2025)

⁶ The Hiroshima Process International Guiding Principles for Organizations Developing Advanced AI Systems // Available at: URL: <https://www.mofa.go.jp/files/100573471.pdf> (accessed: 17.07.2025)

for more flexible and adaptive solutions. The importance of safe AI regulation stems from a need to strike a balance of interests of all stakeholders dealing with artificial intelligence, provide the incentives and promote the development of AI technologies, as well as identify and mitigate the risks related to the development, marketing and use of AI systems.

Rapid progress of generative AI [Li Yao, 2023: 27–31]; [Talapina E.V., 2020: 28–31] is fanning the discussions about its regulation as this technology, despite all benefits, is fraught with significant risk. The importance to regulate the generative AI is to secure legitimate interests of all parties and create an enabling environment for the development of AI technologies while ensuring fundamental rights and freedoms to those dealing with AI-generated content.

Moreover, countries are increasingly keen on marking AI-generated content⁷ [Wittenberg C., 2024: 3–6]. With large generative models massively available, regulators and industry experts worldwide wonder how to mark content for higher trust and lower legal and reputational risks for developers. Marking will allow to identify synthetic content and trace its origin and authenticity to reduce potential threats to users.

Making AI ethical becomes a key regulatory tool to ensure safe technological development and protect human rights. Ethical principles contribute to making AI trustworthy by creating equitable and inclusive conditions with a positive effect for living standards and society's well-being. Many countries have adopted a national code of conduct for AI and set up advisory boards to implement ethical standards.

Against the backdrop of global AI regulatory trends, each country is seeking a specific approach to technological development governance.

Russia currently is intensifying efforts to develop regulatory and ethical frameworks for the development and implementation of AI technologies while attempting to strike a balance between innovations and protection of society's interests. Interestingly, sociological studies in Russia show that AI developers do not see AI regulation as a major obstacle to AI progress, with the share of those with a contrary view down from 35% to 22% according to the survey "Satisfaction of those interested in AI development with working conditions in Russia"⁸ conducted by

⁷ Available at: URL: <https://mit-genai.pubpub.org/pub/hu71se89> (accessed: 11.07.2025)

⁸ Available at: URL: https://ai.gov.ru/knowledgebase/etika-i-bezopasnost-ii/2023_sociologicheskii_opros_udovletvorennosty_usloviyami_raboty_v_rf_grahdan_zainteresovannyh_v_razvitiy_tehnologiy_ii_ncrii/ (accessed: 17.07.2025)

the National AI Development Center under the Government of Russia jointly with the All-Russia Public Opinion Research Center in 2023, and a similar survey of 2021⁹.

Today Russia has a fairly well-developed regulatory framework for AI with documents ranging from strategic plans to standards and regulatory sandboxes. Not following in the wake of the EU with its universal AI Act, Russia has opted for a horizontal rather than vertical regulatory model covering all economic and social sectors [Maslova E.A., 2022: 70–74], as well as public governance.

While there is currently no general AI law in Russia [Sukharev A.N., 2021: 13–15], several attempts to adopt one can be identified:

In late 2016, a draft law “On regulating smart robots” was proposed as a framework of robotics law by Grishin Robotics and Dmitry Grishin, Mail.ru co-founder. According to the drafters, the initiative purported to encourage public discussions on AI and robotics regulation¹⁰.

In 2017, the Center for the Study of AI and Robotics Regulatory Problems has proposed a Model Convention on AI and Robotics. Again, despite the State Duma’s announced intention to consider it, the initiative was conceived to stir up discussion. “The issues of relationship between man and AI have to be regulated shortly”, Sergey Zhigarev, former State Duma Deputy, has claimed¹¹.

Finally, in 2018 a comprehensive study of this problem was conducted as part of the federal project “Statutory regulation of the digital environment” by Dentons, an international legal firm commissioned by the Center for Competencies for Statutory Regulation of the Digital Economy based at the Skolkovo Foundation¹².

In February 2025, public discussions were launched on the draft law “On Regulating AI Systems in Russia” designed to put in place a com-

⁹ Available at: URL: https://ai.gov.ru/knowledgebase/vnedrenie-ii/2024_indeks_gotovnosti_prioritetnyh_otrasley_ekonomiki_rossiyskoy_federacii_k_vnedreniyu_iskusstvennogo_intellekta_ncrrii/ (accessed: 17.07.2025)

¹⁰ Russia likely to become first country to legalize robots // Available at: URL: <https://www.vedomosti.ru/technology/articles/2016/12/15/669703-rossiya-uzakonit-robotov> (accessed 17.07.2025)

¹¹ Available at: URL: <https://robopravo.ru/uploads/s/z/6/g/z6gj0wkwhv1o/file/QcVm7fnR.pdf> (accessed: 12.06.2025)

¹² Available at: URL: <https://www.dentons.com/ru/about-dentons/news-events-and-awards/news/2018/november/dentons-submits-results-of-research> (accessed: 17.07.2025)

prehensive regulatory framework for the development and application of AI in Russia. Drafted to implement the 2030 National AI Development Strategy, it takes into account the provisions of information technology and data security law. A meeting of the Working Group for the AI draft law was held at the State Duma of the Federal Assembly.

Russia has passed 2030 National AI Development Strategy as a strategic planning document approved by Presidential Decree No. 490 of 10 October 2019 “On developing AI in Russia”¹³. In February 2024 the document was considerably amended by Presidential Decree No. 124 of 15 February 2024 “On amending Presidential Decree No. 490 of 10 October 2019 as well as the National Strategy approved by this Decree”¹⁴, with the following sections added:

- support to corporate developers of AI technologies;
- support to research and development for advanced AI design;
- improving AI-related competencies and public awareness;
- encouraging AI introduction across economic and social sectors;
- introducing trustworthy AI technologies;
- establishing a comprehensive system for statutory regulation of social relations for broader and safe use of AI technologies;
- international cooperation for the use of AI technologies;
- expertise, analytical & methodological support to implement the Strategy.

In addition, the “General Provisions” section was revised to include 10 new definitions such as large foundation models, large generative models, trustworthy AI, etc.

Likewise, the section *AI Progress in Russia and Worldwide* was revised in full to include updates on the progress of large language models and generative AI and to reflect AI development outcomes in Russia over 2021–2023, in particular, the number of created education programmes, progress at AI research centers etc., and also national challenges to AI development.

The AI-related activities section was revised in full to include new activities such as:

¹³ Presidential Decree No. 490 “On developing artificial intelligence in Russia” of 10 October 2019 // Available at: URL: <https://www.garant.ru/products/ipo/prime/doc/72738946/> (accessed: 30.06.2025)

¹⁴ Presidential Decree No. 124 “On amending Presidential Decree No. 490 of 10 October 2019 as well as the National Strategy approved by this Decree”. 15 February 2024. // SPS Consultant Plus.

infrastructure: guaranteed demand for cloud computing services and cheap loans to service providers for equipment purchases etc.;

startups: exports and investment raising support;

research: development and adaptation of large language models, as well as funding of AI research including multidisciplinary studies;

talent: comprehensive measures to improve the quality of teaching under the currently available education programmes;

AI introduction in economic, social sectors etc.: binding requirements for AI introduction to receive subsidies; mainstreaming AI into all national projects and public programmes across the board;

regulation: creating conditions for access to data, removing legal barriers to the development and use of large language models including liability problems, and improving the rules of AI ethics;

international cooperation: promoting domestic technologies and ethical standards beyond the national borders.

At the strategic session “AI Development” of 26 September 2023 headed by M.V. Mishustin, Chairman of the Federal Government, it was noted that in terms of AI market regulation it was crucial to make Russia a comfortable jurisdiction for the development of safe AI by adopting a hybrid regulatory approach based on international experience.

In this regard, it was critical for Russia to further improve regulatory terms for national AI development. By 2030:

all the best international regulatory practices shall have been adapted; excessive administrative barriers removed;

large-scale national impact on the evolution of international and regional regulation achieved.

The revised National Strategy points out to a need to create comprehensive system for statutory regulation of public relationships related to the development and application of AI technologies, as well as for safe use of these technologies. For this purpose, the National Strategy identifies 28 regulatory areas (compared to just 9 in its original version).

The regulatory objectives of the revised National Strategy largely purport to ensure regulatory support for the availability of different data to AI developers, with data anonymization, including personal and health data, as a key tool to serve this purpose.

Defining the rules of procedure for large generative models has become a new vector towards a comprehensive regulatory system. That objective requires to remove unjustified regulatory constraints on the devel-

opment and use of these models including by identifying the boundaries of responsibility of developers and by creating conditions to train large generative models on big data.

Thus, the revised National Strategy envisages comprehensive development of AI in Russia including by encouraging the development and introduction of AI solutions, as well as providing an enabling regulatory framework.

In furtherance of Presidential Decree No. 204 “On Russia’s national goals and strategic objectives for the period until 2024” of 7 May 2018¹⁵ and No. 474, including to expedite the introduction of digital technologies across economic and social sectors, the Federal Government has launched the Digital Economy for Russia National Programme (“National Program”)¹⁶.

In particular, under the National Program the Federal Government was to join forces with the regional authorities to establish a regulatory system for the digital economy with a flexible approach to each sector, and introduce civil transactions based on digital technologies.

The National Program included the following federal projects:

- “Statutory Regulation of the Digital Environment”,
- “Talent for the Digital Economy”,
- “Information Infrastructure”,
- “Information Security”,
- “Digital Technologies”,
- “Digital Governance”,
- “Artificial Intelligence”,
- “Developing Satellite-Enabled Internet Access”,
- “Developing Talent for the IT Sector”.

By 2024, in the process of implementing the Federal Project “Statutory Regulation of the Digital Environment”¹⁷ to remove obstacles to digital economic development, a number of regulations were amended

¹⁵ Presidential decree No. 204 “On Russia’s national development goals and strategic objectives for the period until 2024”. 07 May 2018 (as amended on 21 July 2020) // SPS Consultant Plus.

¹⁶ Passport of the national project “Digital Economy for Russia National Program” (approved by the Presidium of the Council for Strategic Development and National Projects under the President of Russia, protocol No. 7. 04 June 2019) // SPS Consultant Plus.

¹⁷ Passport of the federal project “Statutory Regulation of the Digital Environment” (approved by the Ministry of Economic Development) // SPS Consultant Plus.

and new regulations drafted, with a mechanism of regulatory sandboxes enshrined in law¹⁸.

Following expiry in December 2024, the National Program was transformed into the Data Economy 2025–2030 national project, while the Program’s Artificial Intelligence Federal Project was extended.

Moreover, in 2020 the Federal Government approved the 2024 Development Framework for Regulation of Relationships in AI and Robotics (“Framework”)¹⁹. In the wake of progressing public relationships related to development and use of AI and robotics, the Framework had its provisions defined for the period until 2024 while accounting for provisions of the National AI Development Strategy 2030 as amended on 10 October 2019 with regard to AI regulation.

The Framework purported to identify the main approaches to transformation of Russia’s statutory regulatory system to develop and harness digital technologies across the economy in observing individual rights and ensuring security of persons, society and the state.

The Framework’s provisions shape the future AI regulatory landscape which comprises statutory, ethical and technical regulations. Moreover, the consolidated blocks for developing AI statutory regulation addressed by federal projects of the National Program and strategic planning documents for digital change include the following:

- removing administrative barriers;
- mainstreaming AI systems into civil transactions;
- improving data turnover;
- regulatory sandbox mechanism.

In terms of percentage, more than half of the Framework’s provisions were complied with by late 2024.

The following are examples of the implemented Framework provisions.

Federal Law No. 258-FZ “On Experimental Legal Regimes for Digital Innovations” of 31 July 2020²⁰ was approved for targeted develop-

¹⁸ Federal Law No. 258-FZ “On Experimental Legal Regimes for Digital Innovations” of 31 July 2020 (as amended on 02 July 2021) // SPS Consultant Plus.

¹⁹ Federal Government Instruction No. 2129-r “On approving the 2024 development framework for regulation of relationships in AI and robotics” of 19 August 2020 // SPS Consultant Plus.

²⁰ Federal Law No. 258-FZ “On Experimental Legal Regimes for Digital Innovations” of 31 July 2020 (latest version) // Available at: URL: http://www.consultant.ru/document/cons_doc_LAW_358738/ (accessed: 24.05.2025)

ment, testing and introduction of AI technologies to introduce regulatory sandboxes in the area of digital innovations. Also the Government has approved the List of technologies which may be used under experimental legal regimes [Buryaga V.O. et al., 2025: 60–65] for digital innovations²¹ including AI.

Federal Law No. 331-FZ “On Amending Specific National Regulations Following the Passing of the Federal Law “On Experimental Legal Regimes for Digital Innovations” of 02 July 2021²² (satellite law) allows regulatory sandboxes in the following areas: AI — driverless taxis; cargo transport by heavy drones; telemedicine-enabled health services; health and economic big data analysis.

Of 16 sandboxes currently launched, the majority is in transport and health. In furtherance of paragraph 2(b), Presidential Instruction No. Pr-172 of 29 January 2023, efforts are made to extend the list of territories for conducting experiments with unmanned aerial vehicle systems.

Thus, the regulatory sandbox legislation has set the stage for testing highly automated vehicles (HAV).

Driverless vehicle regulation is being developed as part of three regulatory sandboxes²³ (Government Resolution No. 309 of 09 March 2022; Government Resolution No. 1849 of 17 October 2022; Government Resolution No. 2495 of 29 December 2022).

In 2021, it was approved, upon the President’s instruction, a set of measures for testing and phased introduction of highly automated vehicles (HAV) in public roadways²⁴.

The following regulatory sandboxes for digital innovations are now in effect for HAV operations:

²¹ Available at: URL: <http://www.garant.ru/products/ipo/prime/doc/7472381/#1000> (accessed: 19.07.2025)

²² Federal Law No. 331-FZ “On Amending Specific National Regulations Following the Adoption of Federal Law “On Experimental Legal Regimes for Digital Innovations” of 02 July 2021 // Available at: URL: http://www.consultant.ru/document/cons_doc_LAW_389015/ (accessed: 17.07.2025)

²³ Federal Government Resolution No. 309 “On establishing an experimental legal regime for digital innovations and approving the relevant program for operating highly automated vehicles” of 09 March 2022 // Available at: URL: http://www.consultant.ru/document/cons_doc_LAW_411811/ (accessed: 17.07.2025)

²⁴ “Unattended highly automated vehicles to go on test” // Available at: URL: <https://mintrans.gov.ru/press-center/news/9875> (accessed: 17.07.2025)

Under a regulatory sandbox for HAV testing in public roadways available to Yandex Tests LLC, vehicles with a test driver in the driving or front passenger seat can be tested at specific locations in Moscow, Innopolis and Sirius federal territory while unattended autonomous road vehicles can be tested in the Skolkovo Innovations Center and Innopolis (with remote routing and operational control by human operator)²⁵.

Another regulatory sandbox allows HAV operation under the “Driverless logistical corridor” initiative in M-11 “Neva” federal highway between Moscow and Saint Petersburg, M-12 “Vostok” and the Central Ring Motorway for testing digital cargo transport innovations (primarily driverless trucks and related infrastructure) during three years. This sandbox brings together six companies: KAMAZ, Avtotekh, StarLine, Globaltruck Logistic, Magnit, X5 Logistics and GK Avtodor as the infrastructure operator²⁶.

A regulatory sandbox for the delivery of HAV-enabled transport services in specific constituent territories of Russia²⁷.

Also, the Traffic Safety Framework for Public Roadways with Driverless Vehicles passed in 2020 under Government Resolution No. 724-r of 25 March 2020²⁸ envisages the development of road infrastructure for driverless traffic and relevant public policies.

Moreover, work on the draft of Federal Law “On Highly Automated Vehicles and on Amending Specific Regulations”²⁹ designed to regulate manufacturing and operational issues associated with HAV is currently underway.

²⁵ Federal Government Resolution No. 309 of 09 March 2022 // Available at: URL: <http://government.ru/docs/all/139820/> (accessed: 30.01.2025)

²⁶ Federal Government Resolution No. 1849 of 17 October 2022 // Available at: URL: <http://publication.pravo.gov.ru/Document/View/0001202210200037> (accessed: 17.07.2025)

²⁷ Available at: <http://government.ru/docs/all/145583/> (accessed: 17.07.2025)

²⁸ Available at: <https://www.garant.ru/products/ipo/prime/doc/73707148/> (accessed: 17.07.2025)

²⁹ Draft of Federal Law “On Highly Automated Vehicles and on Amending Specific Regulations” // Available at: URL: <https://regulation.gov.ru/projects#-search=%D0%9E%20%D0%B2%D1%8B%D1%81%D0%BE%D0%BA%D0%BE%D0%B0%D0%B2%D1%82%D0%BE%D0%BC%D0%B0%D1%82%D0%B8%D0%B7%D0%B8%D1%80%D0%BE%D0%B2%D0%B0%D0%BD%D0%BD%D1%8B%D1%85%20%D1%82%D1%80%D0%B0%D0%BD%D1%81%D0%BF%D0%BE%D1%80%D1%82%D0%BD%D1%8B%D1%85%20%D1%81%D1%80%D0%B5%D0%B4%D1%81%D1%82%D0%B2%D0%B0%D1%85&npa=116763> (accessed: 17.07.2025)

Progress in public relationships is not possible without assigning liability for unfavorable consequences resulting from the development and use of driverless vehicles.

The 2024 Development Framework for Regulation of Relationships in AI and Robotics identified among AI regulatory challenges those of delimitating liability [Bakhteev D.V., 2024: 12–17] for harm caused through the use of AI and robotics systems.

The President repeatedly pointed out the strategic importance of designing a liability assigning mechanism. As a follow-up to the conference “A Journey to the AI World” of 12 November 2021, the Government was tasked with improving the sandbox application mechanisms for digital innovations with a focus on the need to identify those responsible for harm caused by AI-enabled solutions, as well as with developing a common approach to liability insurance³⁰. In accordance with paragraph 1(e) of the list of instructions following a Federal Government meeting, the Government was asked to consider the issues of delimitating liability for the development and use of AI technologies and sophisticated neural networks³¹. AI-related liability was also part of the President’s instructions following the conference “A Journey to the AI World” of 24 November 2023. The Federal Government was to join forces with the State Duma to amend the legislation taking the earlier instruction into account towards identifying liability for harm to life, health and property as a result of AI testing and use.

Federal Law No. 169-FZ “On Amending the Federal Law on Experimental Legal Regimes for Digital Innovations” of 08 July 2024 approved in furtherance of the President’s instructions and to improve the sandbox application mechanisms³² requires from the parties to a regulatory sandbox to underwrite their civil liability for harm to life, health or property of individuals, or property of legal persons. As another novel feature, this law provides a mechanism allowing to identify those re-

³⁰ List of instructions following the Conference “A Journey to AI World” (approved by the President of Russia, No. Pr-2371 of 16 December 2021) // SPS Consultant Plus.

³¹ List of instructions following a Federal Government meeting. Approved by the President of Russian Federation, No. Pr-1770 of 06 September 2023 // SPS Consultant Plus.

³² Federal Law No. 169-FZ “On Amending the Federal Law “On Experimental Legal Regimes for Digital Innovations” of 08 July 2024 // Available at: URL: <http://publication.pravo.gov.ru/document/0001202407080020?index=2> (accessed: 17.07.2025)

sponsible for harm to life, health or property of individuals or property of legal persons, with a commission to be set up to look into circumstances of the case and issue an opinion.

Along with HAV, AI is increasingly regulated in health [Ibraghi-mov R.S., 2021: 89–92], with legislation consistently improved for public control of safety and quality of software as a medical product. Thus, Article 38 of Federal Law No. 323-FZ “On the Principles of Public Health Protection” of 21 November 2011³³ contains the concept of a medical product defined as a tool, appliance, instrument, equipment, material and other item used in medicine both individually or in any combination, including other accessories required for the product’s intended use (such as software).

Moreover, Federal Ministry of Health Order No. 686n of 07 July 2020 “On amending annexes No. 1 and No. 2 to Ministry of Health Order No. 4n of 6 June 2012 on approving the nomenclature and classification of medical products”³⁴ has introduced a classification of software recognized as a medical product, with the rules for registration of AI systems as health applications approved by Federal Government Resolution No. 1906 “On amending the rules for state registration of medical products” of 24 November 2020³⁵, and a total of 12 national standards for “AI systems in clinical medicine” were approved to the present time.

Another document regulating the transactions with software recognized as medical product, Order No. 1236n “On amending the requirements to the contents of technical/operating manuals of medical product vendors approved by Ministry of Health Order No. 11n”³⁶ of

³³ Federal Law No. 323-FZ “On the Principles of Public Health Protection” of 21 November 2011 // URL: http://www.consultant.ru/document/cons_doc_LAW_121895/ddcfddb49e64f085b65473218611b4bb6cd65/ (last accessed: 23.01.2025)

³⁴ Federal Ministry of Health Order No. 686n “On amending annexes No. 1 and No. 2 to Federal Ministry of Health Order No. 4n of 6 June 2012 on approving the nomenclature and classification of medical products” of 07 July 2020 // Available at: URL: http://www.consultant.ru/document/cons_doc_LAW_359668/ (accessed: 16.01.2025)

³⁵ Federal Government Resolution No. 1906 “On amending the rules for state registration of medical products” of 24 November 2020 // Available at: URL: <http://publication.pravo.gov.ru/Document/View/0001202011270010> (accessed: 10.06.2024)

³⁶ Order No. 1236n “On amending the requirements to contents of technical and operating manuals of manufacturers (producers) of medical products of 19 January 2017, Order No. 11n” of 20 November 2020 // Available at: URL: <http://publication.pravo.gov.ru/Document/View/0001202012210123> (accessed: 17.07.2025)

20 November 2020 contains the requirements that reflect specific features and unique characteristics of software applications.

Registration of medical products is a responsibility of the Federal Health Care Supervision Service, with the procedure to be completed within maximum 50 business days from the date of the relevant decision, a period which does not include clinical testing.³⁷

To handle health data, the Ministry of Health has approved an Order³⁸ approving the procedure for anonymization of details of those receiving medical assistance and undergoing a medical review, examination and certification. This document describes the procedure to anonymize recipients of medical assistance as well as a list of relevant details, requirements to outcomes and methods to be used.

According to Federal Government Resolution No. 2174 “On amending the Provision on the integrated state information system in health care” of 19 December 2020³⁹, a federal integrated electronic health record should provide for:

storage of anonymized health datasets to design machine learning algorithms and methods supporting medical decision-making systems, development and use of AI-enabled technological solutions;

support of annotation, preparation, verification of anonymized health dataset for problem solution including through the use of machine learning methods.

Moreover, in accordance with Federal Law No. 123-FZ “On Experimental Legal Regime to Enable the Development and Introduction of AI Technologies in the Federal City and Constituent Territory of Moscow, and on Amending Articles 6 and 10 of the Federal Law on Personal Data” of 24 April 2020, a regulatory sandbox was established

³⁷ Para 12, Federal Health Care Supervision Service Order No. 3371 “On approving the administrative rules of procedure for provision of state registration services applicable to medical products” of 06 May 2019 // Available at: URL: http://www.consultant.ru/document/cons_doc_LAW_330232/c318e899ce8553837b-d19784d9b3b5ba39d652d6/ (accessed: 17.07.2025)

³⁸ Procedure for anonymization of details of those receiving medical assistance and undergoing a medical review, examination and certification // Available at: URL: <https://www.garant.ru/products/ipo/prime/doc/71910050/> (accessed: 17.07.2025)

³⁹ Federal Government Resolution No. 2174 “On amending the Provision on the integrated state information system in health care” of 19 December 2020 // Available at: URL: <http://publication.pravo.gov.ru/Document/View/0001202012220048> (accessed: 17.07.2025)

to make Moscow a driver of innovations and nationwide focal point for AI developers, as well as to promote technological progress. Parties to the sandbox have access to anonymized data arrays to develop AI technologies and AI-enabled products. AI technologies and products with a proven positive effect for the state and individuals will be implemented for binding use in the territory of Moscow and replicated elsewhere.

Data is essential for AI progress. Pursuant to Federal Law No. 258-FZ “On Experimental Legal Regimes for Digital Innovations” of 31 July 2020 and Federal Law No. 331-FZ “On Amending Specific Regulations Following the Adoption of the Federal Law on Experimental Legal Regimes for Digital Innovations” of 02 July 2021⁴⁰, the Government will afford to those registered as sandbox parties certain compliance exemptions of the following kind: under the experimental legal regime, personal data obtained as a result of anonymization can be processed on a non-consent basis (para 9.1, part 1, Article 6, and part 2.1, Article 10, Federal Law No. 152-FZ “On Personal Data” of 27 July 2006).

Federal Law No. 233-FZ of 08 August 2024, that amends Federal Law No. 152-FZ “On Personal Data” of 27 July 2006 and Federal Law No. 123-FZ of 24 April 2020, was passed after long discussions. These changes were encouraged, in particular, by the President’s repeated instructions (para 1(c), No. Pr-2242 of 31 December 2020⁴¹; para 2, No. Pr-2371 of 16 December 2021; para 12, No. Pr-172 of 29 January 2023) regarding the terms of making data accessible to developers including through anonymization.

Under Federal Law of 08 August 2024, the Ministry of Digital Development have obtained a power to require that personal data operators anonymize personal data they process (except Article 10, part 2.1, and Article 11) on their own account and upload to a state information system (SIS) established for the purpose for building attribute-specific datasets provided that subsequent data processing will not allow to identify personal data subjects. Access and processing will be carried out only via the SIS for a defined range of data subjects, with the relevant procedure to be established by the Federal Government.

⁴⁰ Federal Law No. 331-FZ “On Amending Specific National Regulations Following the Adoption of the Federal Law on Experimental Legal Regimes for Digital Innovations” of 02 July 2021 // Available at: URL: http://www.consultant.ru/document/cons_doc_LAW_389015/ (accessed: 31.01.2025)

⁴¹ Presidential instructions following AI conference // Available at: URL: <http://www.kremlin.ru/acts/assignments/orders/64859> (accessed: 17.07.2025)

Following changes to Federal Law No. 123-FZ "On Amending Articles 6 and 10 of the Federal Law on Personal Data" of 24 April 2020, the Moscow Municipal Government have received a right to decide to form regional datasets, with regional data operators uploading data to the regional information system.

Likewise, there is regulation in Russia related to public-private partnership. Thus, Article 7, Federal Law No. 224-FZ "On Public-Private/Municipal-Private Partnership and on Amending Specific National Regulations" of 13 July 2015 ranges information technologies (assumed to include PC applications, databases, information systems or a combination thereof) among the items of public-private partnership.

This concept naturally includes AI technologies that can be envisaged by a public-private partnership or concession agreement for IT products or IT products plus hardware required for their operation. However, there are no comprehensive regulatory mechanisms that take into account the specifics and peculiarities of AI technologies used in different infrastructure areas.

In addition, there is also regulation of recommender systems in Russia, with Federal Law No. 408-FZ "On Information, Information Technologies and Data Security" of 31 July 2023⁴² providing the rules for transparent operation and use of recommender systems. In particular, it is specified that critical parameters of such recommender systems should be accessible and clear to information resource users. Under new Article 10.2-2, Federal Law No. 149-FZ "On Information, Information Technologies and Data Security" of 27 July 2006, owners of information resources using recommender technologies are obliged to:

- avoid recommender technologies that violate the rights and legitimate interests of individuals and organizations, and avoid using recommender technologies for the provision of information contrary to federal law;

- avoid providing information via recommender technologies without disclosing their use in the given information resource;

- post a white paper on recommender technologies to the information resource where they are used;

- post an email for service of process, name and initials (for a natural person) or business name (for a legal person) to the information resource using recommender technologies.

⁴² Federal Law No. 408-FZ "On Amending the Federal Law on Information, Information Technologies and Data Security" of 31 July 2023 // Available at: URL: <http://publication.pravo.gov.ru/document/0001202307310021> (accessed: 17.07.2025)

Russia has also launched the process of developing technical regulation for AI, with Technical Standardization Committee No. 164 *Artificial Intelligence* (TC-164) established to promote standardization at the national and international levels. TC 164 mirrors international subcommittee SC 42 *Artificial Intelligence* of the Joint Technical Committee (ISO/IEC JTC 1) *Information Technologies*, and also functions as a standing national agency at ISO/IEC JTC 1 SC 42 *Artificial Intelligence*. The Committee was established under Federal Agency for Technical Regulation Order No. 1732 of 25 July 2019.

In addition, on 29 December 2023 the Ministry of Economic Development and the Federal Agency for Technical Regulation has approved the 2021–2024 Long-Term Standardization Priority Program for AI (as amended) which provides for 131 technical standards to be developed in areas such as: “Intersectoral standards”, “Data”, “Information infrastructure”, “Quality”, “Usage options”, “Road transport”, “Water transport”, “Education”, “Health”, “Industry”, “Measuring instruments”, “Construction”, “Spatial data, Earth’s remote probing”, “Specialized equipment”.

While there is no regulation on binding certification in Russia, the Federal Agency for Technical Regulation has registered the Intellimetrics, Russia’s first intersectoral voluntary certification system for AI. With certification to establish compliance of AI algorithms with the requirements, the Intellimetrics will guarantee that AI algorithms perform as advertised and can be used in a specific operational environment. AI will be tested under the national standards developed by TC-164.

Also, Russia has passed the National AI Code of Ethics developed by the AI Alliance with support of the Analytical Center under the Federal Government, Ministry of Economic Development and academic community. The Code provides guidance for the development of AI in Russia to make AI trustworthy for users, society and the state. The document is non-binding, with market participants free to join [Kozlov I.N., 2025: 215–218] and commit to its principles.

Thus, the regulatory landscape for AI has changed considerably in Russia thanks to legislative work to achieve the objectives set, among other things, in the original version of the National Strategy, with the regulatory principles and legal mechanisms of primary importance for AI progress in place as evidenced by the list of regulations approved over the elapsed period in major regulatory domains.

Going forward, the law will not evolve towards a comprehensive regulatory system in AI and robotics, unless legal barriers are systematically identified and addressed, and a vision is adopted on how regulation will progress.

Due to the expiry of the Framework on 31 December 2024, a change of AI regulatory landscape in Russia and updated national strategic objectives for AI, the Association for Artificial Intelligence, an entity that brings together AI market players with a mission of creating a national AI development center and achieving technological leadership in the global market, have prepared an updated draft of the 2030 Framework based on proposals of sectoral organizations. This document was discussed during deliberations of the Federation Council of the Federal Assembly, Ministry of Digital Development, ANO Digital Economy.

The Framework ensured coordination between market players and public authorities in Russia to create an enabling environment for safe development of AI technologies.

Thus, the updated Framework is designed to put in place a modern system of governance for sustainable development of digital technologies to consolidate Russia’s position internationally. The choice of a hybrid approach — regulation by developing principles and standards to govern economic and social sectors where AI is used — underlines the authorities’ desire to establish a balanced and dynamic regulatory framework to match the 21st century challenges and support long-term growth and prosperity.



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